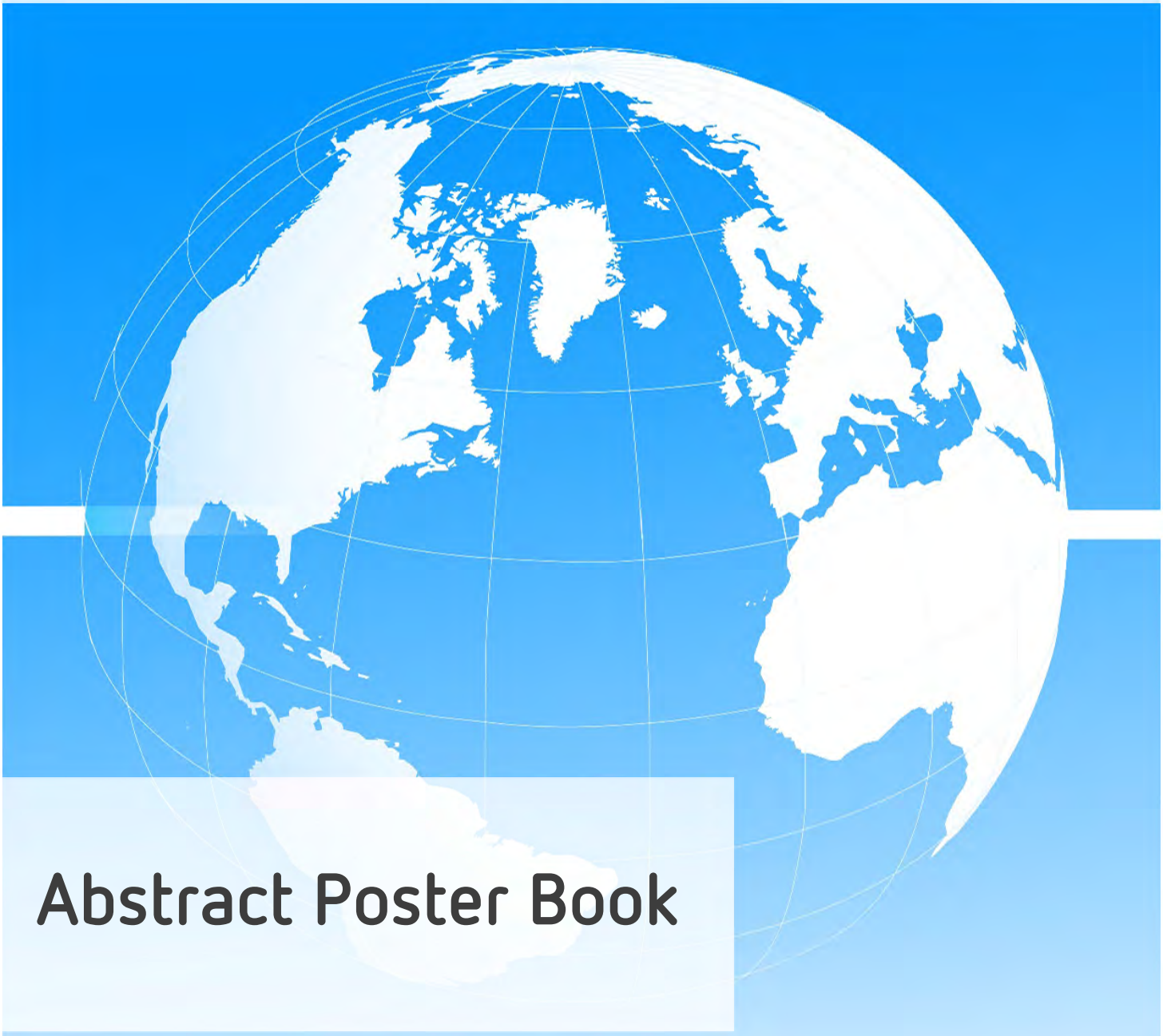
3rd International PPRI Conference

Pharmaceutical Pricing and Reimbursement Policies
Challenges Beyond the Financial Crisis

Vienna, 12-13 October 2015



Abstract Poster Book

WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies

PPRI Pharmaceutical Pricing and Reimbursement Information

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The abstract posters included in the abstract poster book were submitted to the conference organisers of the PPRI Conference 2015.

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Prices of oncology medicines in European countries, Australia and New Zealand

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Background

Medicines are of major relevance for the treatment of cancer. They appear to be among high-cost medicines; however, their prices are not generally known. In this context, the study aims to survey the prices of oncology medicines in European countries, Australia and New Zealand and explore differences across the countries.

Methods

Ex-factory prices per unit for 31 oncology medicines in 16 European countries, Australia and New Zealand were surveyed as of June 2013 and August 2013 respectively. For each medicine, we selected one presentation to be compared. This presentation was either identical in all countries or comparable in a way that it had the same pharmaceutical form and strengths, but the pack size varied.

Medicine price data for the 16 European countries were provided by the Pharma Price Information (PPI) service of the Austrian Public Health Institute. Australian and New Zealand medicine price data were retrieved from the respective Pharmaceutical Schedules: For Australia, the June 2013 dispensed prices were extracted from the February 2013 Efficient Funding of Chemotherapy (EFC) S100 arrangements supplement (still valid in June 2013) for injectable products and from the June 2013 Schedule of Pharmaceutical Benefits for oral products and interferon alfa 2b, and ex-factory prices were calculated by deducing the wholesale mark-up, the pharmacy mark-up and pharmacy professional fees from dispensed prices. New Zealand price data were sourced from the New Zealand August 2013 Pharmaceutical schedule. The price data of all 18 countries are the official, published prices (without consideration of, usually confidential, discounts and rebates).

Results

Data availability was higher in the European countries compared with Australia and particularly New Zealand. Data on all 18 countries were available for 5 out of the 31 products (bortezomib, erlotinib, gefitinib, imatinib, trastuzumab), for four products on 17 countries, for six products on 16 countries, and for five products in 15 countries.

None of the medicines surveyed had a unit price below €10 in the 18 surveyed countries. Five medicines had an average unit ex-factory price between €250 and €1000, and seven medicines had an average unit price above €1000.

A few medicines had lower outliers (particularly Greek and UK prices) and upper outliers (particularly prices in Switzerland, Germany and Sweden). Overall, Greek prices ranked at a low level, whereas Sweden, Switzerland and Germany showed price data in comparably high ranges. No pattern was identified as to whether prices in Australia and New Zealand were high or low compared with European countries.

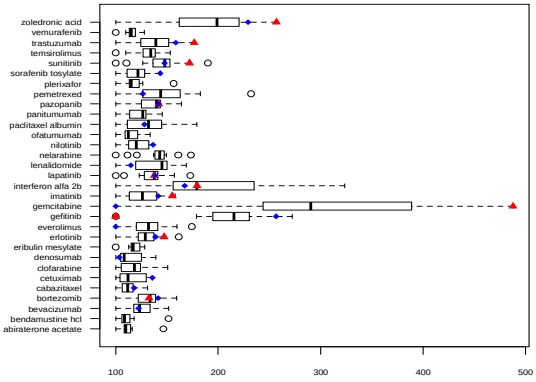

Figure S1: Boxplot of medicine prices (ex-factory price per unit) indexed (price in the lowest priced country = 100), as of June 2013 (August 2013 for New Zealand), in 16 European countries, Australia and New Zealand

(AU (n =18) = blue diamond, NZ (n = 11) = red triangle)

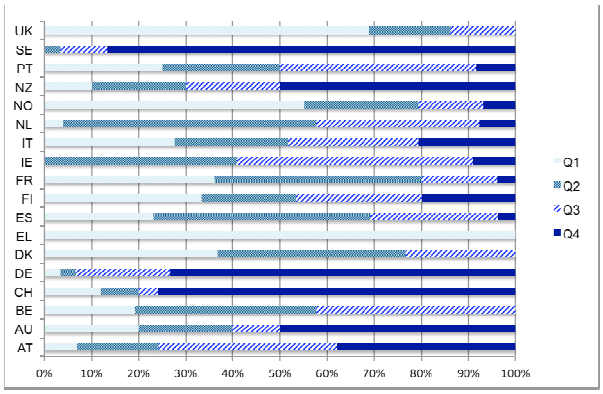

Figure S2: Frequency of ex-factory prices per unit as of June 2013 (August 2013 for New Zealand), ranking in quartiles
(Q_1 = first quartile (<=25%), Q_2 = second quartile (25% – <= 50%), Q_3 = third quartile (50% – <=75%), Q_4 = fourth quartile (75% – <=100%)
n = 31 in DE, DK, SE; n= 30 in AT, FI, IT, NO, UK; n = 27 in ES, FR, NL; n = 26 in BE, CH; n = 24 in EL; n = 23 in IE; n = 21 in AU; n =12 in PT; n = 11 in NZ)

Conclusions

Medicine prices varied across European countries, Australia and New Zealand. While no relevant price differences of Australia and New Zealand in comparison with European countries were found, funding of oncology medicines appeared to be more restrictive in these two countries, and access to be granted at a later stage. However, these official list prices do not include discounts and similar arrangements that are in place for several of the surveyed medicines in a number of countries.

Acknowledgement

The authors thank the colleagues of the Austrian Public Health Institute for providing medicine price data on European countries from their Pharma Price Information (PPI) service.

Access to high technology medicines in Russia

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The access of high technology medicines is restricted for such reasons as pricing and reimbursement policy and medical indications. The most difficulties are presented in children because of lack of clinical data about effectiveness and safety.

Objectives:
to evaluate the acceptability, affordability and availability of high technology medicines and provide the practical recommendations of optimization their access in Russia (for example the biologics in children with juvenile idiopathic arthritis(JIA))

Policies:
Pricing and Reimbursement Policies

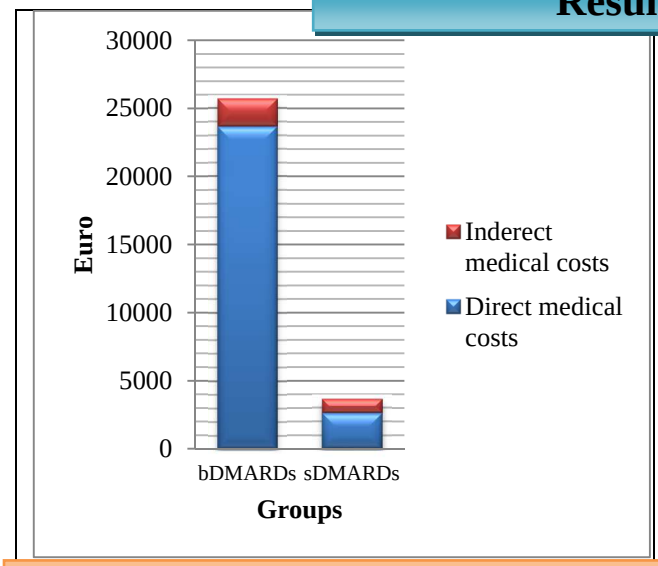
Stakeholders:
Ministry of Health (Federal and Regional levels), key opinion leaders

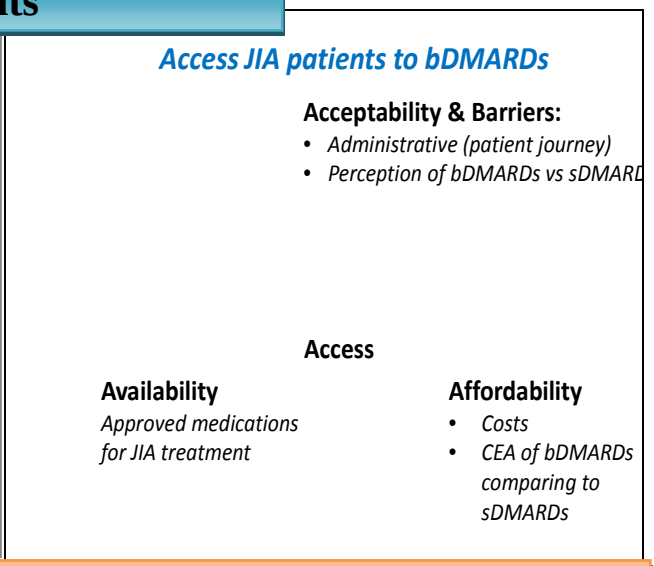
Study design:
Description of clinical and economical effectiveness of biologics and disease-modifying therapy. Policy evaluation according to data of expert's survey (63 heads and clinical specialists)

Time period:
Dec. 2010 - Dec. 2013

Setting:
Study examines the public sector. It is addressed to both the out- and in-patient sectors

Results





Availability: 6 biologics (Infliximab, Adalimumab, Abatacept, Rituximab, Etanercept, Tocilizumab) were available. Most of them were used off-label in patients with severe forms in Federal Medical Institutions.
Affordability: health economics researh helped to include the biologics to the List of Vital and Essential Drugs and increase their affordability. Price negotiation and risk-sharing weren't used for reducing price.
Acceptability: The is the restriction of the access to biologics on regional level.

Conclusions: There is the improvement of affordability of high technology medicines in Russia thanks to the methods of health technology assessment

RETROSPECTIVE FINANCIAL ANALYSIS OF MEDICINES REIMBURSEMENT SERVICES IN COMMUNITY PHARMACY

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BACKGROUND

- A problem of middle-income countries presents an inequality access to medicines. Previous studies have demonstrated that in Republic of Moldova, partially reimbursed medicines did not decrease the burden of expenditures for medicines. The pharmaceutical market comprises 1,125 pharmaceutical retailers enterprises, from which only 238 units are contracted by the National Health Insurance Company, to provide reimbursed medicines dispensing services. The share of medicines delivered from the pharmacies opposite the parapharmaceutical products, is the 92%. For reimbursed drugs, in order to increase economic affordability of the population, pharmacies apply a mark up to 15%, and for unreimbursed medicines, the marks-up is 25% to the purchase price.
- According to state policy in the field of medicine, have to be taken measures to increase people's access to reimbursed medicines in Republic of Moldova, by increasing the number and assortment of medications, reassessment of policy pricing to these drugs, applying a lower mark-up. But all these measures does not guarantee their availability for population. One of the cause is that retailer pharmaceutical companies are not required to provide this kind of service even if the company is contracted, it is not required to hold an assortment of common international names registered in the reimbursement list and at the request of management of pharmacy, pharmacist can refuse to dispense the reimbursed medicine on economic grounds. Global pharmaceutical practice, in the field of reimbursement of medicines, demonstrates the presence of a payment to pharmacies or pharmacists for the dispensing service of this kind drugs, paid by the National Health Insurance Companies.
- Since, the medicines reimbursement system does not regulate the entry prices in the list, a lower marks-up of reimbursed vs non-reimbursed drugs induce refuse of dispensing them to the patient from pharmacies. In this context, the aim of this study was: evaluation of financial attractiveness for community pharmacy to provide medicines reimbursement services and the factors that influence on this process.

PURPOSE

To achieve this goal, the following objectives have been proposed:

- Evaluation of cognitive involvement, of pharmacists in dispensing medicines in community pharmacy;
- Determine the time required for delivery of drugs in the community pharmacy, to the population;
- Analyzing the pharmacy staff;
- Economic and financial analysis of retail pharmaceutical companies in Moldova, on the compensated medicines sector;
- Determination of the profitability of community pharmacies, as a result of dispensing medicines.

MATERIALS AND METHODS

- As methods of study have been used survey, direct observation, break even analysis [1] and literature review. The research was started in April 2014 and ended in May 2015. Study address to revision of mark-up applied by wholesales and retails companies for reimbursed medicines, to improve availability and affordability for outpatient sector on reimbursed medicines [3] and to analyze the capacity of pharmacists in providing cognitive services for reimbursed medicines, with the future possibility of pay for performance service implementation from National Health Insurance Company (NHIC) [2,4].
- To assess cognitive implication level and the working time spent by pharmacist for dispensing: one reimbursed drug, one unreimbursed Rx drug and one OTC drug, was asked pharmacists opinion working in community pharmacies through sociological survey, on a sample of 300 people. Simultaneously, time was assessed by direct observation in the pharmacy.
- The financial analysis was made using data collected from National Bureau of Statistics and NHIC, for 7 - retail pharmaceutical companies, which hold 314 pharmacies and branches , for 2014 year. To evaluate the break even point was calculated transposition coefficient for expenditure every 1 leu cost.
- In accordance with the Law on pharmaceutical activity, the right to dispense Rx drugs have only pharmacists with higher education. In this context, to assess the capacity of accomplishment for delivery service with reimbursed medicines in the pharmacy, was calculated, within 50 community pharmacies, the number of personnel working in the pharmacy; total number of pharmacists, the number of pharmacists with University degree and number of technicians.

Figure 1. Relative frequency of cognitive implication

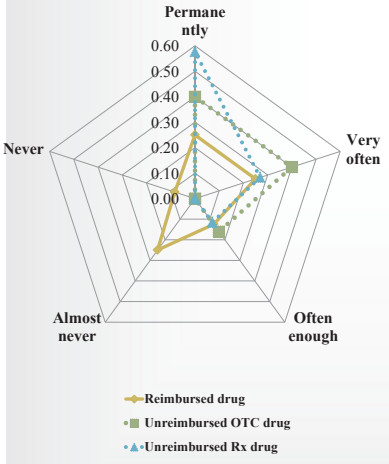


Figure 2. Relative frequency of dispensing time for 3 types of drugs

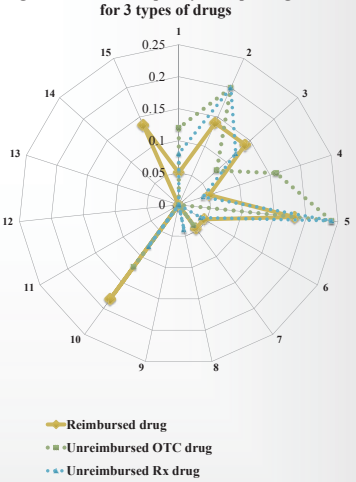
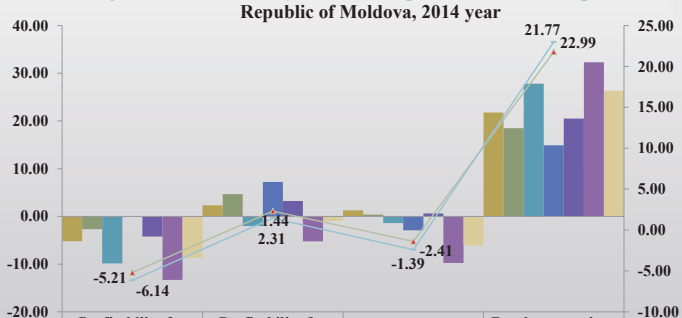


Figure 3. Financial analysis of retailer pharmaceutical enterprises in Republic of Moldova, 2014 year



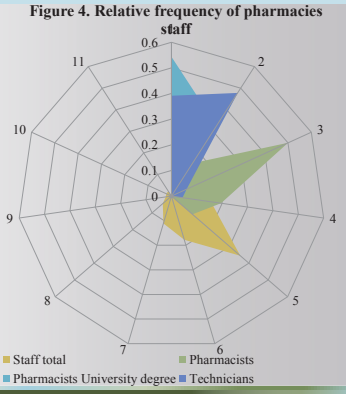
	Profitability for reimbursed drugs, %	Profitability for unreimbursed drugs, %	Total profitability, %	Break even point - for reimbursed drugs , %
A	-5.21	2.31	1.30	21.77
B	-2.68	4.66	0.39	18.48
C	-9.86	-2.01	-1.39	27.82
D	0.07	7.20	-2.92	14.91
E	-4.22	3.22	0.60	20.49
F	-13.32	-5.22	-9.76	32.31
G	-8.73	-0.96	-6.07	26.35
Median	-5.21	2.31	-1.39	21.77
Average	-6.14	1.44	-2.41	22.99

A, B, C, D, E, F, G, - retail pharmaceutical companies, 314 community pharmacies and branches

RESULTS

- The cognitive implication level, for reimbursed drugs was „almost never“ or „permanently“, with a relative frequency 0.25 (Figure 1).
- The most commonly time spent by pharmacist for dispensing was 10 minutes, with a relative frequency 0.18 (Figure 2). These results confirm that pharmacist loses most of their time for technical processing of the prescriptions, fact demonstrated through direct observation of the process.
- Most commonly, in pharmacy, activates only one pharmacist with higher education, who usually is head of pharmacy or head of branch, thing insufficient to provide cognitive services at the dispensing Rx medicines or reimbursed medicines (Figure 4).
- The median of profitability for reimbursed drugs was -5.21%, for unreimbursed drugs +2.16% (Figure 3).
- The break-even point for reimbursed drugs is 22% of mark up. The pharmacies are not convenient to dispense medicines with reimbursed prescription from the lack of benefit for them.

Figure 4. Relative frequency of pharmacies staff



CONCLUSIONS

- It is recommended to review the added mark ups for reimbursed medicines in retail pharmaceutical sector, from 15% to 22% (using regressive mark-ups);
- To introduce continuing education courses for pharmacists in field of adherence and compliance to treatment of patient with non-communicable diseases, for medicines from the reimbursement list.

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Impact of delisting OTC medicines from reimbursement list

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Problem Statement

Over-the-Counter medicines (OTCs) were excluded from reimbursement by law since July 1, 2012. Selected OTCs remained reimbursed with the approval of insurance funds, usually under certain conditions of reimbursement (for specific indications or patient groups).

Methodology

SÚKL´s list of reimbursed medicines valid as of June 1, 2012 was compared to the list of reimbursed medicines valid as of July 1, 2012 to identify OTCs excluded from reimbursement. The financial impact of delisting OTCs was calculated based on consumption data and reimbursement price from the payers. The current reimbursement list (May 2015) was searched to identify the current spectrum of reimbursed OTCs.

Results

There were 238 reimbursed OTCs in June 2012 and 14 OTCs remained reimbursed in July 2012. The reimbursement is limited by conditions of reimbursement for most of reimbursed OTCs. The delisted OTCs saved payers approx. 21,6 mil € (1€ = 27, 624 CZK) in the first year after the delisting. Average price of not excluded OTCs has grown to 12,54 % and average price of excluded OTCs has grown to 10,70 % since January 2012.

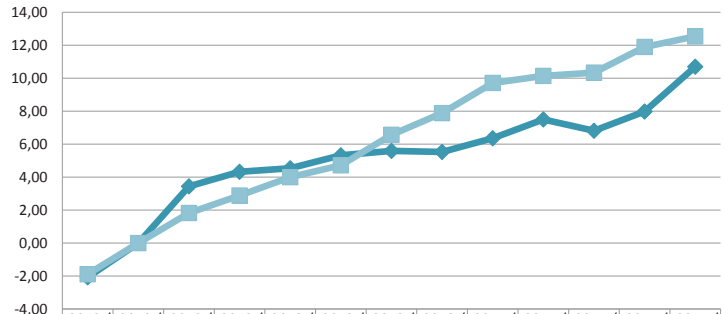
Conclusion

Almost 95 % of previously reimbursed OTC medicines were exluded from the reimbursement system in 2012. OTC medicines that remain in the reimbursement system are reimbursed for example for patients with cystic fibrosis, diagnosed Sjogren´s syndrom (dry eyes), chronic pancreatitis. The payers saved 21,6 mil. € due to the delisting. The delisting did not have a major impact on the price of excluded OTCs.

Reimbursed OTCs by ATC code

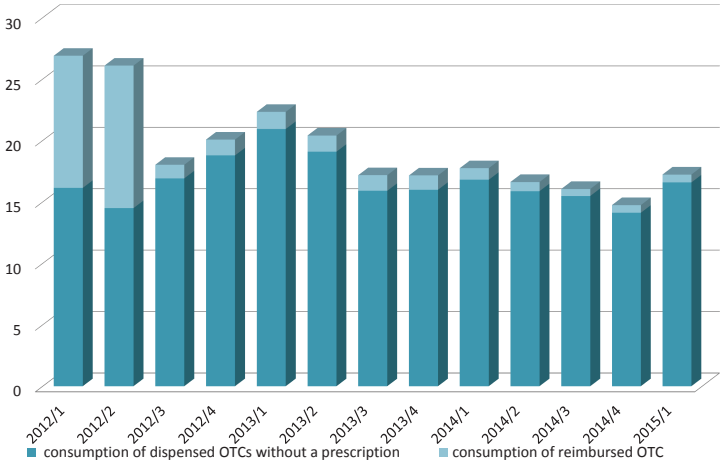
7/2012	5/2015	
A09AA02 multienzymes	**A09AA02** multienzymes	**D02AC** soft paraffin and fat products
B01AC06 Acetylsalicylic acid	**B01AC06** Acetylsalicylic acid	**D02AE01** carbamide
M01AE01 Ibuprofenum (suspension)	**S01XA20** Artifiacial tears and other indifferent preparations	**R05CB06** ambroxol
S01XA20 Artifiacial tears and other indifferent preparations	**A12AX** calcium, combinations with vitamin D and/or other drugs	**R06AE07** cetirizine

Growth of average price of OTCs excluded/not excluded from reimbursement since January 2012 (%)

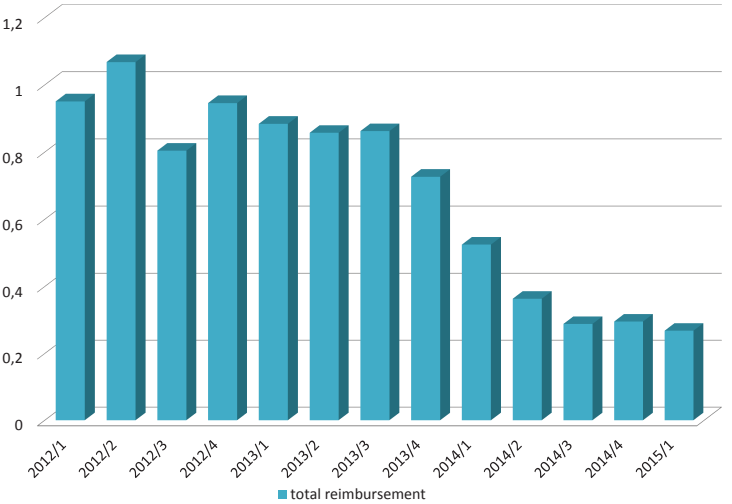


	2012 / 1	2012 / 2	2012 / 3	2012 / 4	2013 / 1	2013 / 2	2013 / 3	2013 / 4	2014 / 1	2014 / 2	2014 / 3	2014 / 4	2015 / 1
exluded OTCs	-2,08	0,00	3,44	4,32	4,54	5,33	5,59	5,53	6,36	7,50	6,81	7,98	10,70
not excluded OTCs	-1,89	0,00	1,82	2,88	4,00	4,72	6,56	7,88	9,71	10,14	10,34	11,89	12,54

Value of OTCs of 1/2012 (EUR)



Expenditure of payers to not excluded OTCs (EUR)



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Generic medicines – more than a cost-saving mechanism

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BACKGROUND

In current times of financial and economic hardship, many governments have accommodated generic medicines as a means to contain increasing pharmaceutical expenditures by imposing different kinds of pricing policies. However, a viable and sustainable generic medicines industry contributes more to society than only an opportunity to contain pharmaceutical expenditures. From a health perspective, generic medicines might also have an important impact on access to pharmacotherapy, innovation and potentially also to medication adherence.

OBJECTIVE

To provide an overview of the added societal value of generic medicines beyond their cost-savings potential through reduced prices. In addition, an observational cast study documents the impact of generic entry on access to pharmacotherapy in the Netherlands.

METHODS

Data from the Medicines and Medical Devices Information Project database in the Netherlands were used for the case study in which the impact of generic medicine entrance on the budget and the number of users was calculated as an illustrative exercise.

RESULTS

Impact on access to pharmacotherapy

Generic medicines play an essential role in treating diseases. They not only increase the affordability of modern day pharmaceuticals, their reduced prices also increase access to pharmacotherapy.
The availability of generic medicines is also likely to increase access to pharmacotherapy for certain medicines of which reduced prices of generic medicines are expected to improve the cost-effectiveness of existing pharmacotherapy, thereby introducing these medicines earlier in the treatment algorithm.
In addition to improving the cost-effectiveness of existing pharmacotherapy, the entry of generic medicines may also make it cost-effective to manage previously untreated patients. Or lead to a more optimal treatment of some diseases.

Impact on medication adherence

By concentrating on the needs of patients and pharmacists, the different types of innovativeness of generic medicines might have a positive impact on medication adherence. However, the reduced prices of generic medicines might also have their impact on medication adherence.
Generic medicines might also have a negative effect on medication adherence, especially in relation to generic substitution. As generic medicines may differ with respect to name, shape, size, colour, taste and inert excipients, the act of substitution may therefore lead to confusion and misperception among patients, especially in elder patients. This is where pharmacists have to step up and play their role by informing and educating patients, as already described above.

Impact on innovation

Innovation is essential for the generic medicines industry, as today's innovative medicines give rise to tomorrow's generic medicines and all generic medicines can trace their origins back to originator medicines.
A robust generic medicines market is generally understood to have a positive impact on innovation in the pharmaceutical sector. Entry of generic medicines generates competition, which is essential for inducing innovation by originator companies.
Generic medicines do not only provide a stimulus for originator companies to innovate, they also encourage generic companies to innovate in order to differentiate themselves in this highly competitive market, for instance, by addressing the needs of patients and pharmacists. Through the creation of another type of 'added value'.

Case study – The Netherlands

Table 1. Additional impact on the number of users

Active substance	Year of generic entry	Number of users in 2013	Number of users possible with 2013 budget if prices remained constant	Additional users through entrance of generic medicines
Omeprazole	2002	1,039,096	117,847	921,249
Simvastatin	2003	1,071,042	124,585	946,457
Amlodipine	2004	447,908	88,164	359,744
Lisinopril	2002	227,301	62,446	164,855
Perindopril	2006	276,703	73,980	202,723
Clopidogrel	2009	127,923	15,171	112,752
Ramipril	2004	57,346	12,999	44,347
Temozolomide	2010	1,107	16	1,091
Alendronic acid	2005	140,178	20,967	119,211
Esomeprazole	2010	243,995	119,162	124,833
Pantoprazole	2009	587,430	134,671	452,759
Fluvastatin	2008	21,327	6,475	14,852
Felodipine	2003	12,183	6,241	5,942
Quinapril	2004	28,473	11,266	17,207

Four different scenarios are calculated in which the cost/DDD of the originator medicine remained at the level of 1 year before generic entry, decreased by 25%, decreased by 50% or decreased to the level of the cost/DDD of the originator medicine in 2013. The data shown in the table are the cumulative additional budget impact for the Dutch government from the year of generic entry until 2013 for the respective scenario. DDD: Defined daily doses.

CONCLUSIONS

Generic medicines offer more to society than just their cost-saving potential through reduced prices. Generic medicines increase access to pharmacotherapy, provide a stimulus for innovation by both originator companies and generic companies and, under the right circumstances, have a positive impact on medication adherence. The case study in the Netherlands shows that the entrance of generic medicines made it possible to treat more patients for the same budget. As such, governments must not focus only on the prices of generic medicines as this will threaten their long-term sustainability. Governments must therefore act appropriately and implement a coherent set of policies to increase the use of generic medicines.

The unintended consequences of pharmaceutical pricing and reimbursement policies: A three-country qualitative study of insurance models in Ghana, Namibia, and South Africa

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Problem Statement

Medicine prices can be a barrier to access as countries strive to align universal health coverage objectives with strict pharmaceutical pricing and reimbursement models. Furthermore, each pricing methodology has challenges, and the choice of pricing methodology is dependent on the country context:

- Ghana's National Health Insurance Scheme adopted a median pricing methodology and a single-tier reimbursement model in the absence of national pricing regulation.
- The Medical Aid Schemes in South Africa and Namibia both used the single exit pricing system, with Namibia using a single tier and South Africa employing a four-tier medicines reimbursement model.

Objective

To assess the pharmaceutical pricing and medicines reimbursement policies (models) in three countries of varying income levels in sub-Saharan Africa.

Methodology

The assessment focused on the strengths, gaps, and key considerations for sustainability in each of the models.

- Qualitative data was collected in Namibia, South Africa, and Ghana in 2014-15 using a Medicines Benefits Assessment tool developed by Management Sciences for Health (MSH). Work was carried out in collaboration with the Systems for Improved Access to Pharmaceutical and Services (SIAPS) Program.
- Interviews were conducted with 89 stakeholders from quaternary, tertiary, and primary care hospitals; private and public pharmacies; medical, dental and pharmaceutical associations; chambers of commerce; and medical aid/insurance schemes.
- Similarities and differences across each of the three insurance systems were analyzed. The analysis focused on pricing policies, coverage gaps, and strengths and weaknesses in each model.

Results

		Ghana	Namibia	South Africa		
Pricing Policy		None	Single Exit Price (SEP)	Single Exit Price (SEP), plus a four-tier reimbursement structure		
Pricing and Reimbursement Model	Pharmacies (private)	NHIS determined median price	SEP + 50% (Margin) + 15% (VAT) *Some meds % margin 10%	**SEP**	**Fixed Fee**	**% Margin on SEP (excl. VAT)**
				< R75	R6	46%
				≥R75-<R200	R15.75	33%
	Dispensing clinics & hospitals	NHIS determined median price	SEP + 30% (Margin) + 15% (VAT)	≥R200-<R 700	R51	15%
				≥R 700	R121	5%
	Patients/ members	No copayment	Flat fee per product and 7.5%-20% or a fee of NAD30; PSEMAS: patient pays 7.5%	5-20% co-payment based on individual scheme strategy		
Objectives of Pricing and Reimbursement Model		a)Improved medicine access b) No out-of-pocket payment c) Controlled margins within supply chain d) Reduced incentive to prescribe outside EML	a)Improved medicine access b) Reduced "out-of-wallet experience" for clients b) Disincentivize dispensing prescribers	a) Improved access b) Legal obligation to offer generic medicine as first alternative to an innovator product c) Sale of medicines at the same price to all customers, regardless of the volume purchased d) Regulated control of all the mark-ups added along the supply chain		
Unintended Consequences		a)"Top-ups" b)Increased stock-outs c) Increased out of pocket payments	a) Increased level of discounting and bonuses on OTC's and sundries b) Increased dispensing of injectables by dispensing prescribers c) lowest-priced generic is not the most sold	a) Increased level of discounting and bonuses on OTC's and sundries; free packs and gift cards b) Introduction of data fees* c) Lowest-priced generic is not the most sold d) Co-payments not imposed on customers		

* Pharmaceutical companies offering pharmacies inappropriately large sums of cash for their sales data in return for stocking their product

Discussion

Each model had its merits and challenges:

- **Ghana:** Stakeholders said the model does not consider factors such as currency depreciation and inflation.
- **Namibia and South Africa:** Dispensing fees were well received, but concerns were expressed about the pricing model not being implemented in the public sector.
- **South Africa:** Regulations being considered to address undesirable consequences of current pricing approach.

Conclusion

Pharmaceutical pricing and medicines reimbursement policies used by Ghana, Namibia and South Africa have a common objective of improved access to medicines. Addressing the unintended consequences will enable countries meet the overall goals of their UHC programs.

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USAID FROM THE AMERICAN PEOPLE
SIAPS Systems for Improved Access to Pharmaceuticals and Services

Unintended consequences of co-payment regulations in Belgium: the case of atorvastatin

*J Fraeyman [1], H De Loof [2], G Van Hal [1], G RY De Meyer [2] , R Remmen [3], Ph Beutels [4]

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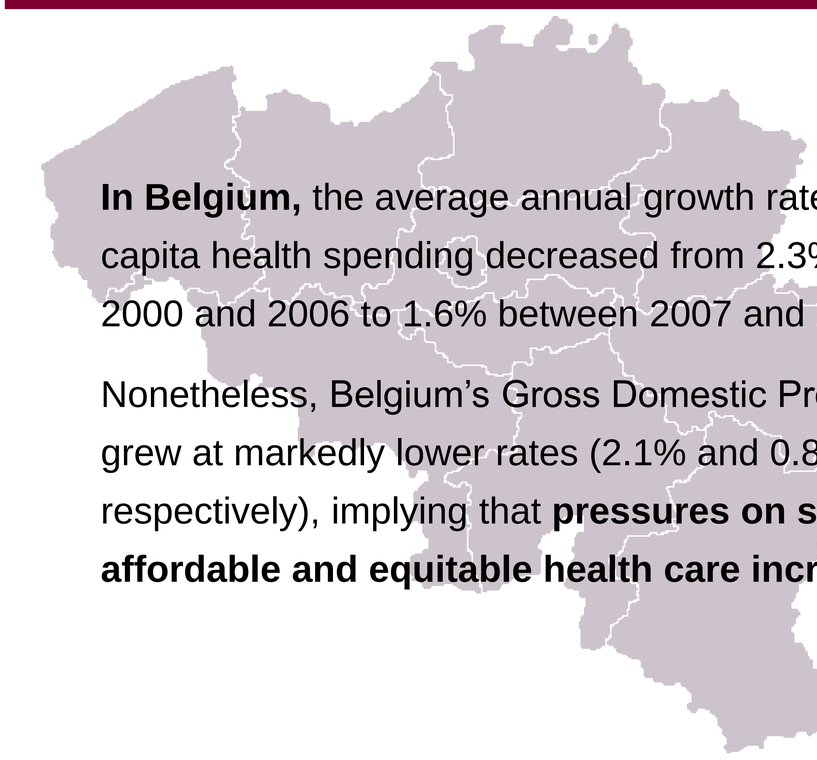
Background



In Belgium, the average annual growth rate of per capita health spending decreased from 2.3% between 2000 and 2006 to 1.6% between 2007 and 2013 [1].

Nonetheless, Belgium's Gross Domestic Product (GDP) grew at markedly lower rates (2.1% and 0.8%, respectively), implying that **pressures on sustaining affordable and equitable health care increase.**

Objectives

We assessed the impact of **co-payment regulations** on prices and sales figures for **atorvastatin in Belgium** (within a reference pricing system) before and after the **patent expiry in 2013.**

Methods

We related **sales figures** to coinciding price evolutions and broke down costs by their bearer (patient, sickness insurance).

We compared:

- **IMS Health database** (pharmacy sales figures)
- BCFI **unit price tables** (Belgian centre for Pharmaco-therapeutic Information)

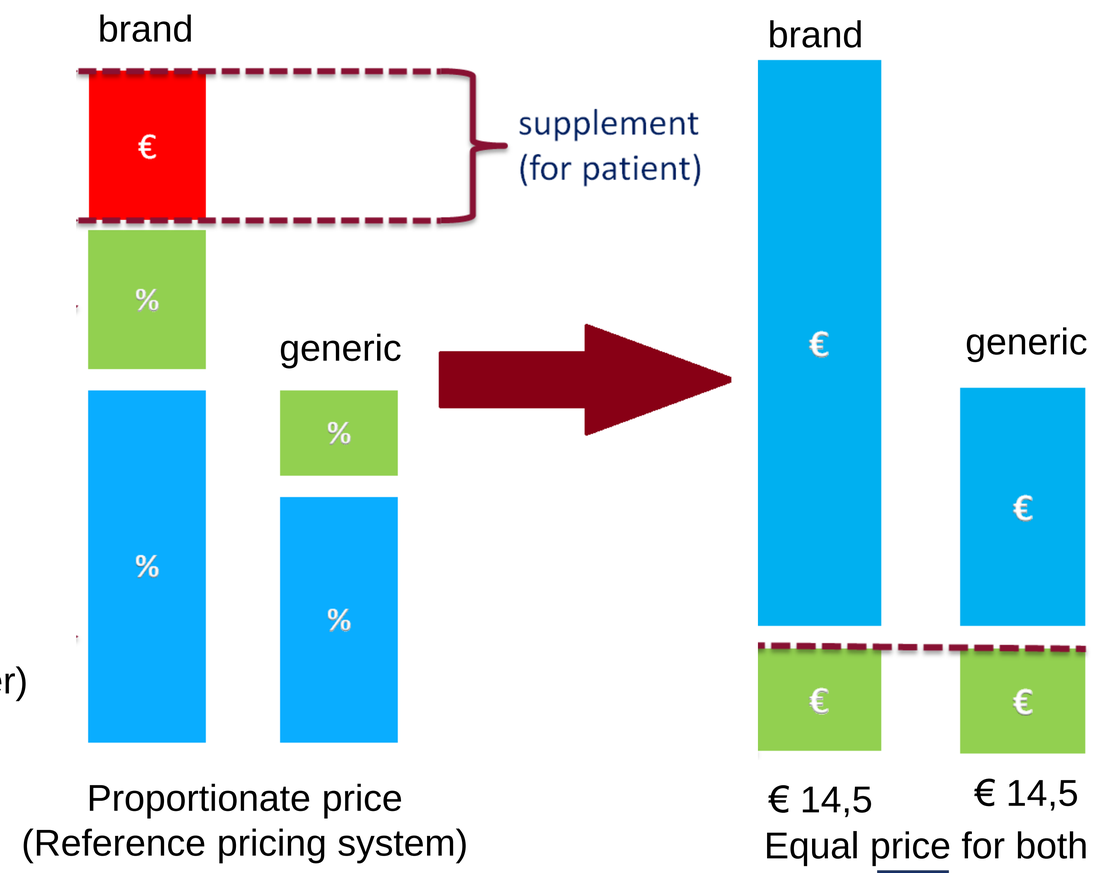
Results

Lipitor® 98*80mg
Public price: 123.51 euro

(After patent expiry)

Atorvastatin Mylan® 98*80mg
Public price: 62,52 euro

(Generic within reference cluster)



Reimbursement cost (by health insurance):
€ 109,1 for brand
€ 48,02 for generic

- No matter the reference price…
- Both '*low-price medicine*'
- High cost for health insurance
- No incentive (for patient nor prescriber) left to choose for a generic…

For this case only:
- Reimbursed packages: 19,777
- Public Price: € 2,157,671
- **Missed-out potential generic savings: 1,000,000**

Conclusion

Looking ahead at the patent expiry of rosuvastatin in 2016, the effectiveness of ***existing regulations*** *to curb growing pharmaceutical expenditures* ***requires urgent reconsideration***, based on the lessons learnt from case studies such as ours

In this case, the **reference pricing system** was a vain attempt to curb public drug expenditures.

A potentially feasible option would be to ***abolish the maximum co-payment level per package*** in the Belgian reimbursement system for therapeutically interchangeable drugs.

Gesundheit Österreich GmbH

DEVELOPMENT OF PHARMACEUTICAL PRICES IN THE FORMER YUGOSLAVIAN REPUBLIC OF MACEDONIA (FYRM) IN COMPARISON TO SELECTED COUNTRIES OUTSIDE THE NATIONAL REFERENCE BASKETS

AUTHORS

- Claudia Habl, Deputy Head of Health Economics Department, Austrian Public Health Institute (Gesundheit Österreich GmbH) claudia.habl@goeg.at
- Kristina Hristova, Director of Pharmacy Sector, Health Insurance Fund (HIF) of the Former Yugoslavian Republic of Macedonia KristinaH@fzo.org.mk

BACKGROUND

Budgetary constraints - with annual growth rates that peaked at 20% - fuelled by the upcoming economic crisis demanded for a change in the pricing model for pharmaceuticals in the Former Yugoslavian Republic of Macedonia (FYRM). Several neighbouring countries were faced with similar challenges, so the Republic of Macedonia carefully looked into their policies and thus introduced external reference pricing in spring 2010 which led to a reduction of prices. The specific was that both, the Ministry of Health (MoH) for the "unique price" (i.e. the maximum price) and the Health Insurance Fund (HIF) as basis for reimbursement, performed price comparisons. The country basket of the MoH includes Bulgaria, Croatia, France, Germany, Greece, Netherlands, Poland, Russia, Serbia, Slovenia, Turkey and the United Kingdom whereas the HIF references to Bulgaria, Croatia, Serbia and Slovenia. Both authorities use the average of the wholesale price in these countries.

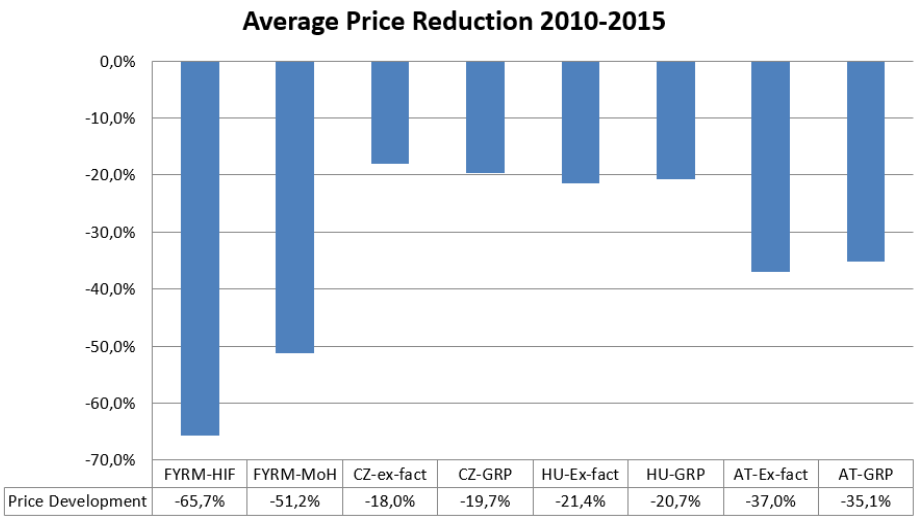
The analysed substances (brinzolamide, cefixime, cyproterone, donepezil, dutasteride, flutamide, leflunomid, levetiracetam, mycophenolic acid, olanzapine, paroxetine, repaglinide, ribavirin, tacrolimus, topiramate and valproic acid/sodium valproate) were selected because they showed the largest differences in the reference prices.

OBJECTIVE

To show the trend of price reductions achieved for selected pharmaceuticals in the FYRM as compared to the non-basket countries Hungary, Czech Republic and Austria.

RESULTS

All of the 16 analysed substances from the Macedonian market were also on the market in Austria, Czech Republic and Hungary; but some only in different presentations or pack sizes and sometimes by different providers (in the case of off-patent products). The prices in the basket countries of FYRM in average went down by a larger extent then in those of the comparator countries as the Graph shows. For the selected group of 36 medicines the HIF country basket achieved a better average price reduction, most likely caused by the predominance of lower prices CEE countries in the basket.



	FYRM-HIF	FYRM-MoH	CZ-ex-fact	CZ-GRP	HU-Ex-fact	HU-GRP	AT-Ex-fact	AT-GRP
Price Development	-65,7%	-51,2%	-18,0%	-19,7%	-21,4%	-20,7%	-37,0%	-35,1%

Despite the overall lower price level in FYRM, one active substance (levetiracetam) was more costly in FYRM than in Austria, Czech Republic or Hungary. In 2010, generally speaking, the medicines analysed were more expensive in Austria than in the compared countries whereby the price difference per medicines was lower in 2015.

CONCLUSION

The inclusion of neither Austria, nor the Czech Republic nor Hungary in the country basket used by the FYRM would trigger further price reductions for the selected medicines. However, the analysis shows that the FYRM has made a huge step forward for medicines prices determination with implementation of both, HIF's and MoH's, pricing methodologies.

BACKGROUND AND METHODS

- ***Policy targeted:*** Analysis of the effects of external price referencing in different countries.
- ***Countries analysed:*** FYRM, Austria (AT), Czech Republic (CZ), Hungary (HU)
- ***Methodology:*** Ex-post cross-country evaluation of pricing trends between 31.12.2010 and 30.4.2015 for selected out-patient medicines that are reimbursed by the Macedonian HIF.
- ***Price Types:*** Ex-factory Price (Ex-Fact), Gross Retail Price (GRP), maximum price
- ***Sources:*** National Macedonian price databases as of 2012 and previous price lists and European Integrated Price Database EURIPID.

FACTBOX EURIPID

- EURIPID database contains data on **official prices of publicly reimbursed**, mainly **out-patient medicinal products** that are published by national authorities in line with the Transparency Directive 89\105\EC.
- It is exclusively available for **national competent authorities for pricing and reimbursement of medicinal products**, who agreed on the rules of the collaboration and who participate actively.
- Currently data of **26 European countries** are available in

A forecasting model for drug utilization and expenditure integrating a Cellular Automata model with the Budget Impact Analysis approach. Preliminary results.

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Background. The considerable pressure on healthcare systems, exerted by increasing expenditures for new drugs, urges specific initiatives, including the development of new models, to optimize the managed entry of new medicines and guarantee their sustainability.
Objectives. To develop a Forecasting Model for drug utilization and expenditure of emerging medicines identified, prioritized and critically assessed by the Italian Horizon Scanning Project (IHSP), integrating a Cellular Automata (CA) model describing the diffusion process on the market with the Budget Impact Analysis (BIA), performed before the market entry of a new drug.
Methods. Selection and critical evaluation of high-impact emerging medicines. Development of CA and BIA models for emerging drugs, using medical prescription data from the administrative ARNO-CINECA databases and sales data from IMS Health, Italy.
Results. The first-in-class emerging anti-diabetic dapagliflozin was selected and critically evaluated by the IHSP about 12 months before the European Marketing Authorization (MA). Other competitors already on the market were identified. A CA model describing the diffusion process of more than 200 Italian antidiabetic products (ATC A10B) (new molecules and new formulations, dosages and packs of already existing drugs) sold between 2000-2014 has been developed and validated. A protocol for the identification of the real-world target population in the ARNO-CINECA database was set up on the grounds of the expected indication for dapagliflozin. The estimation of budget impact of dapagliflozin is ongoing based on the estimation of market shares, through the application of CA Model, the analysis of the identified target population, and the analysis of the potential variations in related healthcare costs for the treatment of type 2 diabetes, after the introduction of dapagliflozin.
Conclusions. The proposed Forecasting Model (C-ToBIA Model) predicts the impact of emerging drugs on the National Health System (NHS), under the sufficient conditions for estimability. The originality of the C-ToBIA Model is basically related to the assessment of emerging drugs 12 months before the MA date, and the estimation of the diffusion process and the potential financial impact before market entry (ex-ante). The C-ToBIA Model will help to timely estimate the possible utilization pattern of new medicines and their potential impact on the National Health System before their market entry.

METHODS

ITALIAN HORIZON SCANNING PROJECT → Prioritization of **emerging drug** with a potential high impact → critical appraisal → *Place in therapy* → identification of **competitors (drug trackers)** already on the market

Emerging drug and comparators

SALES'DATA (IMS HEALTH, ITALY) & DATA FROM ADMINISTRATIVE DATABASE (ARNO-CINECA)

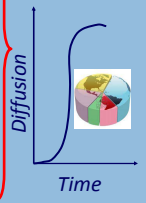
Number and distribution of competitors over time → **CELLULAR AUTOMATA MODEL**

Diffusion of innovation model

Identification of the real-world target population → **BUDGET IMPACT ANALYSIS**

Financial impact on the Italian Health System

C-ToBIA MODEL



RESULTS

Drug selection and evaluation, through the *ITALIAN HORIZON SCANNING PROJECT* (*IHSP*):

Identification and critical appraisal of **DAPAGLIFLOZIN:**

➢ first-in-class inhibitor of sodium- glucose cotransporter 2 (SGLT2), with glucosuric effect

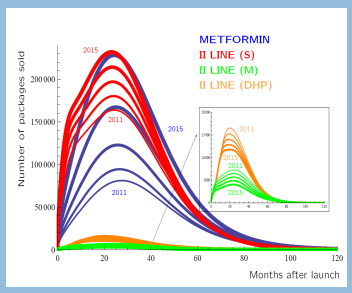
➢ the drug was critically evaluated by IHSP about 12 months before the European Marketing Authorization as:

- monotherapy when diet and exercise alone do not provide adequate glycemic control in patients for whom use of metformin is considered inappropriate due to intolerance;
- add-on therapy in combination with other glucose-lowering drugs including insulin, when these, together with diet and exercise, do not provide adequate glycemic control

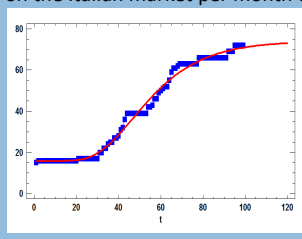
Identification of **competitors already on the market**: antidiabetic drugs (**ATC A10B**)

Development of CELLULAR AUTOMATA MODEL to describe market behaviour of antidiabetic agents

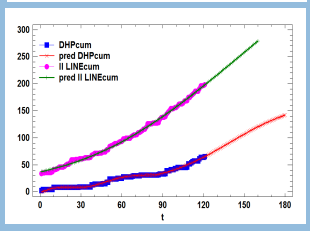
Analysis of **more than 200 Italian** products sold **between 2000-2014**, and development of the diffusion model for antidiabetic drugs (**ATC A10B**), distinguishing between metformin (I line) and other antidiabetic agents (add-on treatments).
Among add-on treatments, the subgroup of products distributed due to higher price through hospital pharmacies (DHP) – instead of community pharmacies – has been isolated.



Forecast of the number of new antidiabetic products that will be introduced on the Italian market per month until 2018



METFORMIN: 7 new products expected until April 2018



ADD-ON TREATMENTS: 104 (68 DHP) new products expected until April 2018

BUDGET IMPACT ANALYSIS for dapagliflozin before market entry (*ongoing*)

A protocol for the identification of the **real-world target population** in the ARNO database has been set up on the grounds of the expected indication.
The estimation of **budget impact** of dapagliflozin is based on:

1. estimation of expected market shares, through the application of CA model

2. analysis of the identified target population through IMS Health Data and ARNO Database

3. analysis of the potential variations in related healthcare costs for the treatment of type 2 diabetes, after the introduction of dapagliflozin

CONCLUSIONS

The present project proposes an original forecasting model, *C-ToBIA Model*, to predict the impact of emerging drugs on the National Health System, under the sufficient conditions for estimability. The originality of the C-ToBIA Model is basically related to two elements:
(i) the assessment of emerging drugs 12 months before the European Marketing Authorization date
(ii) the estimation of the diffusion process and the potential financial impact before market entry (ex-ante)

The C-ToBIA Model will help to timely estimate the possible utilization pattern of new medicines and their potential impact on the National Health System before their market entry.

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Reimbursement policy optimization for Angiotensin-converting enzyme (ACE) inhibitors in Bulgaria: Controlling expenditure without undermining access to treatment

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Introduction and Problem Statement

Angiotensin-converting enzyme (ACE) inhibitors play an important role in the treatment of hypertension (HTN) and heart failure (HF). However a reimbursement policy based only on controlling expenditure and not adequate to the patient access to treatment, prescription regimes and compliance habits could not be able to return expected results for long-term improvement of patients' health.

The study addresses the reimbursement policy of the National Health Insurance Fund, based on payment of a certain percentage from the internal reference price within an INN / International Non-proprietary Name/ group of drugs, i.e. 25%, 50%, 75% or 100%. This reimbursement level affects the percentage of co-payment by the patients, i.e. in the case of ACE inhibitors, the NHIF pays 25% of the internal reference price, while the remaining 75% of the drug's price within the same INN should be paid by the patients.

The study covers the Bulgarian reimbursed market of ACE inhibitors, related to the doctors behaviour and patients flows in the whole country.

Study Design and Methodology

The study design is related to policy evaluation and impact assessment of alternative/what-if policy decisions related here to reimbursement policy optimization. The methodology employed is mathematical modeling and simulation of the ACE inhibitors drugs market with the aid of a computer modelling and simulation software. Such approach enables researchers to design models of dynamic systems and to experiment with different policies related to changes in endogenous or exogenous variables and factors.

Designing and testing a reimbursement policy based on lower rates of patient co-payment, while at the same time providing means for controlling pharmaceutical expenditure, is the focus of this study. The simulation experiments use INN/ACE inhibitors prescription data by the Bulgarian National Health Insurance Fund /NHIF/ and market data by IMS Health. That data is analysed and then used in a system dynamics model accounting for the doctors prescribing behavior, patient flows and fund expenditure, after which a number of policy experimentations are conducted related to the following scenarios: 1/ a base case policy based on 25% level of reimbursement of the ACE inhibitors group within the Positive Drug List by the NHIF; 2/ a policy based on 50% level of reimbursement; 3/ a policy based on 75% level of reimbursement; and 4/ a policy based on 100% level of reimbursement. The three other factors included in the model experimentation are: 1/doctors' prescribing behavior; 2/ patients' compliance to prescribed therapy; and 3/incentives by the government for improving access to treatment.

The what-if scenarios are performed by using an interactive learning environment or the so called 'management-flight simulator', which enables experimentation through instant changes in independent variables and their effect on the dependent variables within the modeled dynamic system. The time period of the study covered a range of 5 years historical performance of the modeled key variables, i.e. patients treated and pharmaceutical expenditure, and 5 year projected performance comparing alternative reimbursement policy scenarios.

Results and Recommendations

According to the comparative analysis of the alternative policies explored, an adequate reimbursement policy is proposed for implementation by the government, accentuating on the need to increase access to ACE inhibitors treatment by motivating doctors to increase prescription and by raising patients' compliance to therapy, while at the same time controlling pharmaceutical expenditure without undermining access to treatment. The results show that lowering the level of patient co-payment by raising the level of reimbursement, coupled with incentives to improve access to therapy and compliance, would increase NHIF pharmaceutical expenditure on one hand, but on the other would increase the number of treated patients and at the same time would provide future savings from hospitalization of potential non-compliant and non-treated patients with chronic cardiac disease and cardiac incidents.

When designing optimal reimbursement policy related to ACE inhibitors, the stakeholders need to account for the dynamic interrelationships among all key independent and dependent factors within a systemic perspective, i.e. reimbursement levels, patient co-payment, access to treatment, compliance to therapy, doctors prescribing behaviour, and government incentives. The study performed accentuate on the imperative to account for the impact of any reimbursement policy before that policy would be implemented and to choose the optimal one among key alternative policies for control of pharmaceutical expenditure without undermining access to treatment and health policy goals.

System dynamics modelling

- Enhance decision support and policy analysis by providing a tool set for what-if experimentation
- Can complement the health care data analysis by providing insight to key dynamic interrelationships and feedback loops among health care market factors
- Does not simply forecast but reveal delayed counter intuitive non-linear effects of policy decisions

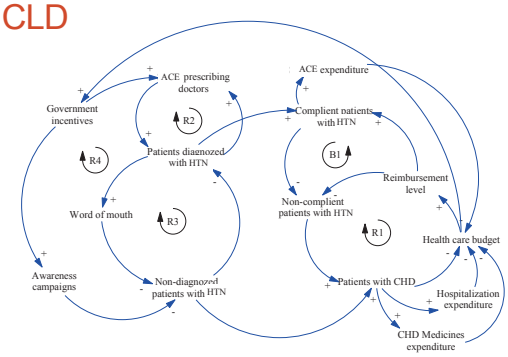
Key modelled variables

- Diagnozed patients with HTN
- Non-diagnozed patients with HTN
- Complient patients with HTN
- Non-complient patients with HTN
- Patients diagnosed with CHD
- Patients non-diagnosed with CHD
- Health care budget / drugs expenditure
- ACE reimbursement level / patient co-payment level
- Doctors' prescribing behavior
- Patients' behavior

Key Hypothesis

- The lower the reimbursement level /a % of the lowest drug price/ is, i.e. the higher the patients' co-payment is, the higher would be the patients' non-compliance rate and vice versa
- The higher the non-compliance rate is, the higher would be the patients with HTN developing CHD and the related costs to the health care budget due to CHD additional medication and hospitalization expenditure
- The higher the reimbursement level is, complemented with Government prescribing and awareness incentives to doctors and patients, the higher the HTN patients' compliance-rate and healthcare budget economies of scale would be

CLD



Results and policy recommendation

1/ A base case prevention policy based on 25% reimbursement	Highest rate of patients' non-compliance, and highest long-term costs to the healthcare system
2/ A prevention policy based on 50% reimbursement	High rate of patients' non-compliance, and high long-term costs to the healthcare system
3/ A prevention policy based on 75% reimbursement	Moderate rate of patients' non-compliance, and lower long-term costs to the healthcare system
4/ A prevention policy based on 100% reimbursement	Low rate of patients' non-compliance, and high long-term economies to the healthcare system
5/ A prevention policy based on 100% reimbursement with doctor incentives to prescribe	Lower rate of patients' non-compliance, and higher long-term economies to the healthcare system
6/ A prevention policy based on 100% reimbursement with doctor incentives and awareness campaigns	Lowest rate of patients' non-compliance, and highest long-term savings to the healthcare system

- The healthcare authorities should avoid chasing short-term savings to the healthcare budget which burdens the healthcare system in the long run with higher rate non-compliant patients, higher rate of patients developing CHD and higher budget deficits due to additional CHD medication and hospitalization expenditure;
- The healthcare authorities would be able to increase significantly patients' compliance, reduce the number of CHD patients and achieve budget economies of scale by 100% reimbursement and incentivizing prescriptions and patients awareness

Pharmaceutical Distribution Remuneration in Europe

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[1] WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Health Economics Department / Austrian Public Health Institute (contact: lena.lepuschuetz@goeg.at)

Background

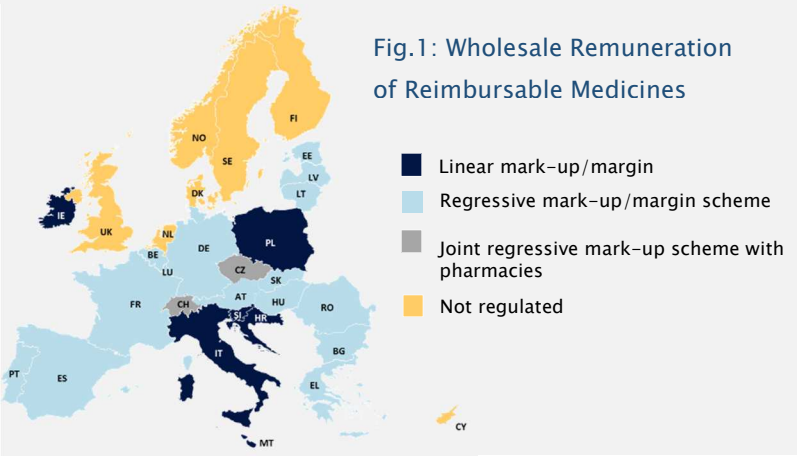
Final medicine prices are considerably influenced by the maximum remuneration allowed to wholesalers and pharmacies. Remuneration of pharmaceutical distribution has to strike a balance between appropriate compensation for supply chain management and further services, while ensuring access and sustainability of public funding.

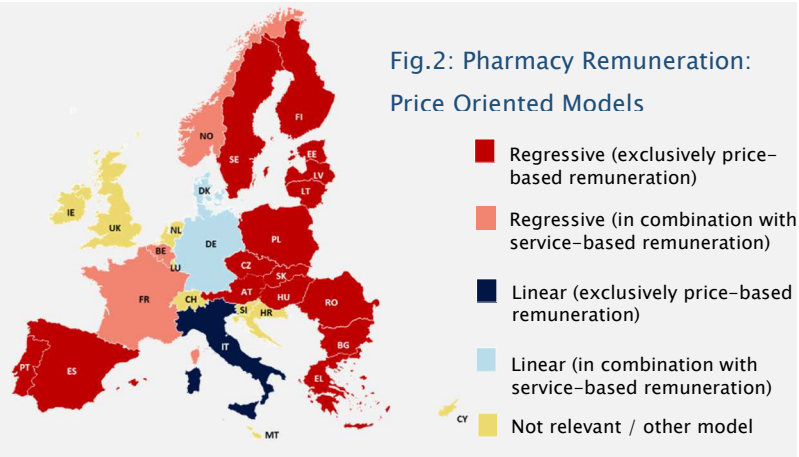
Objective

The study aims to **survey and compare remuneration policies for wholesale and community pharmacies for 30 European countries** (28 EU Member States, Norway and Switzerland).

Methodology

For this purpose **primary data was collected from public authorities, wholesale and pharmacy associations** as well as conducting additional literature and grey literature research. The analysis focuses on the reimbursable segment of the out-patient sector, as of the first quarter of 2015.





Results

The data shows that in Cyprus, Denmark, Finland, the Netherlands, Norway, Sweden and the United Kingdom wholesale remuneration is negotiated between manufacturers and wholesalers. In the remaining countries, a **maximum allowed wholesale remuneration is regulated** on a legal basis, at least for reimbursable medicines. In these countries, wholesale remuneration generally depends on the price of the medicine. **Regressive schemes have become more common** than linear margins/mark-ups.

In 28 of the 30 countries surveyed, pharmacy remuneration is regulated or agreed upon between the pharmacy sector and payers at least for reimbursable medicines, whereas in Cyprus and Malta pharmacy remuneration is not an issue as pharmacies are state-owned and directly belong to public sector.

In 16 of these 28 countries, pharmacy remuneration depends solely on the **price of the dispensed medicine**, and is **usually a regressive scheme**. A purely **performance-based fee-for-service** remuneration is in place in five countries (Croatia, Ireland, the Netherlands, Slovenia and UK). Pharmacy remuneration that is both **price-based and performance-based** exists in seven countries (Belgium, Denmark, Finland, France, Germany, Norway and Switzerland).

Conclusions

Frequently, remuneration is dependent on the price which might incentivise the supply and/or dispensing of higher-priced medicines. In the community pharmacy sector, many countries are thus **moving towards new models which are disconnected from medicine prices and support a wider role of pharmacists as health care provider**. Changes in wholesale and pharmacy remuneration in recent years has happened for cost-containment reasons in response to the crisis as well as to design new remuneration models that are better equipped for the current challenges of supply management and dispensing of medicines.

Falling Through the Regulatory and Pricing Gaps:
What to do about Compounded Drugs, Medical Foods, and Convenience Packaged Products

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Background

Problem: Categories of pharmaceutical products, such as compounded drugs (CDs), medical foods (MFs), and convenience packages (co-packs) are increasingly prescribed at high prices because they are not covered by current fee schedules or regulated by the FDA. The use of these products within California Workers' Compensation System (CA WCS) increased from 6.3% to 12% over 3 years after a 2007 regulation closed this same loop-hole for repackaged drugs. This increased use resulted in $58 million in new billings in 16 months.

The rapid growth in use and high prices for these products is a growing problem for other US State Workers' Compensation Systems and also for healthcare systems in Europe and developing countries.

Solution: California Assembly Bill #378 Effective Jan, 2012

In 2011, California lawmakers enacted Assembly Bill 378 (AB #378), which came into effect January 1, 2012. The legislative intent of this statute was to control the increase in physician-dispensed prescriptions for compounded drugs, medical foods, and convenience packages in CAWCS.

- CD must be billed at the ingredient level
- Prohibited separate reimbursement for ingredients with no NDC.
- Reimbursement for CD ingredients are capped at a maximum of 100% Medi-Cal rates
- CDs, MFs, and co-packs are now also prohibited from self-referral
- The maximum reimbursement for a CD dispensed by a physician = 300% of the physician office's Documented Paid Cost (DPC), but <$20 above DPC

Workers' Compensation System (WCS)
Health insurance scheme which provides wage replacement and medical benefits to employees injured in the course of employment

Objective

To evaluate if state-level pricing schemes/ regulations reduce utilization, billed, and paid amounts of pharmaceutical products that fall through regulatory and pricing gaps, using CA WCS as an example.

Methodology

Data: All drug prescription claims from the CA WCS from 2011 to 2013
Independent Variable: California Assembly Bill #378 effective Jan 1, 2012
Dependent Variables: Prescription frequency, billed, and paid amounts for MF, CD and Co-packs
Study design: Pre-post comparison evaluated by two-tailed T-test

Medical Foods

Foods that are specially formulated and intended for the dietary management of a disease that has distinctive nutritional needs that cannot be met by normal diet. MFs are not approved by FDA, do not require a prescription, and are not on most Fee Schedules.

Convenience Packs

A combination of a generic drug and a medical food, which are manufactured separately, then packaged together and dispensed as a single unit for convenience.

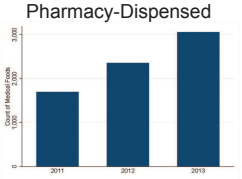
Compounded Drugs

Medications that are produced by combining and tailoring of ingredients to meet individual patient's special medical needs. CDs are regulated by state pharmacy boards if in small quantities.

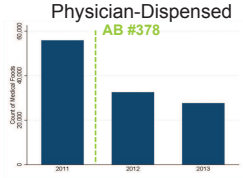
Results

Medical Foods

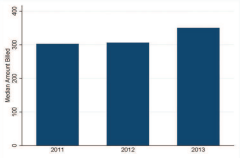
Pharmacy-Dispensed

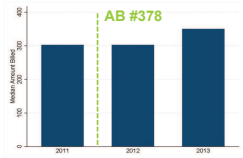


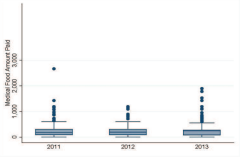
Physician-Dispensed

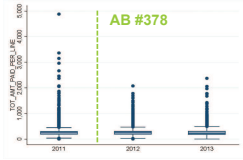


T-Test	Mean Difference	95% Confidence Interval	t	P-value	df
Pharmacy-Dispensed	-.0011	-.0012, -.0010	-15.7675	.0000	2800000
Physician-Dispensed	.0049	.0048, .0050	122.3127	.0000	19000000





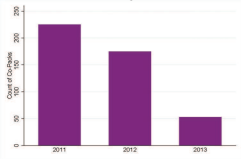




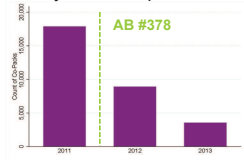
AB #378 is associated with decreased utilization of physician-dispensed MFs as compared with pharmacy-dispensed MF's, where utilization rose significantly. While the median billed amount increased in both datasets, the median paid amount decreased in the physician-dispensed dataset after AB #378.

Convenience Packages

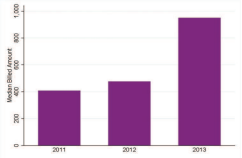
Pharmacy-Dispensed

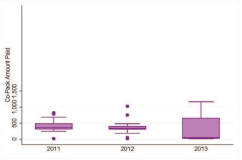


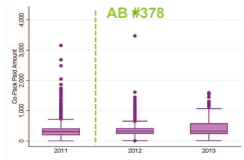
Physician-Dispensed



T-Test	Mean Difference	95% Confidence Interval	t	P-value	df
Pharmacy-Dispensed	.0003	.0002, .0003	12.1223	.0000	2800000
Physician-Dispensed	.0018	.0017, .0018	83.7868	.0000	19000000



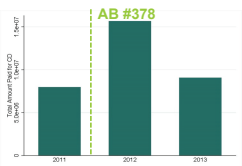




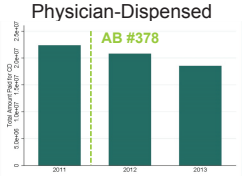
AB #378 is associated with reduced utilization of both pharmacy-dispensed and physician-dispensed co-packs. The median billed amount increased in both dataset. While the median amount paid for physician-dispensed co-packs is greater, the distribution of the amount paid is greater for pharmacy-dispended than pharmacy-dispensed co-packs.

Compounded Drugs

Pharmacy-Dispensed



Physician-Dispensed



T-Test	Mean Difference	95% Confidence Interval
Pharmacy-Dispensed	-39.93	-43.08, -36.78
Physician-Dispensed	2.55	1.60, 3.40

T-Test	t	P-value	df
Pharmacy-Dispensed	-24.83	.0000	118544
Physician-Dispensed	5.29	.0000	739453

AB #378 is associated with a reduction in total cost of physician-dispensed CDs in the CA WCS. In constrast, AB #378 is associated with increased total cost of pharmacy-dispensed CDs.

Conclusions

•Regulations (e.g. AB #378) can reduce utilization of pharmaceutical products that fall outside the normal FDA regulated drug categories. In CA WCS, AB #378 implementation is associated with: 43% reduction of **MF** utilization the first year and 18% reduction the second year, 53% reduction of **co-pack** utilization the first year and 63% reduction the second year, and $2.55 reduction per **CD ingredient**.

•Pricing regulations can reduce pricing differentials and allow health systems to effectively allocate their resources.

•It is crucial to implement comprehensive regulations to control both physician-dispensed and pharmacy-dispensed prescriptions. Patterns indicate that dispensing pharmacies, not regulated by AB #378, experienced a flux of prescriptions that are regulated in dispensing physician practices.

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Reimbursement categories as a way of allocate measures and monitor expenditures on medicines

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Introduction

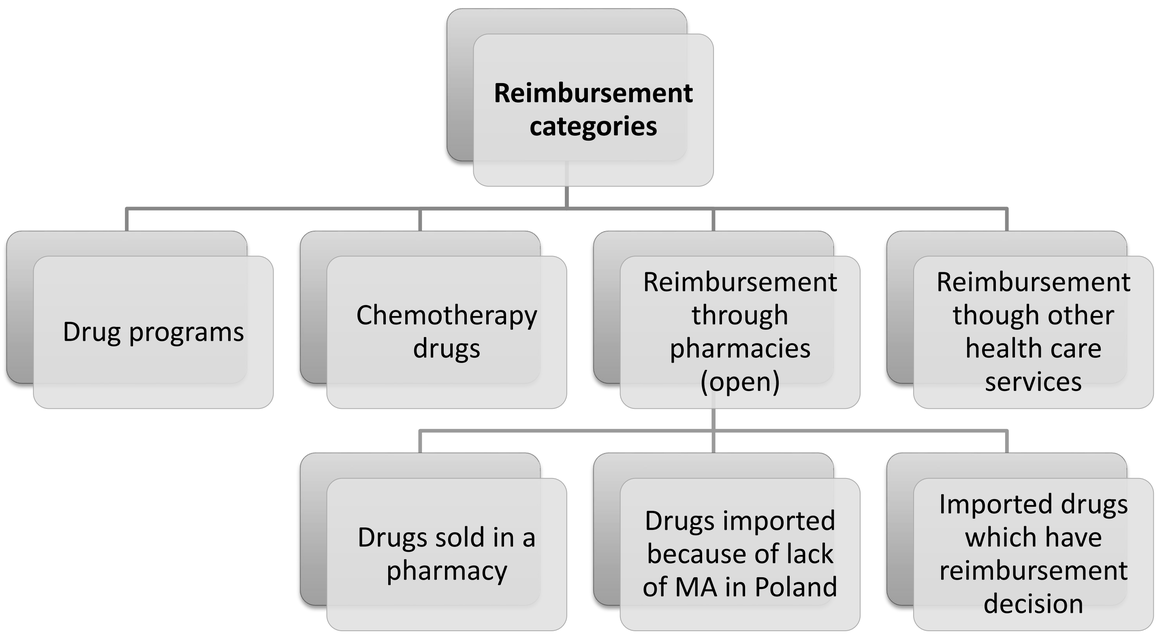
In Poland there are functioning four reimbursement cathegories: drug programs, chemotherapy drugs, reimbursement (of drugs) through pharmacies and reimbursement though other health care services. The first three categories are used mainly. The choice of particular way of financing drugs from public funds in healthcare system may have influence on availability of medicines for patients, planning the budget and controlling expenditures by health authorities. The reimbursement category is proposed by market authorization holder (MAH) in reimbursement submisssion. It seems that the most difficult task is to plan a budget and control it when drugs are sold in pharmacies. However, polish practice shows that the budget for the reimbursement is not depleted and the financial limits are exceeded in drug programs and chemotherapy drugs, which are under thorough supervision.

Objectives

The aim of this work is to compare ways of financing drugs implemented in polish healthcare system in terms of their impact on access for patients, planning the budget, monitoring effects of therapy, controlling expenditures from payer's and patients' perspective.

Methodology

This work is a description of model implemented in Poland and an evaluation of current policy in terms of rationalizing and controlling expenditures and access to health care services. The study examines the public sector and is related to the out-patient as well as in-patient sector because of mixed nature of reimbursement categories. Reimbursement though other health care services is not included in this work due to lack of separate budget for this cathegory (drugs are reimbursed within DRG).



Tab. 1. NHF expenditures on drugs in 2015 (year to date, in thousands PLN)

Description	Planned total budget on reimbur-sement in 2015	Realization (June 2015)	Realization (YTD)	% of realization of total budget on reimbur-sement
Total budget on reimbursement	**10 901 083,00**	**889 080,19**	**5 307 531,06**	**48,69%**
1. drug programs	2 526 438,00	177 868,22	1 056 459,17	41,82%
2. chemotherapy drugs	596 740,00	40 048,86	241 289,09	40,43%
3. reimbursement	**7 777 905,00**	**671 163,11**	**4 009 782,80**	**51,55%**
3.1. drugs sold in a pharmacy	7 743 103,00	669 633,36	3 999 835,39	51,66%
3.2. drugs imported because of lack of permission for Polish market	25 604,00	1 509,80	7 483,10	29,23%
3.3. imported drugs which have reimbursement decision	9 198,00	19,95	2 464,31	26,79%

Results

REIMBURSEMENT OF DRUGS

This cathegory is used for less expensive therapies, which patient can take at home without any special supervision. Patients have easy access to medicines because they can be bought in every pharmacy. Information about prescription is sent to National Health Fund (NHF), but NHF does not receive data on condition, dosing and effects of the therapy so remote monitoring of outcomes is impossible. Due to uncontrol of health needs in out-patient, planning expenditures in this reimbursement category is complicated. There is one budget in this area without any strict structure, which is not depleted every year in Poland. If the budget is exceeded, there will be calculated payback. Since 2012 when payback was established, the budget has never been exceeded.

DRUG PROGRAMS & CHEMOTHERAPY DRUGS

Tab. 2. Comparison of reimbursement cathegories: drug program and chemotherapy drug

The object of comparison	Drug program	Chemotherapy drug
indication	precise reimbursement criteria: indication defined by ICD-10 code and additional in/out criteria (e.g.severity of disease, ECOG status)	indication defined by ICD-10 code, no exclusion criteria
therapeutic area	oncology drugs and drugs for rare diseases	only oncology drugs and drugs supporting chemotherapy
access	by hospitals or out-patient clinics cooperating with hospitals	by hospitals and out-patient clinics cooperating with hospitals
budget	separate budget for every drug	one budget for all drugs in the list
monitoring	separate monitoring for every drug	monitoring for all drugs in the list
cost of therapy	very expensive drugs	differentiated cost of drugs

The healthcare providers (HCP) who want to provide these services have to meet special requirements in terms of staff and equipment what should support proper standard of treatment. Important is the fact that only healthcare providers (HCP) who have the agreement with public payer in this particular area can receive reimbursement for treatment of patients with such medicines, but neither NHF nor HCP are obligated to enter into agreement (HCP on a voluntary basis start the procedure of setting the agreement). Services are provided only to the financial limit established in agreement. Adherence to the financial limit and freedom in concluding agreements may restrict the availability of services, causing: queues or migration of patients in search of treatment. Because of that patients may also incur additional costs. On the other hand, cooperation under the agreement gives NHF knowledge about the availability of services in each region and makes possible to premium HCP who entered into the agreement.

Conclusions

- The choice of reimbursement cathegory depends on MAH, but it may fit in country healthcare strategy and policy.
- Pharmacy distribution gives wider and easier access to drugs than distribution through only contracted healthcare providers (second one may cause queues and burden patients with additional costs).
- Drug programs provide easier control of budget and monitoring of health outcomes (possibility of providing outcome based risk sharing schemes).
- The most comprehensive data on epidemiology, costs and effects can be collected when distribution is concentrated in few or several specialized centers than in thousands of pharmacies.
- Agreements on services connected with cathegories drug program and chemotherapy drug allow monitoring of epidemiology and availability of resources in the healthcare system (equipment, facilities and staff) and controlling expenditures, but people are deprived of treatment (causing among others social discontent) or limits are exceeded when budget was not well estimated.
- Careful analysis of health needs and use of incentives for healthcare providers to conclude contracts with NHF may allow a proper allocation of resources and ensuring patients an equal access to services in each region of the country.

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Impact of Generic Price Linkage System and Reference Price System on Prices of Pharmaceuticals – Comparison of Austria and Finland

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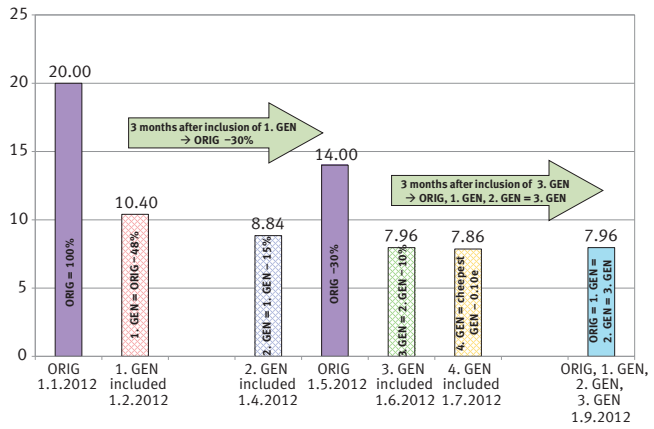
1 Social Insurance Institution, Research Department, Finland;
2 WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Austrian Public Health Institute, Austria

Background

Policies aiming to lower prices and to enhance the utilization of generics have been introduced in many countries.

In **Austria** prices of the generics are controlled by a Generic Price Linkage (GPL) System (Fig. 1).

Fig. 1. *Example of the Austrian GPL System.*



In **Finland** the price of the first generic has to be 40% lower than the price of the originator. The originator and the generics are included in the Generic Reference Price System (RPS).

Aim of the study

To assess the effect of Generic Price Linkage System and a mixed system that includes GPL, generic substitution and reference pricing by comparing number of generic products entering the market, prices of generics and prices of original products in Austria and in Finland.

Data of the study

Products (10) included into the Finnish Reference Price System in 2010–2012:

- active ingredients with highest expenditures
- reimbursable and generics available also in Austria
- most used strength and package size in both countries

Wholesale prices (EUR/DDD) during the 6 months before and 12 months after generic entry in 2009–2013.

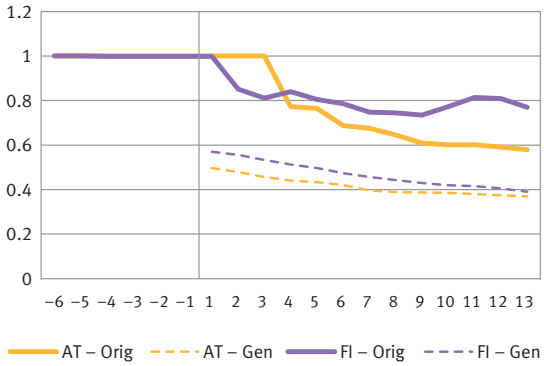
Table 1. *Active ingredients of the study.*

Active ingredient	Indication	Expenditure in Finland in 2009, million €
Esomeprazole	Peptic ulcer	34.3
Candesartan	Hypertension	23.3
Clopidogrel	Antithrombotic	14.0
Rivastigmine	Dementia	12.5
Lercanidipine	Hypertension	10.7
Pramipexole	Parkinson disease	10.4
Valsartan	Hypertension	10.3
Galantamine	Dementia	8.5
Latanoprost	Glaucoma	8.5
Mycophenol mofetil	Transplantation	7.5

Results

In both countries substantial price reductions took place after generic entry (Fig. 2).

Fig. 2. *Mean monthly prices of originators and generics as indices, all study products (1 = price of the originator before generic entry).*



- Prices of the 10 original products had fallen, on the average, in 12 months after generic entry

  46% in Austria (range 10–70%) and
  21% in Finland (range 0–60%)

- One year after generic entry mean prices of the generics were, compared to prices of the originators before generic entry,

  66% (range 50–70%) lower in Austria and
  59% (range 40–90%) lower in Finland

- Mean number of generics per active ingredient on the market was

  6.3 in Austria and
  5.1 in Finland

Discussion

It seems that the Austrian pricing system is more efficient to lower the prices of both originators and generics.

Possible weaknesses of the Finnish system are:

- prices of originators can stay at high level
- maximum prices of generics are not reviewed but stay permanent
- competition between products is short-term and only few products stay on the market leading to quite concentrated generic markets

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Kela

The Impact of Ghana's National Health Insurance Scheme Median Pharmaceutical Pricing Methodology and Reimbursement Policy on the Pharmaceutical System

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[1]Systems for Improved Access to Pharmaceuticals and Services, Center for Pharmaceutical Management, Management Sciences for Health, Arlington, Virginia, USA, 22203

Background

Over ten years after the establishment of the National Health Insurance Scheme (NHIS) in Ghana, the median pricing methodology for pharmaceuticals remains a topic of debate due to negative outcomes. Ghana's pharmaceutical system has limited local production capacity and is heavily dependent on importation. Medicine prices continue to rise and medicine reimbursement amounts constitute increasingly larger proportions of overall claims values. With finite NHIS resources, this presents a sustainability challenge.

Methodology

The SIAPS qualitative assessment tool for medicines benefits management programs was used to interview pharmaceutical system stakeholders from healthcare facilities, importers/wholesalers, Ministry of Health, professional organizations in the Greater Accra, Cape Coast and Kumasi regions of Ghana about the impact of pricing policy.

Mr. Eghan interviewing claims office worker and pharmacist at Ga South Municipal Hospital, Weija Accra Ghana

- 60 facilities were selected based on NHIS claims values and facility type; 29 granted interview access and quantitative medicine pricing data was shared by 3 facilities.

Table 1: Geographical distribution of interview and data collection sites

Type	Location	Number with lowest claim values	Number with highest claim values
CHPs compound	Accra	1	1
Pharmacies/chemists	Accra	3	2
Private hospital	Accra	3	3
Public hospital	Accra	3	3
Maternity home	Accra	5	0
CHPs compound	Cape Coast	3	3
Pharmacies/chemists	Cape Coast	2	3
Private hospital	Cape Coast	2	3
Public hospital	Cape Coast	3	3
Maternity home	Cape Coast	1	0
CHPs compound	Kumasi	1	1
Pharmacies/chemists	Kumasi	1	3
Private hospital	Kumasi	1	2
Public hospital	Kumasi	1	2
Maternity home	Kumasi	1	0

- 33 distinct tracer medicines were selected; pricing data from all 3 sources were available for 8 medicines (Artemether/Lumefantrine 20mg/120mg tablets, Cetirizine 10mg tablets, Albendazole 200mg tablets, Cefuroxime 250mg tablets, Metronidazole 100mg/5ml suspension, Metronidazole 200mg, Metronidazole 400mg tablets and Paracetamol 500mg tablets).
- Data was then compared to reimbursement prices listed in the July 2014 NHIS subscriber handbook.

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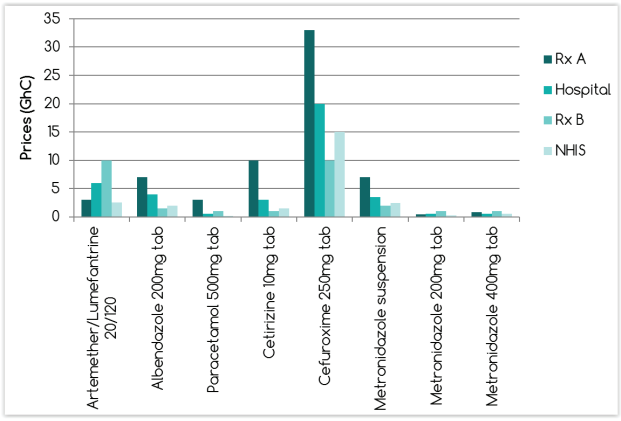
Results

- NHIS prices are on average 37% below market prices (MPs) for the selected medicines
- Range is -50%-93% difference from MP, median is 50%

Figure 1: Market prices for medicines compared to NHIS reimbursement prices



- Paracetamol had the highest price disparity (MPs were 60-93% higher than NHIS prices)
- In Rx B, 50% of the highlighted medicines were less than NHIS prices
- From the interviews
  - NHIS median pricing methodology is viewed as inefficient and outdated
  - This methodology does not consider importation fees, foreign exchange, demand and supply chain challenges
  - Ripple effect on the entire pharmaceutical system
    - Proliferation of low quality medicines to match low prices
    - Irrational medicine use
    - Inaccurate billing
    - Unauthorized copayments to match price differences
    - Inability to restock
    - Denial of service to NHIS patients

Dr. Dumebi Mordi reviewing patient medication records with staff member at Assin Nsuta Presbyterian Health Center, Cape Coast, Ghana

- The prices are updated too infrequently to match market fluctuations
  - NHIS price list was last published in July 2014
  - Foreign exchange (which has heavy influence on medicine prices) of the US Dollar to Ghana Cedis changes on a daily basis

Lessons Learned

- Pharmaceutical pricing and reimbursement policies should be evidence based and informed by analysis of detailed medicine consumption data and economic factors that impact pricing in an import based pharmaceutical sector.
- Detailed deliberation about medicines benefits during initial UHC designs and policy discussions
- Medicine pricing should be in the forefront of discussions to develop and strengthen universal health coverage plans

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SIAPS Systems for Improved Access to Pharmaceuticals and Services

Reimbursement measures in European countries – findings of a bibliometric literature review

Sabine Vogler[1], Nina Zimmermann[1], Antonio Olry de Labry[2], Jaime Espin[2]

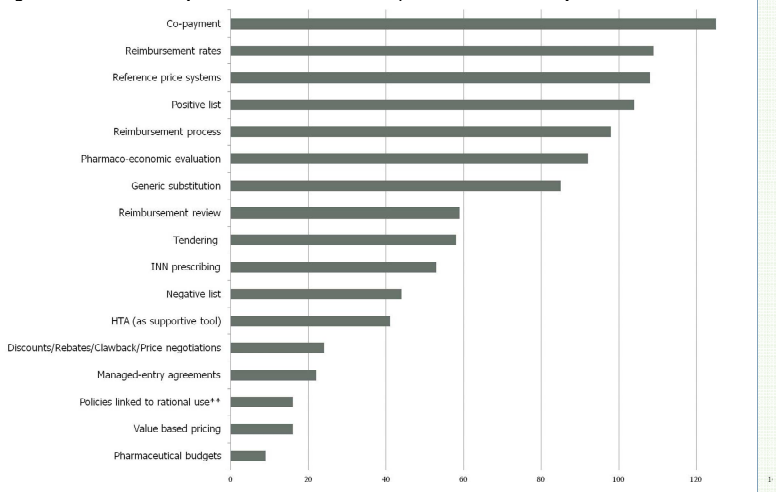
1) WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Health Economics Department, Gesundheit Österreich GmbH (Austrian Public Health Institute), Stubenring 6, 1010 Vienna, Austria.
2) Escuela Andaluza de Salud Pública, Campus Universitario de Cartuja, Cuesta del Observatorio, 4, 18011 Granada (Spain).

Background: Policy-makers aim to achieve the partially conflicting objectives of equitable access to medicines, cost-containment and sustainable funding as well as reward for innovation. To do so, a range of policy options is available that has been extended in recent years to meet new challenges. **Objective**: To identify existing pharmaceutical reimbursement policy options in European countries

Methodology: A literature review was carried out using thesaurus and free terms in several databases and grey literature. Setting: out-patient and in-patient sectors including possible measures at the interface of out-patient and in-patient sectors and stakeholders involved: State (as regulator), third party payers and patients (funders); pharmaceutical industry. Inclusion criteria: Studies or documents published between 1993 and February 2013 in all EU languages performed in all 28 European Union (EU) Member States and European Economic Area.

Results: 244 publications were selected, 61% of the selected studies were published between 2007 and 2011. Most literature referred to a sole country, particularly to large countries such UK and Germany. Descriptive work constituted a major body of literature; an impact assessment of policy measures was undertaken in 29% of the publications. Figure 1 shows the most frequently mentioned in the publications.

Figure 1: Reimbursement policies identified in literature, from 1995 till February 2013*



In total 1063 reimbursement policies were mentioned in 244 articles, several articles/publications mention more than one reimbursement policy.
** Examples are prescription guidelines or monitoring of prescription patterns.
Source: Literature review performed by the authors

Conclusions: Standard elements of reimbursement systems in European countries were identified in several publications, whereas newer policy options were covered less frequently in literature.

In the 1990-ties and early years of the new millennium, descriptive studies about national reimbursement systems were predominant, supplemented, at a later stage, by descriptions and analyses of generic policies. In the new millennium, discussions about value assessments and the importance of HTA and pharmaco-economics, frequently understood as contrast to the pricing policy of external price referencing, were found. Policy options for new, high-priced medicines were particularly addressed in literature of recent years.

Gesundheit Österreich GmbH

Escuela Andaluza de Salud Pública
CONSEJERÍA DE SALUD

Funding Source: Consumers, Health and Food Executive Agency (CHAFEA) of the European Commission (Health Programme 2008-2013).

Determining the prices of the medicines in the absence of superiority over alternative medical technology

Maciej K. Pomorski[1], Aneta Lipińska[1], Wojciech Matusewicz[1], Katarzyna Jagodzińska-Kalinowska[1]

[1]Agency for Health Technology Assessment and Tariff System

Problem Statement

When there are randomized clinical trials (RCT) which prove that the new technology is better than the drug or non-drug medical technologies currently financed, the price of new technology can be negotiated based on the clinical effectiveness, cost effectiveness and budget impact. But when there are no RCT, which prove that the new technology is better than the currently financed by the public payer drug or non-drug medical technologies, on the basis of art. 13 sec 3 of the Reimbursement Act (RA), Marketing Authorisation Holder (MAH) is obliged to perform the price equal to the cheapest reimbursed alternative.

Art. 13 sec 3 of the RA the exact wording: "If the clinical analysis, (...), does not contain RCT proving the superiority of the drug over the medical technologies (…) currently financed in this indication, the official sales price (net price + VAT) of the drug, must be calculated in a way that, the cost of using it would not be higher than the cost of the cheapest alternative, which has the best ratio achieved health outcomes/cost".

Objectives

Presentation of a method offered by the RA (from 2011), which allows to determine the prices of the medicines in the absence of superiority over alternative medical technology. This price is calculated by the Agency for Health Technology Assessment and Tariff System and must be presented in the Recommendation of the President of the Agency for Health Technology Assessment and Tariff System.

Methodology

The primary goal of the RA is to implement the principle of economical production. This should be kept in mind, while interpreting its content, because while maintaining the standard described in the act, it allows one to approach to each drug individually.

At the beginning one needs to find all the comparators currently financed in this indication and set their outcomes/cost ratio. Then, to choose the one that has the best result. Next step is to search for RCT proving the superiority of the proposed drug over the designated comparator. In cases, where there are no such RCT in MAH's submission, the official sales price of the drug, must be calculated in a such way, that the cost of using it would not be higher than using the designated comparator. This has significant consequences because Ministry of Health is obliged to use the calculated price in final reimbursement decision.

The poster presents the most complex cases we have searched through Recommendations of the President of the Agency for Health Technology Assessment and Tariff System from 01.2012 to 04.2015. We selected two most interesting cases where the calculation of the price based on the Art. 13 sec 3 Reimbursement Act was not so obvious.

First example is polipill compared to the separate tablets with the same substances. There were no studies that demonstrate the superiority of the polipill in comparison to monotherapies. The law says that, the cost of therapy with polipill proposed by the applicant cannot be higher than the cost of therapy with the same substances in separate tablets.

Second example is an add-on therapy. There were no conclusive results, which proves the superiority of the proposed added drug to the standard therapy over the standard therapy alone, so the cost of the drug cannot be higher than the comparator. This price was proportionally calculated to the share of the total cost of the treatment, which was equal to the cost of the treatment with the exception of add-on therapy.

Results

First example: polipill

Drug A and drug B were financed in the same indication as new submitted drug (polipill) (Tab. 1). Two tablets (one with drug A and another with drug B) and one tablet of polipill contains the identical amount of the same active substances. So according to art. 13 sec 3 RA the calculation was simple, price of the drug A plus price of the drug B. Price from the reimbursement submission was higher than the calculated one.

Tab. 1. Prices for two drugs in separate tablets and in a one polipill.

Item description	Price (€)
Drug A (30 tablets)	14
Drug B (30 tablets)	20
Maximum price of the polipill (30 tablets) according to the RA	34
Price proposed by MAH (30 tablets)	58

Second example: add-on therapy

One cycle of financed standard therapy costs 1032 € (Tab. 2). According to reimbursement submission the new technology should be used with standard therapy (add-on therapy). MAH didn't show RCT proving that add-on therapy is better than the standard therapy. So there was a necessity to calculate the price according to art. 13 sec 3 Reimbursement Act.

Cost of one cycle of the therapy (standard+add-on), taking into account the price of a new drug from application, was 10 032 €. Cost of add-on therapy accounted for 90% of the whole cost. So according to art. 13 sec 3 RA the maximum cost of one cycle of add-on therapy was 926 € (90% of one cycle of standard therapy). On this basis, price of the new drug was 239 €. The price proposed in the reimbursement submission was almost 10 times higher than the calculated one.

Tab. 2. Price and cost for for standard therapy and its alternative proposed by MAH.

Item description	Value (€)
Standard therapy (cost per cycle)	1 032
New add-on therapy proposed by MAH (cost per cycle)	9 000
Maximum price of the drug calculated according to the RA (add-on therapy)	239
Price of the drug proposed by MAH	2 350

Conclusion

The price is easy to set if there are few comparators or RCT. It is more difficult when the number of comparators is much higher and there are a lot of RCT with different outcomes. In these cases calculating the price is labour-intensive. The new Reimbursement Act offers the tool to set the maximum price for the drugs without superiority proven in RCT, by a comparison their cost with the cost of the cheapest comparator or a comparator with the best cost-effectiveness ratio. This price can be used as the starting point in the price negotiations from the payer's perspective. This price, presented in the Recommendation of the President of the Agency for Health Technology Assessment and Tariff System can provide the Ministry of Health stronger negotiating position.

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EXPLORING THE IMPACT OF HEALTH-CARE COST SHARING MECHANISMS IN HEALTH SERVICE USERS FOR ALL THE 27 MEMBER COUNTRIES OF EU

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Introduction

✓Pharmaceutical expenditures are growing at a faster rate than GDP or other health care expenditures,

✓Pharmaceutical pricing and cost-sharing are among the most prevalent methods of influencing excessive demand,

✓In cost-sharing the common ground ends up being the personal financial consequence of each patient since the choice of treatment depends on him, which is expected to cause a decline in the excess demand,

✓The most frequently used mechanisms of cost-sharing are co-payment, co-insurance and deductible.

Objective

The main objective of this study is to investigate the cost-sharing mechanisms in pharmaceutical expenditure in EU-27 and to further explore the impact of policies on the broader NHS.

Methodology

An extensive analysis of the targeted policies and practices was carried out based on the data exported from the databases of the OECD, PubMed and Google Scholar. This study was based on data between February and March 2015.

Results

✓ In the European North cost-sharing has traditionally been an integral part of their NHS,

✓This cost-sharing policy has lead to significant impacts on Health Care Systems, such as the control of excess demand and health services as well as the control of moral hazard,

✓Cost-sharing policy has affected users as well. For instance, compensation issues in the case of biosimilars have not yet been resolved and the rate of visits in Non-Governmental Organizations and other social clinics has increased tremendously (up to 23 %).

Table 1. Cost-sharing Mechanisms in Selected EU Countries (last updated: 2014)

COUNTRY	CO-PAYMENT	CO-INSURANCE	DEDUCTIBLE	PRE-PAYMENT CERTIFICATE
Portugal	•			
Spain	•			
Greece	•			
Cyprus	•			
France	•	•		
Netherlands	•		•	
Belgium	•	•		
Germany	•		•	
Austria	•			
Czech Republic	•	•		
Poland	•	•		
Slovakia	•	•	•	
Hungary	•	•	•	
Sweden	•			
Denmark	•		•	
UK				•

Figure 1. Pharmaceutical Expenditures of the EU South as % GDP

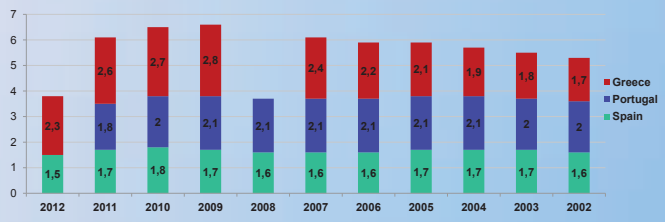


Figure 2. Pharmaceutical Expenditures Western Europe as % GDP

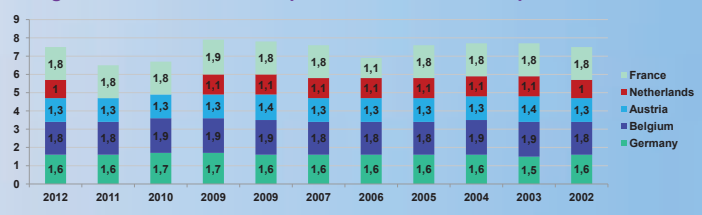


Figure 3. Change of Fixed Co-Payment of Austria between 2000 and 2013

Figure 4. Pharmaceutical Expenditures Eastern Europe as % GDP

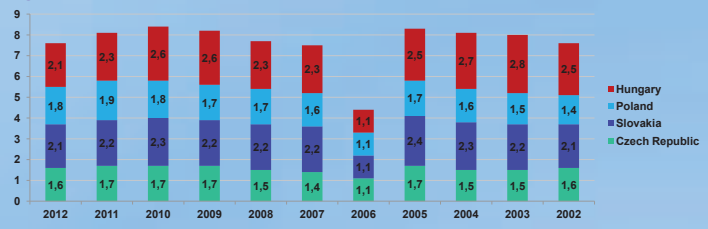


Figure 5. Pharmaceutical Expenditures of the European North as % GDP

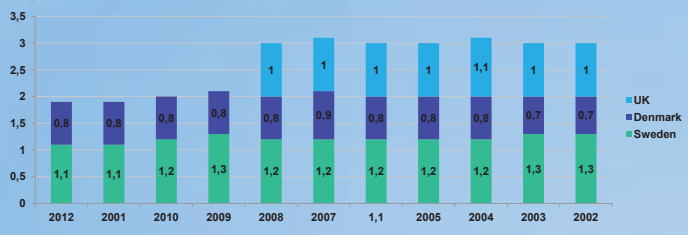
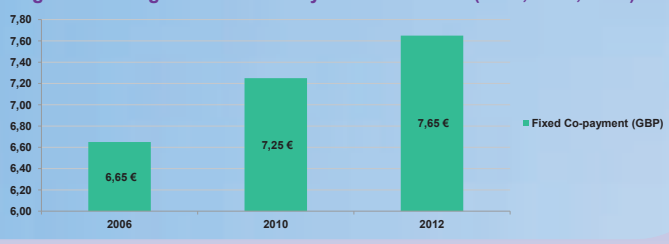


Figure 6. Change of Fixed Co-Payments of the UK (2000, 2006, 2012)



Conclusions

The implementation of a strong cost-sharing mechanism can facilitate a sustainable and efficient NHS system based on the principle of equal rights. Up until now, all changes within NHS systems were proved necessary for ensuring viability and sustainable development. This policy appears to be a step in the right direction for improving the scope and the quality of the services offered by the NHS. However, possible adverse effects can occur.

Optimising Prescribing in Primary Care: An Evaluation of Financial and Clinical Parameters

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ProCare Health NZ was responsible for data collection and statistical analysis of primary outcomes for the purposes of this research. The University of Auckland contributed towards the research by providing grounds for data access and result interpretation and ongoing academic support for the student researchers. New Zealand WPRO region number 13 is the region covered by this research.

INTRODUCTION

In New Zealand, the health care system is predominantly funded by general taxation which accounts for more than three quarters of health services provided. The New Zealand health budget stands at $13.983 billion (NZD). More than three-quarters of health funding is allocated to District Health Boards. Approximately 20% of public funding is used to finance national services, such as mental health services and about 1.6% is used to fund the operation and management of the Ministry of Health. This funding is then further distributed amongst Primary Health Care Organisations (PHO's) for use in the public sector.

The research carried out aimed to encourage evidence-based cost-effective pharmaceutical prescribing, reduce medicine related adverse reactions, improve patients' quality of life and reduce pharmaceutical wastage amongst selected populations pertinent to the ProCare PHO. Prescribing data was evaluated and interventions were subsequently developed in an attempt to improve pharmaceutical prescribing by General Practitioners (GPs) across an enrolled population.

OBJECTIVES

To evaluate the effectiveness of interventions being developed to optimise prescribing by GP's, while recognising stand-alone factors affecting prescribing patterns of medicines targeted by the programme. Other medicine information sources which influence GP prescribing recognised while conducting the research will also be documented and followed up as further study possibilities.

POLICY TARGETED

Pharmaceutical prescribing of medicines, in particular medicines available funded through the Pharmaceutical Management Agency (PHARMAC) were evaluated to observe trends in prescribing. These funded medicines are generally generics which are highly accessible to populations in which they are necessary.

METHODOLOGY

Design and setting: Retrospective delay analysis of pharmaceutical data was conducted using Excel to identify potential reductions in expenditure and volume of targeted pharmaceuticals and pharmaceuticals overall. A pilot prospective, cross-sectional study investigating the perceptions held by GP's regarding the influence of Optimising Prescribing interventions on their prescribing practices was also carried out. An overview of methodology and interventions used is shown below in *Figure 1*.

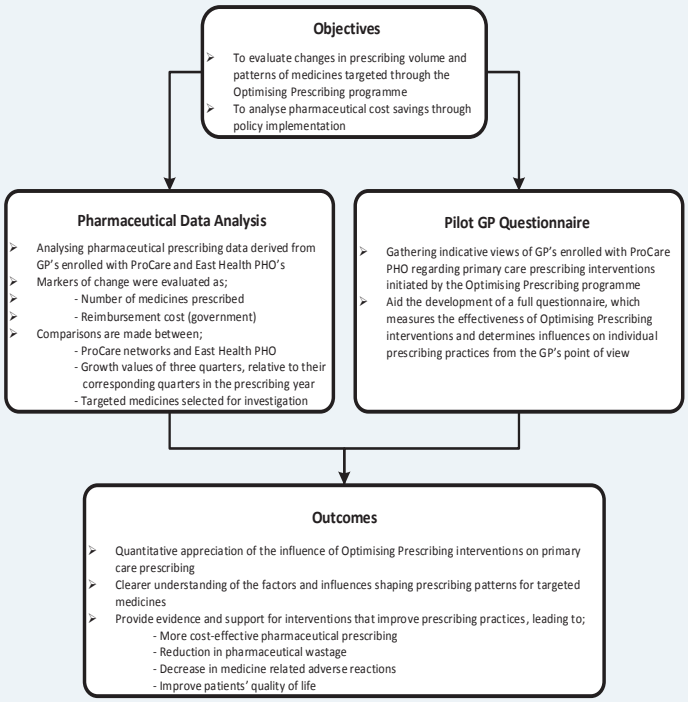

Figure 1: Schematic of research methodology

Population: Patients enrolled with ProCare PHO across Auckland and GPs responsible for their care were recruited for the purposes of this research.

Outcome measures: reduction in prescribing volume versus cost reduction analysis, GP behaviour change in relation to changes in prescribing habits.

Analysis: Pharmaceutical data, overall and for each targeted medicine, was analysed and presented in terms of quarterly growth values in a table and as prescribing trends on a graph documenting prescribing data of the study period from July 2009 to March 2011 shown in *Figure 2* below.

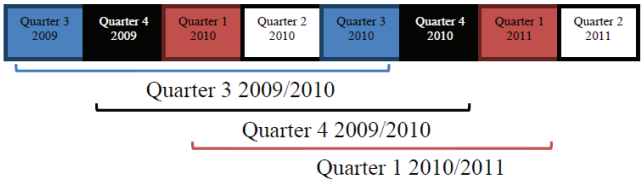

Figure 2: Schematic of quarterly comparisons.

Periodic analysis of data was carried out using the following equation listed as *Figure 3* below.

$$\frac{Value\ of\ Quarter\ X\ 2010 - Value\ of\ Quarter\ X\ 2009}{Value\ of\ Quarter\ X\ 2009} \times 100$$

$$= \textbf{\textit{Actual \% Growth between Quarter X 2009 and Quarter X 2010}}$$

Figure 3: Analysis of quarterly data calculation

RESULTS

Some medicines showed changes in prescribing volume and pharmaceutical expenditure in response to initiation of the interventions. For example, the prescribing volume of calcium carbonate in ProCare Network Manukau and East Health dropped sharply after the initiation of Optimising Prescribing interventions, which consists of medicines information bulletins and cell focus groups. However, the prescribing volume of calcium carbonate in ProCare Network Auckland declined before the intervention was initiated, implying that there are other sources of influence involved which can be seen by the fall in prescribing volume from July Quarter 3 in *Figure 3*. From the pilot survey, Best Practice Advocacy Centre (BPAC) was cited by GPs as the most influential source of medicines information in their prescribing practice.

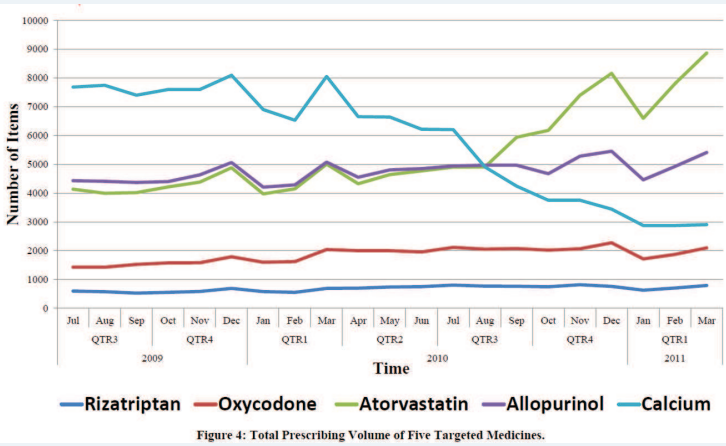

Figure 4: Total Prescribing Volume of Five Targeted Medicines.

CONCLUSION

From this research, there is evidence which shows that Optimising Prescribing interventions are effective in influencing GP prescribing practices. Several factors were recognised to be instrumental in shaping the prescribing patterns of medicines targeted by this research. Seasonal variations, population growth, change in subsidy status and removal of special restrictions were some of the elements which influenced the pattern of prescribing in primary care.

The impact of prescribing interventions directly targeted at the GP at the grassroots level appears to have maximal impact in consideration and conservative prescribing going forward.

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Insurance-based risk-sharing agreements

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Background

- Stretched healthcare budget have been tensing up patient access negotiations between healthcare payers and manufacturers. Data and the associated evidence available at registration are often deemed insufficient to accurately estimate the real-life clinical outcomes and budget impact. Payers want to reduce budget uncertainty and manufacturers need to evolve in a competing healthcare environment.
- As risk-sharing agreements (RSAs) reduce the payer exposure to the financial risks associated with the introduction of a new healthcare intervention, they are on the rising trend. However, engaging in a RSA should be cautiously thought and planned as those contracts entail important financial implications, especially for the manufacturer.

Objective

- Describe the insurance approach in the financial evaluation of a RSA.
- Provide two examples where payers decided to reduce their uncertainty about a specific outcome.

Methodology

- When a contract about a health product is concluded with a manufacturer, a payer becomes "exposed" to numerous uncertainties and associated financial risks [1]. For instance, effectiveness might be too low (e.g. oncology products are less successful than anticipated from the Phase III study) or implementation might be too complex (e.g. the onset of an outbreak cannot be tackled due to supply issues for vaccines and antiviral/antibiotic drugs). Fortunately, these risks can be outsourced and mitigated by introducing a third-party insurance actor in the negotiation. In exchange of a premium paid by the manufacturer or the payer or shared by both, the insurance actor will refund the payer if a pre-defined risk realizes (e.g. lower effectiveness than expected or shortage issue during an outbreak) [2].
- For illustrative purposes, two real examples have been selected from different disease areas: oncology and infectious diseases. In both cases, a professional insurance actor has ingested the risks the payer was not ready to take on.

Results

Disease area	Oncology	Infectious diseases
Year	2010	2013
Manufacturer	Roche	None
Payer	Chinese insurance companies	US insurance companies
Insurance actor	Swiss Re	SCOR (French reinsurer) and actors from the financial market investing in a special purpose vehicle (SPV), Atlas IX Capital Limited
Uncertainty	Percentage of successfully treated cancer patient in real-life(i.e. effectiveness)	Extreme mortality level among US insurance portfolios
Context	2010. The Chinese insurance companies do not want to reimburse oncology products by fear of rocketing-up after-treatment costs.	2013. US insurers (and SCOR) seeks protection against extreme mortality events (namely pandemics) across the U.S. and the District of Colombia.
Solution		

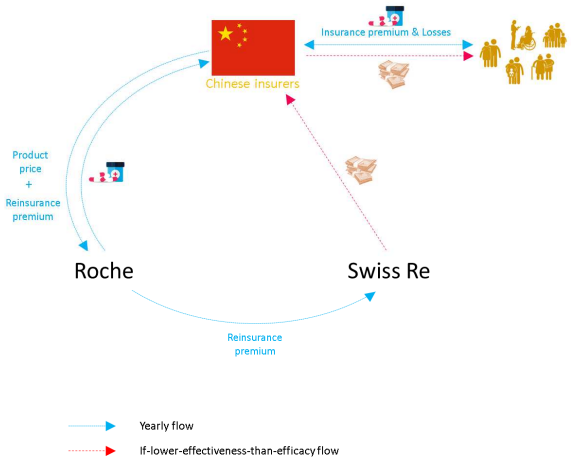

Figure 1 - Roche proposed the Chinese insurers to have oncology costs covered if the effectiveness of its product was lower than expected.

Roche decided to bring the reinsurance firm Swiss Re into the game with a single purpose in mind: reinsuring the insurers [3]. In other words, helping the Chinese firms lessen the risk of covering cancer patients (Figure 1). By leveraging its experience in other markets and its expertise in data analysis and cancer reinsurance, Swiss Re was also able to bring technical support on the insurance product design and pricing. Access doors to oncology care for China's new emerging middle class laid wide open. After a few years (Figure 1), Roche had sold millions of Herceptin medicines, millions of life had been saved and Swiss Re hold up a flag in a new important market for its future development [4]. A win-win-win strategy.

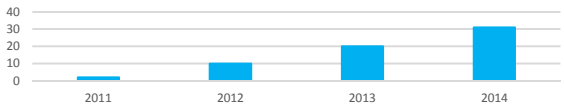

Figure 2 - Number of insurance policies sold by Roche covering cancer treatment in China since contract conclusion (millions).

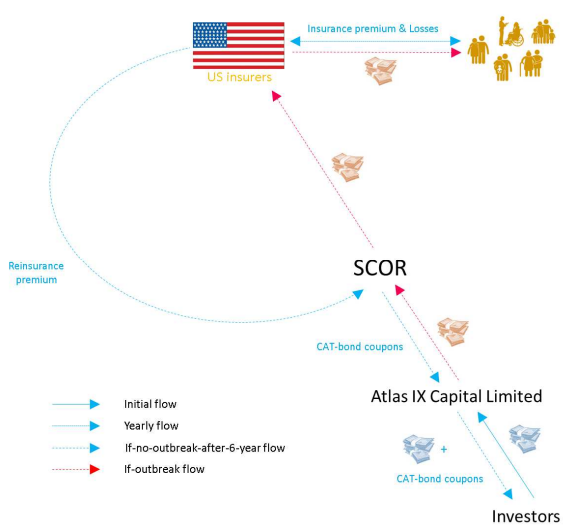

Figure 3 - A health manufacturer could propose adequate health products aiming at reducing the cost of outbreak risk, currently supported by SCOR and the financial market.

As SCOR did not want to keep the whole pandemic risk inside its own structure, it decided to outsource (part of) it to the financial market. How? It mandated Aon Benfield Securities to launch a BB-rated Special Purpose Vehicle (SPV), the Atlas IX Capital Limited. By issuing mortality catastrophe bonds (CAT-bonds) on the financial market, it was able to raise more than $125m of retrocessional reinsurance protection for the French reinsurer SCOR (Figure 3). The mechanism is the following. If the trigger (based on mortality data from the U.S. CDC) rise to a high level, the collateral (money from the investors) will be exhausted and the CAT-bond investors will not receive anything [5]. On the opposite, if the risk does not realize, investors will make a healthy return. How to further reduce this cost of risk for an insurer/reinsurer? By teaming up with a health manufacturer. Aside from financial compensations, medical interventions could also have been considered by the US insurers or SCOR, such as antibiotics, pandemic vaccines or antiviral/antibiotic drugs. Their use would tackle the onset of an outbreak and would therefore reduce the reinsurance premium or the CAT-bond coupons (Figure 2).

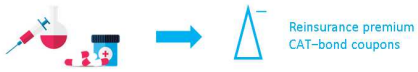

Figure 4 - Using antibiotics, pandemic vaccines or antivirals would help tackling an outbreak at its ignition and would therefore reduce the cost of risk.

Disclosure

The content of this article merely reflects the authors' opinion and does not engage in any way the companies mentioned in the present article. Those companies are only mentioned by the authors for illustration purpose. The authors have no conflict of interest to declare.

Conclusion

- Thanks to insurance and financial concepts, new ways of financing access to medical innovation exist.
- On one hand, to reduce budget uncertainty, payers are ready to take a forward step as long as such agreements work in the long run.
- On the other hand, seeing the fierce competition on the market, health manufacturers now need to start to provide riskless healthcare solution to payers.

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[5] http://www.artemis.bm/deal_directory/atlas-ix-capital-limited-series-2013-1/

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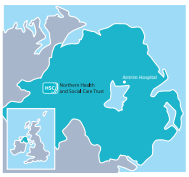

Medicines Optimisation in Northern Ireland

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[2] Digitalis Mm Ltd Ireland

Introduction

In Northern Ireland (NI), a Medicines Optimisation (MO) project has been successfully implemented by the Northern Health and Social Care Trust (NHSCT) over the last few years and continues to be developed. Historically, the approach taken to reduce medicines expenditure has been to focus almost exclusively on costs and cost-cutting initiatives. This methodology has had only limited success, as it fails to address the more fundamental aspects of the quality and safety of medicine use. Hence, in NI a new strategy was adopted, based on the premise that quality and safety drive health gain and economy. Thus, the model STEPSelect was developed (Safe Therapeutic Economic Pharmaceutical Selection) to ensure that medicines selection is fundamentally based on clinically related content such as efficiency, safety, documented effects on clinical end points and ease of administration.

STEPSelect

The STEPSelect method looks in the first instance at the clinical features of health technologies. At a later stage of the evaluation, product quality and fitness for purpose are assessed (the so-called risk assessment stage) as well as the budget impact of a health technology and appropriate procurement steps and processes. Evaluations are carried out by Expert Groups, which are composed on the basis of a multidisciplinary nature consisting of clinicians, pharmacists, nurses and other staff as appropriate.

STEPSelect is a web based tool developed by Digitalis Mm Ltd, enabling clinicians and other health care providers and managers to comprehensively select and procure medicines and medical devices.

Stage 1: Clinical Evaluation

- Literature evidence compiled by professional editorial network of Digitalis
- Review evidence supplied by Pharmaceutical Industry: Additional to the Literature Review (STEPSelect) & best evidence
- Assign scores to each product and relative weights to each selection criteria
- Ranking of chemical entities to proceed to Stage 2

Stage 2: Safety & Risk Assessment

- Product samples obtained from Industry
- Assessed using modified versions of national QC and Risk Assessment tools for Medicinal products: Product Quality and Fitness for Purpose (PQFFP) & Medicines Error Potential Assessment (MEPA)
- PQFFP (Pass/ Fail) ; MEPA (Low, Med, High)
- Ranking of chemical entities & MEPA scores to proceed to Stage 3

Stage 3: Budget Impact Analysis

- Annual usage data obtained to allow comparison of products within the same class
- Ranking of chemical entities to proceed to Stage 4

Stage 4: Contract & Guidance

- Guidance produced - will inform service of products suitable for prescribing first line in NI
- Relevant contracts put in place

Benefits

- Reduced medicines related adverse events
- Improved Quality:
  Drug Selection based on safety & efficiency, then cost
- Improved Efficiency:
  Cost-effective drug selection
  Reduced stockholding & reduction of out of date stock
- Robust, Transparent, Defensible process

Efficiency Gains

In NI the STEPSelect technology has been applied to procurement of medicines in many different therapeutic groups such as statins, erythropoietin stimulating agents (ESA's) and the use of biologicals in rheumatoid arthritis. Results with the method have invariably been positive in terms of support by clinicians and quality and cost reductions of prescribing, often in the region of 20-25% per therapeutic group.

Hospital Prescribing £ per need weighted patient (McKinsey Report 2010)

N.Ireland	£58
N. Ireland 7%	£54
N.Ireland 16%	£50
England	£64

Interactive Website

- Tablet devices for Expert Group members
- Project mentor
- Project key for limited access for special target groups
- e-sessions to highlight choices for special interest groups
- Comprehensive stakeholder input via these interactive mechanisms

Summary

- Supports a clinician driven procurement process
- Process is based on the principles of quality and safety
- Supports guidance and formulary development and maintenance
- Maximises health care resource utilisation
- A key component of Medicines Optimisation

Conclusion

STEPSelect is just one of the strategies adopted in NI to optimise the use of medicines. In 2015, the NI Government decided to fund a new initiative setting up a "Medicines Optimisation Innovation Centre" (MOIC). MOIC will actively promote the experience of NI in MO across the EU and beyond and has started working with many governments and public health insurance agencies as well as the World Bank. MOIC is in the process of applying for WHO Collaborating Centre status for MO. It will also continue to develop new initiatives to further enhance MO.

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moic
Medicines Optimisation Innovation Centre

BIOSIMILAR MEDICINES

Creating Sustainable Competition in an Era of a New Patent Cliff in Biological Medicines

European Biosimilars Group
EGA sector group

Maarten Van Baelen / Pieter Dylst, European Generic and Biosimilar Medicines Association (EGA)
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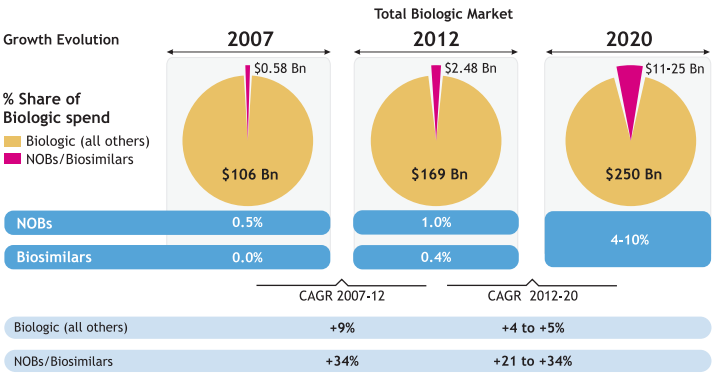
Background

For many years, European governments have sought to ensure a high degree of competition in off-patent pharmaceutical markets in order to generate price competition - and consequently benefits, such as improved patient access or savings for payers after patent expiry.
Biological medicines today account for 27% of pharmaceutical sales in Europe and their growth continues to outstrip total pharma (5.5% vs. 1.9% between 2012-2013). With many of Europe's top selling biological medicines facing patent expiration before 2020, expectations are high from payers seeking to generate savings as these products face direct competition for the first time from biosimilar medicines. However, in order to deliver these benefits, it is imperative that the biosimilar medicines market remains sustainable.

Biosimilar Medicines - Growing Importance

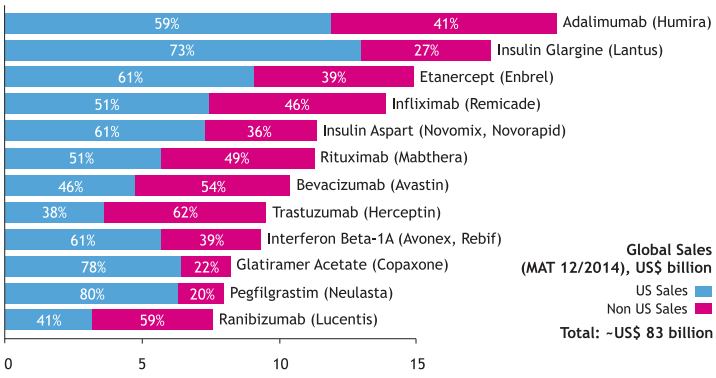
The global biological medicines market is expected to reach $250 billion by 2020 and will experience its own patent cliff: 12 biologic compounds that generate $83 billion in sales face patent expiration.

Evolution of global total biologic market



Source: IMS Health (2014) - Searching for terra firma in the biosimilars and non-original biologics market.

Products that will lose patent protection by 2020 in Europe

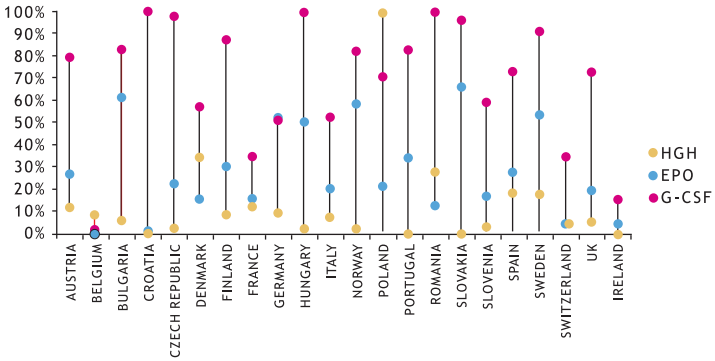


Source: Rickwoord S (2015) - Perspectives on the evolving biosimlars landscape. Presented at EBG BIOS16 Conference, London.

Current Uptake of Biosimilar Medicines

Uptake of biosimilar medicines varies by country and by therapeutic area.

Biosimiliar penetration (% of treatment days 2013)



Source: IMS Institute (2014) - Assessing biosimilar uptake and competition in European markets.

Biosimilar Medicines Opportunities

Biosimilar medicines provide opportunities not only to payers but also to patients and prescribers.

Source: GfK (2014) - Factors supporting a sustainabl European biosimilar medicines market.

Sustainability Policy Framework

Policy development to establish and maintain a sustainable biosimilar medicines market requires holistic understanding of the dynamics of the market from all stakeholder perspectives, a common shared understanding amongst all stakeholders of the comprehensive benefits that biosimilar medicines offer, and rational decision-making aligned with this understanding.
Four elements, considered holistically, provide a sustainability policy framework for the biosimilar medicines market. All four elements are required for sustainability and will lead to clinical, economic and patient benefits.

Conclusion

Biosimilar medicines will grow in importance in the years ahead and will provide a unique opportunity for governments, payers, prescribers and patients. Governments and payers must realize that biosimilar medicines are different to generic medicines and as such must be treated differently. A sustainability policy framework for biosimilar medicines, considering 4 elemenst holistically, will be necessary to continue benefiting from biosimilar medicines opportunities in the long term.

Availability and prices of essential medicines for chronic diseases in older people in the Asia Pacific Region

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Study supported by the China-Australia Centre for Health Sciences Research

Background

The objective of this study was to assess the availability and prices of essential medicines for chronic diseases in 11 countries, namely China, Fiji, India, Indonesia, Lao, Malaysia, Mongolia, the Philippines, Sri Lanka, Thailand and Vietnam. The study was carried out at an international level.

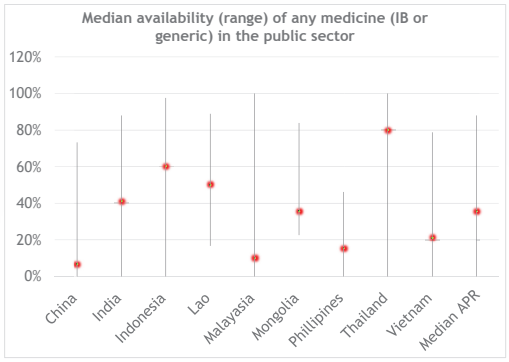
Methods

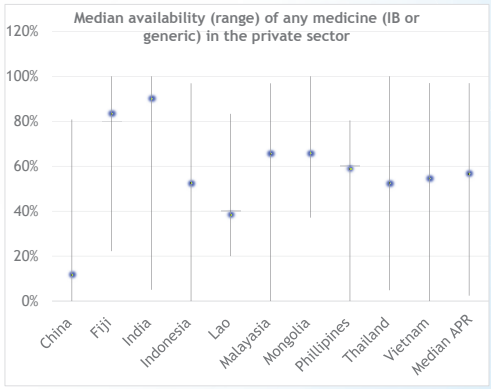
Data on the availability and price of 15 medicines used for chronic diseases prevalent in the older population were obtained from facility-based surveys conducted in 11 countries between 2001 and 2013 (Health Action International's database on medicine prices).

Prices were converted into the base year of 2014. Patient prices were adjusted for inflation and purchasing power parity and procurement prices for inflation and official exchange rates. Data were analysed for lowest priced generic (LPG) and innovator brand (IB) products in both the public and private sectors.

Results: availability

The median availability of any medicine (IB or LPG) in the public sector was 35.5% compared to 56.7% in the private sector. Thailand and Indonesia had the highest levels of availability in the public sector (80% and 60.1% respectively) while in the private sector it was India and Fiji (90% and 83.4% respectively).





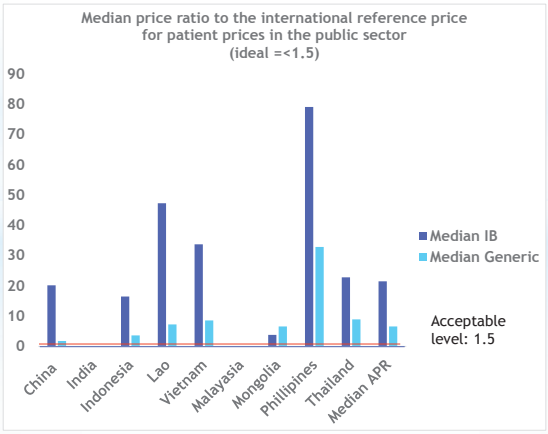
Results: prices

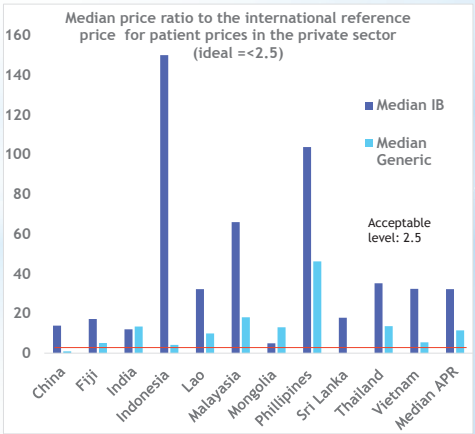
Countries in the Region paid 1.4 times the international reference price (IRP) to procure LPGs and 9.1 times the price for IBs.

India and Fiji achieved low procurement prices (0.4 and 0.6 times IRP for LPGs) while the Philippines had the highest procurement prices for both IBs and LPGs.

In general, patient prices were lower in the public sector than in the private sector (21.5 times IRP vs 32.2 times for IBs and 6.6 times vs 11.5 times for LPGs).

In the public sector, Malaysia and India provided medicines free of charge while the Philippines charged the highest price.





Conclusions

The availability and prices of medicines for chronic conditions were highly variable across the Asia Pacific Region. Medicines were more available in the private sector, but at an excessive price. Implementation of policies to improve the availability and reduce the prices of essential medicines for chronic diseases is needed.

Transitioning to a national health system in Cyprus: A stakeholder analysis of pharmaceutical policy reform

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Introduction

Currently, the country's health system consists of a public and a private sector. The government pays for public-sector health care while patients and private health insurers pay for private-sector health care (**Figure 1**).

Who is eligible for public-sector coverage? About 83% of the population:

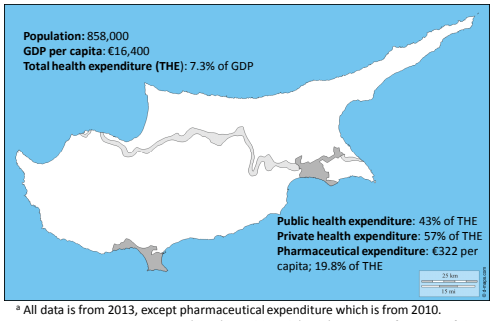
1. Individuals with annual incomes ≤€15,400
2. The chronically ill
3. Civil servants

In 2013, Cyprus agreed to a memorandum of understanding with international creditors which called for the introduction of a national health system by mid-2016. The system is now expected to be implemented in 2017.

Objective

1. To review the pharmaceutical sector in Cyprus in terms of the availability and affordability of medicines
2. To explore pharmaceutical policy options for the national health system finance reform expected to be introduced in 2017

Figure 1. Key statistics about Cyprus and its health system, 2013[a]

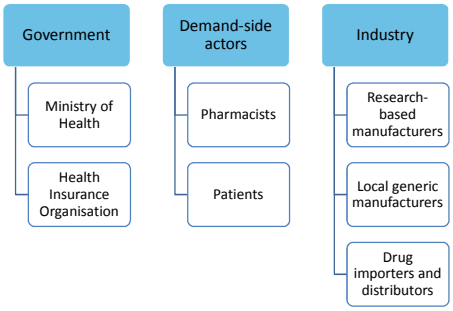


[a] All data is from 2013, except pharmaceutical expenditure which is from 2010.
Sources: European Commission (2014); World Bank (2014); Ministry of Finance of the Republic of Cyprus (2014); http://www.d-maps.com/carte.php?num_car=2160&lang=en

Methods

We conducted semi-structured interviews (**Box 1**) in April 2014 with senior representatives from seven key national organizations (**Figure 2**) involved in pharmaceutical care. The captured data were coded and analysed using the predetermined themes of pricing, reimbursement, prescribing, dispensing and cost sharing. We also examined secondary data provided by the Cypriot Ministry of Health; these data included the prices and volumes of prescription medicines in 2013.

Figure 2. Stakeholder groups represented by interviewees, Cyprus, 2014



Note: Interviews took place in April 2014 at the headquarters of the health ministry's Department of Pharmaceutical Services, Nicosia, Cyprus

Box 1. Semi-structured interview template

1. What are the strengths and weaknesses of the pharmaceutical policies in the public and private sectors?
2. Which policies should be changed before the introduction of the national health system reforms?
3. Which policies should be applied in the new system?
4. What are the key barriers to the successful implementation of the health-care reform?

Results

We identified several key issues, including high medicine prices, underuse of generic medicines and high out-of-pocket drug spending (**Table 1**).

Most stakeholders recommended that the national government:

1. Review and refine existing pricing policies, such as the external price referencing system
2. Introduce a national reimbursement system
3. Incentivize the prescribing and dispensing of generic medicines

We identified four key barriers to the successful introduction of a comprehensive drug-benefit plan:

1. Many of the policy options would need to be accompanied by legislative changes
2. Differences in opinion between stakeholders over which policies to apply
3. Disagreements over how to allocate responsibilities to governmental agencies
4. Difficulty of raising awareness about the benefits of greater generic drug use

Table 1. Drug expenditure in the public and private sectors, Cyprus, 2013

Category	Expenditure (millions of €)[a]	
	Public sector	Private sector
Prescription drugs[b]	98.5	80.6
Inpatient	59.5	9.7
Outpatient	39.0	70.9
On-patent originator brand	7.7	8.4
Off-patent originator brand	10.8	46.6
Generic	19.3	11.4
Vaccines and others	1.2	4.5
Over-the-counter drugs	5.0	14.3
Total drug expenditure	**103.5**	**94.9**

[a] Excluding value-added tax
[b] Inpatient and outpatient drugs are sold in hospital and retail pharmacies, respectively
Source: Data provided by the Department of Pharmaceutical Services, Ministry of Health, Nicosia, Cyprus

Discussion

In many countries, the main objectives of pharmaceutical policies are to ensure equitable access to – and the good quality and rational use of – effective drugs.

Over the next few years, there is a need to update the legislative and institutional framework in Cyprus and to acquire data, through pilot studies and simulations, on how health care might operate under the new system.

The government should work to eliminate the four barriers and prepare for unforeseen problems that inevitably accompany large-scale changes to health systems.

Study limitations:

1. Personal bias
2. No representatives from the Cyprus Medical Association were available for an interview
3. Study only looked at reform in the pharmaceutical sector

The findings of this study are meant to inform the ongoing policy deliberations in Cyprus. They can also be used to inform discussions in other countries aiming to establish a comprehensive drug-benefit plan under universal health coverage.

Conclusions

In Cyprus, if the national health system is going to provide universal health coverage in a sustainable fashion, then the national government must address the current issues in the pharmaceutical sector. Importantly, the country will need to increase the market share of generic medicines to contain drug spending.

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This poster summarizes the findings of the following study:

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ACTION TOWARDS COST-EFFECTIVE MEASURE IN IMPROVING MEDICINES WASTAGE

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CONTEXT

An assessment of cost-effective actions to improve public healthcare institutions' medicines wastage

TARGET POLICY

Management of medicines wastage policy and practice

REGION COVERED

National level

MALAYSIA

OBJECTIVE

i) To evaluate the pharmaceutical allocation towards the competency of medicines wastage management

ii) To evaluate the value of medicines disposed due to expiry and returned medicines.

PROBLEM STATEMENT

- Medicines wastage is one of the important issues in the pharmacy services.
- Causes the financial burden to the country.
- Weakness on the proper management of the medicines will not only will affect :
  - ◊ the institution's financial status.
  - ◊ Leads to a long chain of bad reaction towards the **storage**, **distribution** and the **availability** of the medicines to the patients.

SETTING

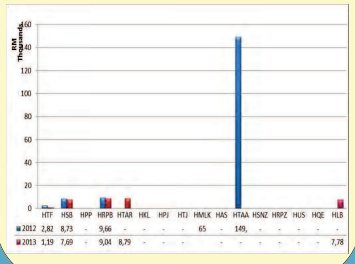
- Addressing **in** and **out-patient** setting of public sectors facilities in Malaysia.
- It involved **major**, **specialised** and **semi-specialist hospitals**

RESULTS

Preliminary results indicated that in the year 2012, RM 149,000 were recorded as the highest cost of medicines wastage despite the guidelines indicate it should be zero in figures. While in the year 2013, RM 1,119.00 was the lowest value indicated in that particular year.

The study outcome is expected to analyse the trends and value mounted for medicines wastage for a proper planning and assessment of pharmaceutical procurement management.

Value of medicines disposed



METHODOLOGY

i) **Quantitative study** conducted in a **cause-effect relationship** mode of study.

ii) Data involving major public hospitals in Malaysia was collected using **simple random sampling**.

iii) Value of medicines disposed **(independent variables)** was the procurement value of those medicines that need to be disposed. The disposal of the medicines was due to its expiry. The value measured was the procurement cost in monetary **(Ringgit Malaysia).**

iv) Pharmaceutical Managerial Procurement **(dependent variable)** was measured through the annual medicines allocation for the major public hospitals. The unit of the allocation measured was in monetary value **(Ringgit Malaysia).**

v) The data collected were analysed using **SPSS** and **SEM**

INTERVENTIONS

- ◊ **Acknowledgement** of the wastage value recoded from the study to the **stakeholders** and **public procurement personnel.**
- ◊ Intended interventions would be the **mathematical model** for the wastage value forecasting which will be useful in the pharmaceutical budget projection and management.

CONCLUSION

The findings are expected to drive the urge of better medicines wastage management and finally generate room for **pharmaceutical innovation for the cost-effective tools** towards the **efficient handling of monetary** and **medicines stock**

COST-CONTAINMENT OF NON-FORMULARY MEDICINES ACCESSIBILITY : MALAYSIAN EXPERIENCE

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CONTEXT

Management of non-formulary medicines accessibility to the public.

TARGET POLICY

- The National Medicines Policy focusing on the accessibility and availability of medicines in the public healthcare institutions in Malaysia is targeted to be reviewed.
- It included the pharmaceutical procurement practice in procuring the non -formulary medicines in public healthcare institutions

OBJECTIVE

i) To **scrutinize** the public pharmaceutical procurement practice on the non-formulary medicines availability.

ii)To **assess the effectiveness** of the public pharmaceutical cost containment approach in the public pharmaceutical fiscal sustainability.

LESSONS LEARNED & SUCCESS FACTORS

- Definite **expenditures of the non-formulary medicines procured** were identified.
- The **monetary incurred, facilities involved** and **quantity of non-formulary medicines procured** will later helpful in terms of **forecasting pharmaceutical allocation**.

PROBLEM STATEMENT

◊ As in Malaysia, we are operating the public healthcare system through a fully subsidised mode, thus a proper management on the procurement and pharmaceutical inventory are crucial.

◊ This is because the increasing trends of pharmaceutical expenditures as the Malaysian population grows, the total financial allocation for MOH has also expands from RM 15 million in 2010 to RM 16 million in 2012.

SETTING

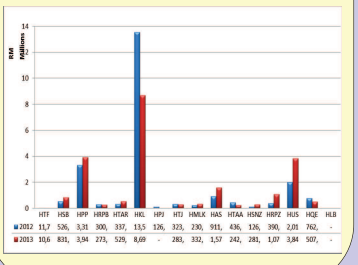
- Addressing **in** and **out-patient** setting of public sectors facilities in Malaysia.
- It involved **major**, **specialised** and **semi-specialist hospitals**

RESULTS

The need for the patient healthcare demands are under the purview of the government as we are conducting a subsidised healthcare system. Thus, the availability of the medicines in the public institutions is restricted to their formulary. However, in certain circumstances, the patient conditions might lead to the need of non-formulary medicines. Thus, this will indirectly lead to the burden of expenditures.

As in this study, p value of 0.046 and 0.007 were obtained for the correlation of the non-formulary medicines cost and the hospital financial allocation. The significant correlation shown has proven that this variables are among the important components in assessing the pharmacy service competency.

Value of Non-Formulary Medicines Procured



METHODOLOGY

i) A **quantitative study** and conducted in a **cross-sectional study design**

ii) **Purposive sampling method** was applied in the study sample selection.

iii)The targeted samples to be involved in the selection were the **public healthcare institution** in Malaysia.

iv) The study were conducted in the **13 major public hospitals in Malaysia.**

v) The data and information on the pharmaceutical procurement of non-formulary medicines management, financial allocation and expenditures on pharmaceuticals purchased in the selected facilities for the three consecutive years of 2011,2012 and 2013 were collected and analysed statistically

INTERVENTIONS

◊ The identification of the **factors contributing** towards the **pharmaceutical allocation** in terms of procurement made.

◊ The factors identified are beneficial for **newly suggested SOPs for procurement** involving non-formulary medicines as to ensure cost containment approach is being practised.

CONCLUSION

The outcome obtained aimed to **fulfill the research gap in medicines policy** towards the **financial sustainability** of the pharmaceutical services in Malaysian public healthcare institutions

Review of Ongoing Initiatives in China to Enhance Prescribing Efficiency
Influence and future directions

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Marion Bennie (NHS Scotland; SIPBS, UK) **Alexander** E Finlayson (University of Oxford, UK)

INTRODUCTION

Pharmaceutical expenditure grew at over 16% per annum in China during the past decade due to several factors including urbanization, ageing populations and the expansion in medical insurance. Alongside this, the financial support from the government to public hospitals declined steadily from approximately 60% of hospital revenues in 1980s to 8.2% by 2003.

In recent years Chinese government made much effort on drug price reduction to address the increasing of pharmaceutical expenditure.

AIMS

To appraise the influence of the various measures affecting the prescribing of originators versus generics on their subsequent utilization patterns and expenditure in high-volume classes to provide future guidance.

METHODS

Principally a narrative review of published studies on the utilization and procured expenditure for the proton pump inhibitors (PPIs) as well as CV medicines including statins and the renin–angiotensin inhibitor drugs between 2004 and 2013 in the largest teaching hospital in Chongqing District as representative of China

RESULTS

------**PPIs:** The prescribing of PPIs rose 10.4 fold from 2004 to 2013 (Figure 1), greatest with injectable PPIs. At one stage (2008 and 2009), injectable PPIs accounted for 42% of total PPIs.

Utilization of oral generic PPIs grew faster than oral originators leading to oral generic PPIs at 82% - 87% total PPIs between 2007 and 2013. Generic oral omeprazole in 2010 was 87% below 2004 originator prices. However, injectables typically 4.3 to 6.8 fold more expensive than equivalent orals – with the high utilization of more expensive oral forms and injectables increasing expenditure 10.1 fold during the study period.

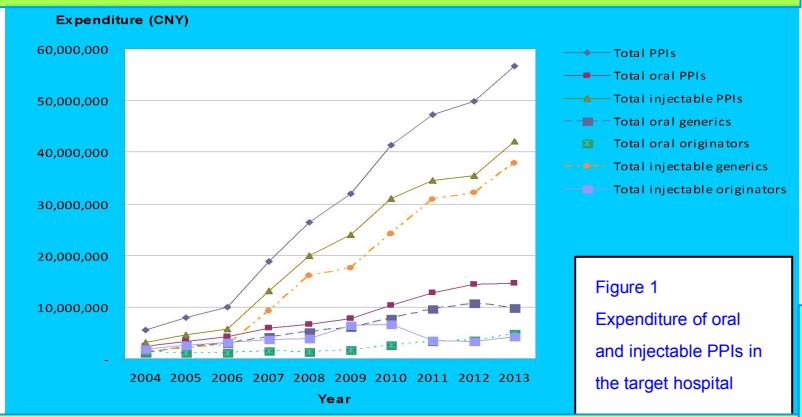

Figure 1 Expenditure of oral and injectable PPIs in the target hospital

------**Cardiovascular and Cerebrovascular Medicines:** Total expenditure increased 4.85-fold over the 7 years, with the share of Traditional Chinese Medicines (TCMs) increasing from 35% in 2006 to 57% in 2012 vs. chemical products

Various pricing models can be seen. A substantial drop in prices does appear to affect subsequent use (always negatively).

RESULTS (Continued)

------**ARBs:** Overall utilization of generics single ARBs fluctuated between 22% and 31% from 2006 to 2012 despite increasing availability of generics. For Fixed Dose Combinations (FDCs), generics rose from 11% in 2006 to 20% in 2012

Only a marginal price decrease for single originator ARBs combined at 7% in 2012 vs. 2006, compared with a 44% procured price reduction for generics – highest at 54% for telmisartan.

Table Utilization of single and FDC ARBs in the target hospital

ARBs	2006	2007	2008	2009	2010	2011	2012
Candesartan	36960	62580	70560	60480	30880	52400	91590
Irbesartan	46550	84700	156602	255240	384850	358200	492120
Losartan	61740	114597	182700	252210	414400	379400	537880
Telmisartan	23912	71218	191968	203420	268800	345072	610050
Valsartan	18060	38150	103663	154560	179200	290080	454405
Irbesartan FDC	2800	27314	71610	116060	178080	216720	335720
Losartan FDC	19306	38850	78400	79100	122990	131600	193970
Valsartan FDC			350	1960			
Total	209328	437409	855853	1123030	1579200	1773472	2715735

-----**Statins:** Statin utilization rose 32 and 54 fold separately in the two studied hospitals, with atorvastatin (originator) the most utilized (Figure 2)

The overall utilization of generics increased from 18% of total statins in 2004 to 28% in 2013 in the main hospital. Procurement prices fell over time, greatest for generic simvastatin (-74 to -91%) mirroring data from European countries

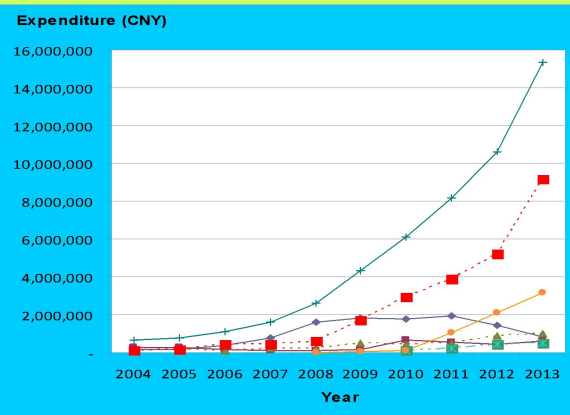

Figure 2 Expenditure of statins in the Chongqing hospital

CONCLUSIONS

- Encouraging to see high utilization of generic PPIs and low prices for oral generic PPIs as well as other generics
- Estimated that restricting the formulary to just one statin, ARB or PPI based on the cheapest procured product would have saved 50-84% of total accumulated expenditures for the respective classes
- However, real progress to enhance the rational use of medicines in China will only be made by addressing the current perverse financial incentives for both physicians and hospitals, with both groups seeking to enhance their income from the drug procurement process

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VALUE OF GENERIC MEDICINES: A HEALTH ECONOMIC STUDY

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Background

Generic medicines provide an opportunity to obtain similar treatments at lower costs for patients and payers, while liberating budgets for financing new innovative medicines. It is estimated that generic medicines bring cost savings for each EU member state of 40 billion euro every year (1). The debate on generic medicines has been centered on affordability and cost-savings so far. Positive health impacts of generic medicines has, however, been scarcely discussed. The aim of the study is to examine the value of generic medicines in a more comprehensive way, particularly including the patient-related value. Thus, the focus of the study is to analyze the health impact of generic medicines in terms of relevant health outcomes and medication adherence.

Methodology

The analysis of the clinical benefits and health outcomes is based primarily on a structured literature review in relevant literature databases with focus on medical and economic journals or references (e.g. Pubmed or Econlit). Additionally, an internet research was conducted to identify scientific reports and papers from influential stakeholders and institutions. The volume and sales data for Germany was extracted from the Drug Prescription Report 2014 (2). The study was conducted for three selected drug classes: antihypertensives, adjuvant endocrine therapy for breast cancer, and anti-depressants. The results for the first two indications are shown in the poster.

Results

Hypertension- and Breast cancer-related Mortality Rates

Fig. 1: Hypertension-related mortality in EU- and OECD-countries, 1980-2010

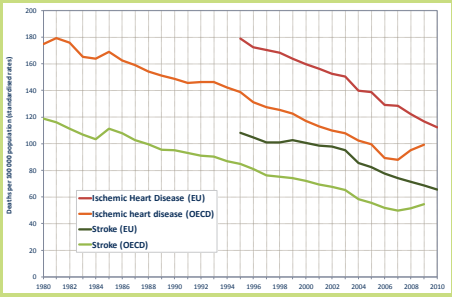
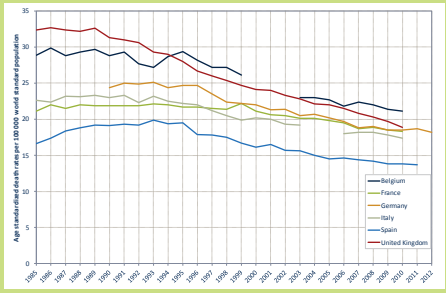


Fig. 2: Breast cancer-related mortality in selected European countries, 1985-2012



Antihypertensive drugs reduce the risk of cardiovascular and all-cause mortality in hypertensive patients (3). Since 1980 the mortality caused by stroke or ischemic heart disease decreased in the EU countries (Fig. 1). According to clinical data, adjuvant endocrine therapies (tamoxifen and aromatase inhibitors) for breast cancer reduce patient mortality. Since 1985, breast cancer mortality rates dropped in the EU countries (Fig. 2) (4). There are several reasons for the decline of the mortality rates of both diseases: prevention measures, implementation of guidelines, improved medicinal treatment options, behavioral changes etc.

Germany: Generic Market Entry Hypertension and Breast Cancer

Fig. 3: Change of generic market share, prescriptions and sales of antihypertensives

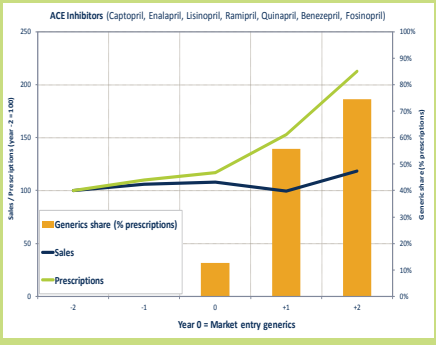
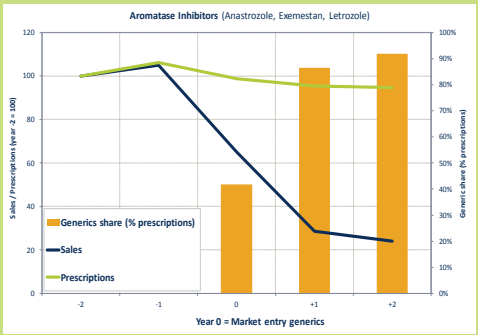


Fig. 4: Change of generic market share, prescriptions and sales of aromatase inhibitors



For the indication hypertension, there has been generic competition in all drug classes in the EU, starting in the early 1970s (diuretics) up to more recent generic market entries like angiotensin-II-antagonists (losartan) in 2010. In Germany, treatment utilization measured by the number of prescriptions dispensed, doubled with the market entry of generics (Fig. 3). Two years after the launch of a generic medicine, about three quarters of all prescriptions were for generics. Sales, in contrast, kept almost stable, indicating that more patients had been treated within two years after generic market entry without noticeable rise in cost.

Germany: Generic Market Entry Breast Cancer and Adherence

For hormone receptor-positive breast cancer, generic medicines for tamoxifen were launched in the mid 1980s, followed by generic medicines for the aromatase inhibitors in 2011. The drug market for aromatase inhibitors showed a rapid generic penetration after generic market entries (Fig 4). The generic volume share rose to more than 90% two years after generic medicines were launched. Though treatment utilization very slightly decreased after the launch of generics, while sales decreased by almost 80% in the same time period.

The results on the impact of generic medicines on adherence are inconsistent: Co-payments for patients tend to impair patients adherence. As generic drugs are associated with lower co-payments a positive effect of generics on adherence is expected to be more significant in health systems with relatively high patients co-payments for branded drugs. Furthermore education measures regarding generic medicines can positively impact the adherence (5). Though the process of generic substitution is prone to negatively influence patients adherence as the substitution to a generic drug can cause confusion and reduce patients' willingness and ability to take their medication (6).

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Discussion and Conclusion

Mortality rates for stroke, ischemic heart disease and breast cancer decreased in the European countries during the time period when generic medicines were launched. Though the reasons for the improved health of patients are multifactorial and improved medicinal treatment option is one of the relevant factors improving the health of patients. As demonstrated for the German antihypertensive market, the utilization rates for patients can improve with the launch of generics and more patients receive a necessary treatment. Though in life-threatening diseases, such as breast cancer, this is not the case, as physicians do not withhold treatments for patients. The patient-related-value of generic medicines therefore varies between diseases and depends strongly from patients access and costs for available treatments.

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Policy options to deal with high-cost medicines – Survey with European policy-makers

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Objective

To survey whether and which **pricing and reimbursement policy options** European countries have been implemented for **new premium-priced medicines**.

Methodology:

- **Cross-country survey** with **policy-makers responsible for pharmaceutical pricing and reimbursement** in 42 countries (all EU Member States, 9 further European countries and 5 non-European countries) for pricing and reimbursement policies in **out-patient and in-patient sectors**.
- **Responses** were received from **27 European countries** and **Canada,** data as of February – March 2014

Scope: 'New / Innovative' medicines
Common definition is lacking.
From a public health perspective, the level of **innovativeness of a medicine** is primarily defined by the **benefits the medicine generates for patients**. These benefits can be in the therapeutic or clinical domain, the quality of life domain, but also in the socio-economic domain. Examples of benefits in the socio-economic domain include a medicine that would prevent (expensive) hospital admissions or that would enable patients to work.
(Source: Vienna WHO CC Glossary)

Scope: high-priced medicines
No clear international definition.
The **high price itself might not be the decisive criterion**, but also **the use / demand** for the product resulting in high costs for the treatment of the patient.
A broad definition of a new premium-priced medicine in this research context is one whose acquisition cost is greater than 10,000 Euro per patient for a yearly therapy for the public payer and which is replacing an existing medicine (whose costs public payers were already paying).

Results

Country specific definition on high-priced medicines?	
No	**21 countries**: BE, DK, CA, CH, ES, EE, EL, FI, HR, HU, LV, LU, MT, NL, NO, PL, RS, SI, SE, SK, UK
Development	**AT:** a definition on high-cost and specialized medicines was developed at time of the survey
Country-specific definition	**AL, CZ, FR, IS, IT**

Pricing and reimbursement in the out-patient sector	Pricing and reimbursement in the in-patient sector
Overall, the rules for pricing and reimbursement of new premium-priced medicines **do not differ** from the ones for the other medicines	In principle, **no specific P + R procedures** for premium-based medicines in many countries, but specific funding models, processes, schemes: e.g. DK, NO
Increased **use of HTA** and **pharmacoeconomic evaluations**	**Funding outside the DRG system:** individual product reimbursement (AT, BE, EE, FI, FR)
Frequent use of price-volume agreements, managed-entry agreements, risk-sharing schemes and **similar** was reported from some countries (e.g. ES, FR, PL, HU; SK – 'conditional categorization')	**Special agreements between hospitals and social health insurance**: costs for medicines used in hospitals are (partly) funded by social health insurance (FR, EL, NL – new arrangement since 2013, SI; NO – TNF and MS medicines & (since 2014) some oncology medicines are funded by hospitals
	Special programs: LV, PL
	Special funds: Cancer Drug Fund (UK)

Horizon scanning was reported only from few countries (Canada, Italy, UK).

Reported challenges
- **Concerns about access and sustainability**, in the light of balancing the need to provide access to new high-cost medicines with given budgetary restraints,
- **Question about value-for-money** of the new medicines, **with limited data and evidence** available about the added value,
- **Issue on pricing**, on how to be able to reduce the price of these medicines, particularly given the frequent use of the external price referencing policy, and
- **Concerns about limited coordination between sectors** (out-patient / in-patient sector and different payers/jurisdictions)
- **New biological medicines**

Discussion and conclusion

Though European governments were concerned with the cost issue due to new medicines, **specific pricing and reimbursement policies have yet to be thought through in a systematic manner.** Prioritization processes will increasingly be required for the introduction of new medicines. **Lessons learned: Prioritization should incorporate the principles of collaboration and transparency**: Cooperation between countries in Europe and stakeholder dialogues could be further strengthened. This needs to involve better balancing of the value of innovation with equitable, affordable patient access.

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THE EFFECTIVE AND INNOVATIVE COST SAVING OF SOFTWARE IN MANAGING UNREGISTERED DRUGS

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CONTEXT

A better management of awareness program and inspection activities amongst general retailers

OBJECTIVE

To develop the software in managing unregistered drugs through awareness program and inspection activities.

PROBLEM STATEMENT

- The Annual Report of Enforcement Pharmacy raiding of unregistered drugs has shown an increasing trend and possibility that the seized value will keep on increasing year by year.
- No available reference as a guide to the public specifically to the general retailers and enforcement pharmacist towards unregistered drugs.

USEFULNESS

- Provide easy access information on location of the general premises for enforcement pharmacy department to do the monitoring and planning in managing unregistered drugs.
- Help to educate public and general retailers on the registered drugs.
- Aid public to decide on the health products they want to buy and consume.

DISCUSSION

- A high percentage of didn't know what registered drugs is amongst owner of general retailers at city.
- The existing of premises in that area might be difficult to control by Enforcement Officer because of the capacity of the citizen and premises.
- The monitoring of the premises by enforcement officer cost a lot of money because there is no specific database that can be used as a reference and it is very tedious in gathering all of the information about the general retailers premises.
- Therefore, the findings from this study can be used as platform to improve current program to ensure that these activities are worth and cost-saving.

RECOMMENDATIONS

- Review the law and regulations to increase the **PENALTIES** are appropriate.
- Provide a **DATABASE** that specifically about unregistered drugs that can be assess by consumers.
- A strong commitment, shared responsibility and coordination from **DIFFERENT ORGANIZATIONS**. To discuss any problem related with unregistered drugs and come out with a better solution.
- Improve **INTERNATIONAL COLLABORATION**, together to help in combating this issues.
- Increase the **TECHNOLOGY** improvement in the **DETECTION** of unregistered drugs. For example, kits to detect food or drink of health products that contaminate with poison example, Viagra, Sibutramine and Steroid.
- Districts, Municipal and City Council need to have a **RULES/ AGREEMENT** to be sign by general retailers that want to sell any health products or OTC drugs; to ensure they aware or understand what registered drugs is.
- MOH under Enforcement Division need to consider to increase pharmacist, public, and general retailers' awareness in this field by making the current **AWARENESS PROGRAM** advertising throughout Malaysia.

CONCLUSION

This result will be used as a pioneer study and as a reference for future study. In addition, the data retrieved from the inspection form will also be used for the development of awareness and inspection software include all the detail of the premises in geographical or location of the premises.

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