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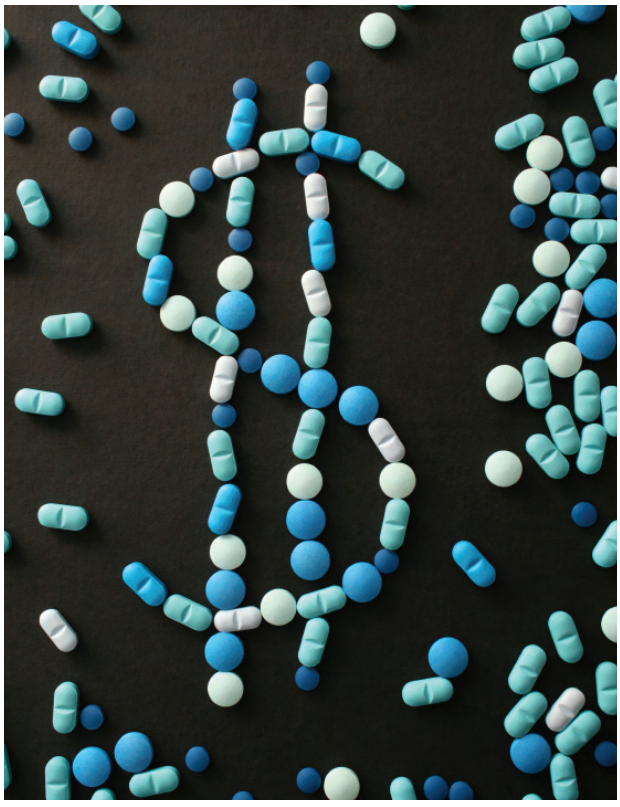
Southern Med Review

An International Journal to Promote Medicine Use and Access Research

Special issue on access to medicines, pricing and generics



Medicine prices, availability and affordability in Vietnam and Thailand

Medicine pricing policy in South Africa

Consumers' perception of generic medicines in Malaysia

Policy reforms and generic medicines in Australia

Anti retroviral therapy in a South African public healthcare setting

Retail pharmacy sector in low and middle income countries

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Context: In developing countries where health systems and health policy are constantly evolving, there is a great need to publish informative research. However, there are few avenues to do so due to, also inexperienced or untrained researchers, topics out of the scope of current mainstream journals and limited funding are some of the other challenges.

Aims and Objectives: *Southern Med Review* provides a platform for researchers to disseminate commentary and empirical research findings, with a view to improving the rational use of and access to essential medicines.

About the Journal: The *Southern Med Review* is an independent, open access, not for profit, peer reviewed journal which is published 2-4 times a year from Auckland, New Zealand. If you have interesting work to share, please contact the editor: editor_smr@yahoo.com or z.babar@auckland.ac.nz.

Southern Med Review welcomes feature articles, research papers, learning in practice, pharmacy in our part of the world, policy briefs, letters to the editor and other forms of scholarship. Full research papers should not exceed more than 4000 words. All other forms of articles should be within the range of 3000 words. Articles must be submitted in Vancouver Style, which is a numerical style that follows the rules established by the International Committee of Medical Journal Editors (http://www.icmje.org/).

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Contents

Access to medicines: Complex entities and behaviors seem unavoidable

In most markets, a bargain or deal is arrived at when the seller agrees to part with his goods for an amount of money offered by the buyer. This describes the market for houses, foods, appliances, clothing, electronics and nearly everything else. Pharmaceuticals do not fit into that category. For one thing, the buyer (or patient) did not select the product, but instead, used a purchasing agent – the prescribing physician. Next, the buyer does not know the price of alternative options and does not have information about relative effectiveness. This makes the market for medicines somewhat unique.

If that were not stress provoking enough, the buyer is likely to learn that the medication is not a cure, but rather is means to control symptoms and that the patient is expected to take the drug daily for the rest of his/her life. And if that were not enough of a shock, the cost to the patient is likely to be a significant portion of the family income in developing countries. The physician neglected to mention that the new, reluctant purchase might cause gastritis, sexual dysfunction, a rash, fevers, headaches, or hundreds of other adverse events. This is a rather unfortunate but realistic view of a prescription drug purchase.

What can we expect to result from this situation? It is logical that the patient will seek a cheaper source of the product, driving him to the bazaar where there is a great possibility that a counterfeit or substandard product will be offered or even worse yet, a totally different product that may be expired, spoiled or present in the market in excess quantity.

However, the side effects are another story. If they are severe enough, the patient will determine that a total lack of compliance eliminates both the financial and adverse event problems.

Another scenario is one where the patient at a clinic receives a written prescription after waiting five hours to see the physician and then is told that another four hours wait is required to obtain the medication, if it is in stock.

Neither scenario is an encouraging one. In fact, if one wanted to design a system to discourage pharmaceutical therapy, either or both of these scenarios would be ideal strategies, and yet this is exactly the scene faced by millions of patients everyday.

If the patient waits for the medication, and it is in stock, we have to hope that it is not counterfeit, substandard, adulterated, expired or ineffective because of abusive storage conditions.

In many countries, physicians are scarce and patients seek care from local healers, village elders, religious leaders, and shamen. If these sources of care prove to be unhelpful multiple times, the ill will deal with medical problems with home remedies and treatments used in that tribe for many generations.

A possible solution for some of this is for us to adopt a new paradigm in seeing that patients get the best drugs possible. We need to join forces with government ministries, professional societies, pharmaceutical manufacturers and representatives from the distribution sector to see that several "As" are achieved.

The patient gets the appropriate medication only when there is a concordance of several endeavors. To achieve success, we need to have:

- Availability
- Affordability
- Access

The drug has to be available at the dispensing site; not out of stock, back ordered or expired. The drug has to be affordable by the intended patient. Access and availability are meaningless if the patient does not have the financial resources to enable attaining possession of the product. And there must be access. The patient who can't cross the river to the clinic site, or who doesn't have the strength to travel five hours will not try to get there, even if the drug is in stock and he can afford it.

So our mission in patient care as health professionals requires us to use a bigger picture of our variety of obligations to incorporate concern about access, affordability and availability.

Albert I. Wertheimer, PhD, MBA
Temple University, USA.

Medicine prices, availability, and affordability in Vietnam

Anh Tuan Nguyen[1,2], Rosemary Knight[1], Andrea Mant[1], Quang Minh Cao[3], Martin Auton[4]

[1]School of Public Health and Community Medicine, University of New South Wales, Australia

[2]Department of Pharmaco-economics and Pharmaceutical Management, Hanoi University of Pharmacy, Vietnam

[3]Ministry of Health of Vietnam, Hanoi, Vietnam

[4]Health Action International, Amsterdam, the Netherlands

Address for correspondence: Anh Tuan Nguyen, School of Public Health and Community Medicine, University of New South Wales, Australia. E-mail: tuan.nguyen@student.unsw.edu.au

Abstract

Objective: To assess the price, availability and affordability of a sample of medicines in Vietnam.

Methods: Data on the price and availability of 42 medicines were collected using the standard World Health Organization/Health Action International (WHO/HAI) methodology in five geographical areas in Vietnam. The median price of these medicines was compared with the Management Science for Health international reference prices (IRPs), expressed as median price ratios. Affordability was measured as the number of days' wages required for the lowest-paid unskilled government worker to purchase one course of therapy. Of the 42 medicines studied, 15 were chosen for international comparison, which were included in at least 80% of other country surveys using the WHO/HAI methodology.

Results: Public sector availability of generic medicines was 33.6%. The median public procurement price was 1.82 times the IRPs for generics, but for some individual medicines it was less than half the IRP. The price to patients in public outlets was higher than in private pharmacies. Adjusted for Purchasing Power Parity in 2005, the lowest generic prices in private pharmacies were still 8.3 times the IRPs. Treatments were thus unaffordable for a large part of Vietnam's population.

Conclusions: Medicines in Vietnam were high in price, and low in both availability and affordability, especially in the public sector. To make public facilities a primary treatment option for the poor, Vietnam must reduce medicine prices in this sector by improving procurement efficiency, ensuring and promoting low-priced generics, and regulating reasonable mark-ups.

Keywords: Medicine prices, availability, affordability, pricing policy, Vietnam.

Introduction

Globally, medicine prices are often high and unaffordable not only for large sectors of the population in low- and middle-income countries, but also for sizeable segments of the population without adequate social protection or insurance in high income countries[1,2]. Too little is known, however, about the actual prices people pay for medicines and how these prices are set. Patients, and even government authorities dealing with medicines, often do not know what the lowest prices are and how they vary[3]. Sound national medicine pricing policy needs to be evidence based and grounded in reality, requiring empirical data about the real affordability of medicines for the whole population.

Vietnam's progress in health care is greater than would be expected from its development level. Several health-related targets set under the Millennium Development Goals have been attained well ahead of time[4]. Yet, Vietnam's total spending on health was at 5-6 % of gross domestic product (GDP) from 2000 to 2005[5]. Government health spending accounts for only a quarter of total expenditure, and the remaining three-quarters is drawn from direct patient out-of-pocket payments[5-7].

Medicine expenditure accounts for a large component of total health care costs. In 2005, Vietnam spent Vietnamese dong (VND) 50,530657 million on health (USD 1 = VND 15,907.00), of which 53.3% was for medicines, an almost threefold increase in absolute terms from 2000[5]. Rising prices for medicines have been reported to account for most of this increase[8]. From 2003 to 2004, prices of some medicines soared fourfold[9], and the medicine and health component of the consumer price index (CPI) increased by 13.8%, almost doubled the CPI[10].

In addition, there is evidence that pharmaceutical companies set medicine prices in Vietnam higher than in some other countries. For example, prices of locally produced antiretroviral medicines (ARVs), although considerably lower than those of

imported ARVs, were still five to seven times higher than current international lowest prices[11]. Another example is that the retail price of 100 tablets of 150mg ranitidine (Zantac) in Vietnam was higher than that in Australia, New Zealand, and Pakistan[12]. This made medicines even less affordable for the Vietnamese population at a time when the Gross National Product per capita of Vietnam was USD 240, lowest among these countries.

To provide comparable, evidence-based information for policy makers, a survey to measure the price, availability and affordability of a standardized set of medicines in Vietnam was undertaken.

Methods

The methodology developed by the World Health Organization (WHO) and Health Action International (HAI) for assessing medicine price, availability, and affordability was used in this study as follows[1].

Sampling

A systematic sampling method was used to select medicine outlets. Five geographical regions in Vietnam, namely Hanoi (Capital), Haiphong (North), Danang (Central), Daklak (Central Highland) and Ho Chi Minh City (South) were selected as survey areas. In each area, the main general public hospital was chosen as the sampling site. Six other public health facilities reachable within four hours' drive from the main hospital were also randomly selected. The for-profit medicine outlets of these public health facilities, where patients are charged for medicines, constituted the public sector sample. The private sector sample was identified by choosing one private, for-profit retail pharmacy closest to each of these public outlets. In each public health facility, apart from its for-profit medicine outlet, the not-for-profit component of the pharmaceutical department, which mainly serves insured patients, was selected as the other sector.

Medicines

Of the 42 medicines included in the survey, 25 belong to the list of core medicines included by WHO/HAI, and 17 were selected as supplementary medicines (Table 1). The core list medicines were selected on the basis of global disease burden while the supplementary list was chosen for local clinical relevance, with input from practicing pharmacists, academics, and experts from the Drug Administration of Vietnam and WHO. For each medicine, information was collected on the availability and price of both the innovator brand (IB), and the lowest-priced generic equivalent (LPG) found at each medicine outlet.

Data collection and entry

Twenty trained data collectors in pairs visited medicine outlets and recorded data on a standardized form, with the support of a representative of the provincial health bureau in each survey area. Four types of prices were recorded namely procurement price and patient price in public medicine outlets, patient price in private pharmacies and insured patient price in the

Table 1. Basket of 42 medicines surveyed in Vietnam in 2005

No	Medicine Name	Core List (yes/no)	International comparison
1	Aciclovir 200 mg capsule/ tablet	yes	yes
2	Amitriptyline 25 mg capsule/ tablet	yes	yes
3	Amoxicillin 250 mg capsule/ tablet	yes	yes
4	Atenolol 50 mg capsule/ tablet	yes	yes
5	Beclomethasone 50 mcg/ dose inhaler	yes	yes
6	Captopril 25 mg capsule/ tablet	yes	yes
7	Carbamazepine 200 mg capsule/tablet	yes	no
8	Ceftriaxone 1 g/vial injection	yes	yes
9	Ciprofloxacin 500 mg capsule/tablet	yes	yes
10	Co-trimoxazole 8+40 mg/ml suspension	yes	yes
11	Diazepam 5 mg capsule/ tablet	yes	no
12	Diclofenac 25 mg capsule/tablet	yes	no
13	Fluoxetine 20 mg capsule/tablet	yes	yes
14	Glibenclamide 5 mg capsule/ tablet	yes	yes
15	Hydrochlorothiazide 25 mg capsule/tablet	yes	yes
16	Indinavir 400 mg capsule/ tablet	yes	no
17	Losartan 50 mg capsule/ tablet	yes	no
18	Lovastatin 20 mg capsule/ tablet	yes	no
19	Metformin 500 mg capsule/ tablet	yes	no
20	Nevirapine 200 mg capsule/ tablet	yes	no
21	Nifedipine Retard 20 mg tablet	yes	no
22	Omeprazole 20 mg capsule/ tablet	yes	yes
23	Phenytoin 100 mg capsule/ tablet	yes	no
24	Ranitidine 150 mg capsule/ tablet	yes	yes
25	Salbutamol 0.1 mg/dose inhaler	yes	yes

No	Medicine Name	Core List (yes/no)	International comparison
26	Acetylsalicylic acid 500mg tablet	no	no
27	Amoxicillin + Clavulanic acid 500mg/125mg tablet	no	no
28	Cefuroxime 250mg tablet	no	no
29	Chlorpheniramine 4mg tablet	no	no
30	Clotrimazole vaginal 100mg tablet	no	no
31	Co-trimoxazole 480mg tablet	no	no
32	Dexamethasone 0.5mg tablet	no	no
33	Digoxin 0.25mg tablet	no	no
34	Enalapril 5mg tablet	no	no
35	Erythromycin 250mg tablet	no	no
36	Furosemide 40mg tablet	no	no
37	Gliclazide 80mg tablet	no	no
38	Ketoconazole 5g, 2% cream	no	no
39	Loratadine 10mg tablet	no	no
40	Metronidazole 250mg tablet	no	no
41	Nifedipine 10mg tablet	no	no
42	Piroxicam 20mg tablet	no	no

pharmaceutical departments of public hospitals. The procurement price data were collected only if public medicine outlets had invoices available as evidence. The unit prices were calculated and checked by area supervisors at the end of each day of data collection. Five area supervisors were also responsible for validation of 10% of all data collected from medicine outlets. Checked data were then entered into a pre-programmed Medicine Price Workbook (version 4.01) using a double entry technique. Data checking function of the Workbook was run to highlight outliers for verification.

Data analysis

Price results were calculated for each medicine only if the medicine was found in at least four medicine outlets and were reported as median price ratios (MPR) for each medicine type in each sector. The MPR is the ratio of a medicine's median price across outlets to a median international reference price (IRP), an external standard to make drug-drug comparisons. In this study, the median unit prices in the Management Sciences for Health (MSH) Price Indicator Guide were used as the IRP because of their wide availability and annual updating. The 2004 MSH IRPs were used as defaults since the Vietnam survey was conducted in 2005. They are the median of actual procurement prices offered by not-for-profit suppliers or international tender prices to developing countries for multi-source products[13]. Cut-off points of MPRs of 1.0 and 1.5 for public procurement price and public patient price, respectively have been considered acceptable local price ratios[14]. Affordability was assessed as the number of days' wages the lowest paid un-skilled government worker would have to earn to purchase one course of treatment for common health conditions.

Local comparison analysis was conducted across five surveyed areas namely Hanoi, Haiphong, Danang, Daklak and Ho Chi Minh City following the method published by Babar et al[15]. Only medicines found in all five regions were selected for price comparison using a Kruskal-Wallis test with $p < 0.05$ being used as the significance level.

For the international comparison, 15 out of the 42 medicines studied, were chosen (Table 1) following the methodology of a secondary analysis published by Cameron et al[16]. Vietnam was not included in the secondary analysis since its data were not available in the HAI global database of survey results. Therefore, in this study the data from Vietnam were compared with the results reported by Cameron et al to assess Vietnam's position regarding medicine price, availability and affordability among countries of similar economic status as well as within the same region.

In 2007, Vietnam was ranked in the low income group according to the World Bank and in the WHO Western Pacific Region (WPR). India was excluded from the comparison, although also in the low income group in 2007, because of the unique nature of the Indian pharmaceutical market.

Most comparable countries conducted their survey in 2004, using MSH 2003 median unit prices as the IRP. Therefore, the medicine price data in Vietnam for international comparison were adjusted from 2004 MSH IRPs to 2003 MSH IRPs, taking into account a correction for inflation or deflation between the survey year 2005 and the base year 2004 (using CPI) and adjusting for the purchasing power parity (PPP) of the Vietnam currency (VND)[17].

Although the patient price data were corrected for inflation/deflation and also adjusted for the PPP of VND, the procurement price data were not adjusted for PPP, but for exchange rates using the official exchange rate for the USD in the survey year. This was because most public procurements should have been able to purchase comparable prices by using competitive international tenders, regardless of the purchasing power of the local currency.

Results

Of the outlets sampled, data for procurement prices were collected from 31 public medicine outlets, public patient prices from 33 public medicine outlets, private patient prices from 33 private pharmacies, and public insured patient prices from 35 public hospital pharmaceutical departments.

Medicine availability

The mean availability of IBs and LPGs was 19.6% and 33.6%, respectively in the public sector, 34.7% and 58.1%, respectively in the private sector, and 10.9% and 40.4%, respectively for insured patients in the not-for-profit public sector. Low availability of LPGs was also found for essential medicines. Of the 42 medicines studied, 35 were listed in the Vietnam National Essential Drug List[18]. A separate availability analysis for these 35 medicines showed that in the public sector, mean availability was 19.6% for IBs and 37.1% for LPGs.

Overall, all sectors showed greater availability of LPGs than IBs. However, the opposite applied to some individual products, namely atenolol, nifedipine, and salbutamol inhaler. Data for beclometasone inhaler and fluoxetine were not recorded in any medicine outlets.

Medicine prices

The public procurement sector prices were 8.29 times the IRPs for 23 IBs and 1.82 times the IRPs for 33 LPGs (Table 2). Prices of seven IBs, acetylsalicylic acid, atenolol, ciprofloxacin, diclophenac, loratadine, nifedipine, omeprazole, and piroxicam and of one LPG, piroxicam, exceeded 10 times the IRPs. The public procurement system seemed highly variable, since it could also procure some extremely cheap LPGs such as dexamethasone and losartan with prices of 0.4 and 0.21 times the IRPs, respectively. Prices for individual medicines were fairly stable across outlets for IBs, whereas they varied dramatically for LPGs. Some medicines had prices varying between less than one to tens of times the IRPs, an example being piroxicam (0.85 times the IRPs to 23.80 times the IRPs), showing both reasonable and excessive prices for the same medicine.

Following adjustment for PPP in 2005, the public patient sector prices were 46.58 times the IRPs for IBs and 11.41 times the IRPs for LPGs; 44.61 for IBs and 8.30 for LPGs in the private sector and 38.88 for IBs and 8.59 for LPGs for insured patients. In the private sector, among 24 medicines for which both IB and LPG were found together, IBs were 5.6 times more expensive than LPGs. This sector also witnessed substantial price variability across outlets for both individual LPGs and IBs.

Affordability

Affordability was largely dependent on the choice of therapeutic classes, types of medicines and sectors. For example, in 2005 a worker would have had to work 0.7 days to treat an acute respiratory infection with LPG amoxicillin (250 mg three times daily in 7 days) but would pay 15.9 days' wages with LPG ceftriaxone (1vial 1g daily in 7 days) in the public sector. The same treatment required the worker to earn 83 days' wages extra to afford IB ceftriaxone rather than LPG (98.9-15.9).

With chronic diseases such as a peptic ulcer, a one-month treatment using IB ranitidine (150 mg twice a day) cost 22.1 and 21.1 days' wages in the public and private sector, respectively. While low-priced generics of ranitidine were available in the private sector, the LPG ranitidine would have cost the worker 1.3 days' wages. Meanwhile, in the public sector, the so-called LPG ranitidine would have cost 13.9 days' wages, an added 12.6 days' wages compared with the private sector. If prescribed IB omeprazole (20 mg daily) instead, the cost would have been 50.9 days' wages in the public sector and 48.9 days' wages in the private sector (Figure 1).

Table 2. Median price ratio* of IBs, LPGs in public procurement sector, public sector, private sector, and other sector (not-for-profit public sector) in Vietnam in 2005.

Medicine types	Public procurement prices	Public sector prices	Private sector prices	Other sector prices
	Adjusted for official exchange rate Q4 2005†	Adjusted for PPP of VND in 2005 ‡		
IBs	8.29	46.58	44.61	38.88
LPGs	1.82	11.41	8.30	8.59

IB=innovator brand. LPG=lowest-priced generic. PPP: Purchase Power Parity. VND: Vietnam currency unit. *Ratio of the median local price to the MSH international reference price. †Official exchange rate for US dollar in quarter 4, 2005: USD 1= VND 15,907.00. ‡PPP of VND in 2005: international dollar 1=VND 3,218.607.

Information on the official conversion rate for USD was from The International Monetary Fund: International Financial Statistics[32] and source of national PPP was The International Monetary Fund: World Economic Outlook Database[33].

Variation across regions

Consistent with the national trend, the mean availability of sampled medicines was higher for LPGs than for IBs and higher in the private sector than in the public sector for both IBs and LPGs in all five regions. The two main hubs for distribution of pharmaceuticals to the North and South of Vietnam, Hanoi and Ho Chi Minh City, had the highest mean availability among regions. In Hanoi, 72.4% LPGs and 43.2% IBs were available in the private sector and in Ho Chi Minh City 65.3% and 52.4%. Haiphong had the lowest mean private sector availability of 39.8% for LPGs and 15.6% for IBs.

Of all 84 medicines studied (42 IBs and 42 LPGs), 12 medicines were found in all five regions. A Kruskal-Wallis test revealed no significant difference in MPRs level of these 12 medicines across five regions with χ^2 (4, n=120) = 1.763, p = 0.779.

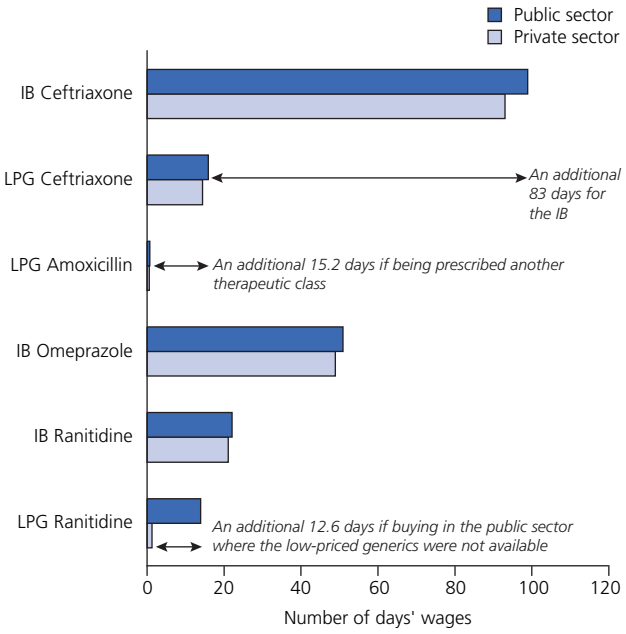


Figure 1: Differences in affordability of a treatment for an acute respiratory infection and a one-month treatment for a chronic peptic ulcer between therapeutic classes, types of medicines and sectors in Vietnam.

IB=innovator brand. LPG=lowest-priced generic.

International comparison

Medicine availability

The mean percentage availability of the sample of 15 LPGs in Vietnam was 34.8% in the public sector and 56.0% in the private sector, similar to the average of country-level mean percentage availability of medicines across World Bank low income countries. Compared with the Western Pacific Region, Vietnam had lower availability of medicines in the public sector but slightly higher availability in the private sector.

Medicine prices

While other low income countries achieved an average public procurement price of 17% higher than the IRPs for LPGs, the Western Pacific Region and Vietnam both had procurement prices averaging 44%-45% more than the IRPs (Figure 2). For individual medicines in this sector, results varied and were not consistent with the overall data for Vietnam and the Western Pacific Region. The price for LPG amoxicillin 250 mg was the same in Vietnam and in the Western Pacific Region, whereas for LPG glibenclamide 5 mg, it was fourfold higher in Vietnam than in the Western Pacific Region. In contrast, the price was lower in Vietnam for LPG ciprofloxacin 500 mg (1.45 vs. 2.55).

Medicine prices to patients in Vietnam were higher in the public sector than in the private sector for both IBs and LPGs (32.12 times the IRPs for IBs and 7.53 times the IRPs for LPGs in the public sector versus 31.75 for IBs and 6.09 for LPGs in the private sector). This trend deviated from other countries where medicines in the private sector were often more highly priced [16]. Compared with the average level in the Western Pacific Region, Vietnam had markedly lower prices for LPGs in both the public and private sector, but only slightly lower prices for IBs in the private sector. The trend was similar for individual amoxicillin 250 mg, whereas it was in the opposite direction for salbutamol 0.1 mg/dose. Ciprofloxacin 500 mg was recorded as having substantially lower prices for both IBs and LPGs in both sectors in Vietnam than in the Western Pacific Region (Table 3).

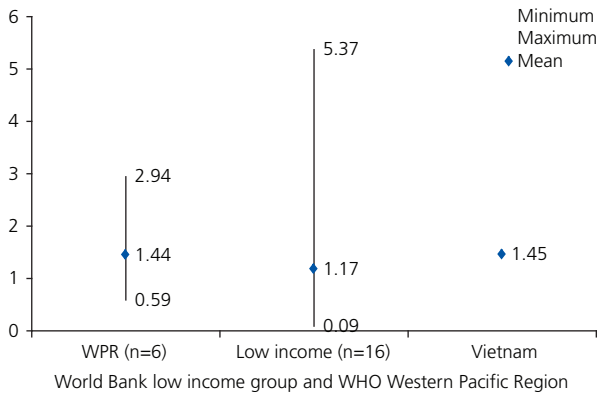
In the private sector in Vietnam, the median brand premium (the percentage difference in price between IBs and LPGs for matched pairs of medicines) was 460%, much higher than the average brand premium of 337.7% in this sector among the World Bank low income group[16]. For some individual medicines, such as ciprofloxacin 500 mg capsule/tablet or omeprazole 20 mg capsule/tablet, the figure was as high as 2,233.3% and 2,560.1%, respectively.

Affordability

Despite the substantially lower prices, medicines in Vietnam were much less affordable than in the Western Pacific Region. Table 4 summarizes the affordability of treating one acute infection and three chronic illnesses in different sectors for LPGs and IBs between Vietnam and the Western Pacific Region.

Discussion

In 2005, Vietnam faced the inadequacy of the public system in terms of medicine supply for the poorest sector. In contrast to elsewhere, Vietnam medicine prices in the public sector were higher than in the private sector. Public procurement and public patient prices were high for both LPGs and IBs. While LPGs were of low availability, a large number of IBs were found in public medicine outlets. Medicines were unaffordable for the lowest paid unskilled government worker, thus being unaffordable for the large percentage of the population who earn less than this benchmark.



Source: Adapted from Cameron A. et al. 2009[16]

Figure 2: Median price ratio* in public procurement for LPG medicines in Vietnam in comparison with those in the World Bank low income group and the WHO Western Pacific Region.

WPR: the Western Pacific Region. *Ratio of the median local price to the MSH international reference price.

Table 3. Median price ratios* of public procurement prices, public patient prices, private patient prices for LPG medicines, and private patient prices for IBs in Vietnam in comparison with those in the Western Pacific Region in the base year 2004.

	Public procurement prices		Public patient prices for LPGs		Private patient prices for LPGs		Private patient prices for IBs	
	WPR[16]	Vietnam	WPR[16]	Vietnam	WPR[16]	Vietnam	WPR[16]	Vietnam
Median across basket of 15 medicines	1.44 (n=6)	1.45	11.95 (n=4)	7.53	11.25 (n=6)	6.09	34.21 (n=5)	31.75
Amoxicillin 250 mg capsule/tablet	1.23 (n=4)	1.20	9.32 (n=3)	6.96	11.08 (n=5)	6.09	26.23 (n=2)	†
Ciprofloxacin 500 mg capsule/tablet	2.55 (n=1)	1.45	81.71 (n=1)	7.53	32.94 (n=4)	5.65	195.96 (n=3)	131.80
Glibenclamide 5 mg capsule/tablet	1.68 (n=4)	6.67	56.97 (n=1)	36.51	34.59 (n=4)	30.43	99.57 (n=3)	160.64
Salbutamol 0.1 mg/ dose inhaler	0.95 (n=4)	†	4.64 (n=2)	†	4.32 (n=6)	5.56	8.60 (n=5)	9.88

Data for WPR are mean (number of surveys). WPR: the Western Pacific Region. LPG=lowest-priced generic. IB=innovator brand. *Ratio of the median local price to the MSH international reference price. † median price ratio was not calculated since medicine prices were found in less than four medicine outlets

Lack of availability of low-priced generics in the public sector made the lowest-priced generics in this sector for some medicines (such as ranitidine) still more than ten times the IRP. Adjusted for the PPP in 2005, the price of LPG ranitidine in the public sector was 27.42 times the IRP, while in the private sector it was 2.52 times the IRP. Hence, simply promoting the use of generics will not result in savings for patients without mechanisms to ensure a low price for generics. Fixing prices through comparative pricing systems, where the price of the drug of interest is compared with those of similar products within a country or of identical or interchangeable products in other countries, may be an option[19,20]. A more flexible alternative is a reference pricing system where a reimbursement ceiling is set for a drug based on the prices of equivalent products already marketed[21].

In 2005, the public procurement system was found to be inefficient as Vietnam had to purchase LPGs at a price 82% higher than the IRP. Due to lack of a sound and clear regulation of mark-ups in the public sector at the time of the survey, there were mark-ups of 13.8% for IBs and 26.8% for LPGs. High mark-ups on high procurement prices led to high patient prices in this sector. To make public facilities a primary treatment option for the poor, Vietnam must reduce medicine prices in this sector by improving procurement efficiency and regulating reasonable mark-ups. The implementation of these interventions may be feasible since financing for medicines in the public sector remains partly within the government's control.

Unlike findings from almost all other comparable low income and Western Pacific countries, where public sector prices were usually lower than or equal to private sector prices[16], a lower private sector price in Vietnam reflected the role of this sector in supplying medicines to the population. However, when buying a sample of 15 medicines from private pharmacies in 2004, patients still had to pay 6.09 times the IRPs even for the LPGs. The situation was worse if patients were prescribed IBs, which had a brand premium of 460% in the private sector. These results indicate huge scope for reducing drug spending or creating efficiencies with more people getting treatment with the same expenditure through appropriate use of generic medicines. Nevertheless, to ensure the success of a strong generic policy, apart from mechanisms to ensure the low price of generics, four preconditions must be met: the existence of supportive regulations; the operation of reliable quality assurance; the attainment of professional and public acceptance; and the existence of financial incentives[22].

Affordability of medicines remains a major problem for Vietnam. Results from this study, however, show that affordability varied with therapeutic classes and types of products. Therefore, improvement in the rational use of medicines and patient choice is likely to play an important future role, especially given that self-treatment and irrational prescribing and dispensing are common in Vietnam[23-26]. Interventions that have proved effective in developing countries include financial measures (e.g. direct financial incentives)[27] and professional measures

Table 4. Number of days' wages of the lowest-paid unskilled government worker needed to purchase a course of treatment in Vietnam in comparison with those in the Western Pacific Region.

	Public sector, LPG		Private sector, LPG		Private sector, IB	
	WPR[16]	Vietnam	WPR[16]	Vietnam	WPR[16]	Vietnam
Adult respiratory infection; amoxicillin 250 mg capsule/tablet, three per day for 7 days	0.4 (n=3)	0.7	0.4 (n=4)	0.6	0.5 (n=2)	†
Diabetes; glibenclamide 5 mg capsule/tablet, two per day for 30 days*	0.7 (n=1)	2.6	0.7 (n=4)	2.1	1.6 (n=3)	11.3
Ulcer; ranitidine 150 mg capsule/tablet, two per day for 30 days*	1.2 (n=4)	13.9	1.7 (n=6)	1.3	5.5 (n=3)	21.1
Asthma; salbutamol 0.1mg/dose inhaler, 200 doses	1.1 (n=2)	†	0.7 (n=6)	3.1	1.4 (n=5)	5.5

Data for WPR are mean (number of surveys). WPR: the Western Pacific Region. LPG=lowest-priced generic. IB=innovator brand. *One month has been used as a course of treatment for chronic illnesses. † number of days' wages was not calculated since medicine prices were found in less than four medicine outlets

(e.g. standard treatment guidelines; essential drug lists; drug and therapeutics committees; problem-based basic professional training; and targeted in-service training of health workers)[28]. Multi-component interventions have so far proved to be a good way to improve pharmaceutical practice in Vietnam and are thus likely to hold the most promise for better access to more affordable medicines for the whole community[29,30]

This study only gauges the cost of a single medicine, whereas there were often more than three medicines in one prescription[23,31]. The present study also does not measure other treatment costs such as consultation fees and diagnostic tests. Moreover, many Vietnamese earn less than the lowest-paid government worker. Therefore, unaffordability of medicines in Vietnam is likely to be underestimated. Compared with those in the Western Pacific Region, medicines in Vietnam were less affordable despite having markedly lower prices. This result indicates a much lower average salary level in Vietnam than in the Western Pacific Region. While improving people's incomes across society is a long term goal, a new financing approach such as universal health insurance might be a solution that Vietnam needs to achieve soon.

The significance of this study is that, to our knowledge, it provides the most thorough picture of medicine prices in Vietnam to date, using the standardized WHO/HAI methodology making it possible to compare results with those in other countries at the same development stage and within the same region, a task that previous studies failed to achieve[1]. Moreover, the Vietnam analysis shows significant intra-regional differences. Although the inter-regional analysis cannot fully explore these features, they are critically important data for understanding within-country pharmaceutical trends and hence, for national policy formulation and analysis

Contributors

All authors contributed to the paper's conception and design. ATN and MA did the analysis and interpretation of the data. ATN drafted the paper with the contribution of RK, AM, QMC and MA. All authors participated in critical revision and have approved the final version for submission.

Conflict of interest statement

We declare that we have no conflict of interest.

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Medicine prices in Thailand: A result of no medicine pricing policy

Cha-oncin Sooksriwong [1], Worasuda Yoongthong [2], Siriwat Suwattanapreeda [3], Farsai Chanjaruporn [4]

[1,3]*Social and Administrative Pharmacy Excellence Research Unit, Faculty of Pharmacy, Mahidol University, Thailand*

[2,4]*Drug Control Division, The Office of Food and Drug Administration, Ministry of Public Health, Thailand*

Address for correspondence: Cha-oncin Sooksriwong, Social and Administrative Pharmacy Excellence Unit, Department of Pharmacy, Faculty of Pharmacy, Mahidol University, Bangkok, Thailand. E-mail address: pycss@mahidol.ac.th

Abstract

Objectives: The main goal of this study was to document the situation of medicine prices in public and private health sectors for policy recommendation.

Methods: A field study to measure prices of selected medicines was undertaken in Thailand using a standardized methodology developed by the World Health Organization (WHO) and Health Action International (HAI). Prices of 43 medicines were measured in health facilities and pharmacies in the capital city and three districts in different parts of Thailand. Medicine prices were expressed as the ratios relative to a standard set of international reference prices (median price ratio or MPR).

Results: The public sector procured generics and innovator brands at 1.46 and 3.3 MPR while patients paid 2.55 and 4.36 MPR, respectively. Private pharmacies procured lowest price generics at 1.48 MPR and innovator brands at 9.67 MPR.

Because of no medicine pricing policy in Thailand, it was found that between public and private sectors, among different public hospitals, and among different private pharmacies, the same generic products were procured and sold to patients at different prices. The median mark-up for innovator brands were 31% in the public sector and 22% in the private sector. For lowest priced generics, the median mark-up were 80% in the public sector and 96% in the private sector. Different prices for the identical product were problems to the health insurance organizations in terms of reimbursement, and to patients in terms of fairness.

Conclusion: The results highlight priority areas for action by the Ministry of Public Health and others in improving the drug pricing systems. The price regulation system should be implemented at every level of drug supply chain and appropriate pricing strategies should be employed.

Keywords: Medicine pricing, medicine price policy, Thailand

Introduction

Thailand employs some health policies to indirectly control the medicine prices and expenditure in the public sectors. The examples of these policies are the implementation of the National Drug List, the National Health Insurance Schemes and utilization of the Drug Related Group (DRG) to reimburse the inpatient expense for government workers. But there is no policy to regulate the drug pricing both in the public or private sectors, and whether it is the procurement or selling prices.

In 2006, about 60% of medicines were imported; 40% were locally produced[1]. The Commission of Food and Drug Administration requires all manufacturers to have Good Manufacturing Practices (GMP) certification[2]. Assurance of bioequivalence is required for the registration of generics (in addition to quality assurance). The Ministry of Public Health regularly tests medicines once marketed. The Pharmacy and Therapeutic Committee of each public hospital selects medicines for their institution and some medicines are procured through a group purchasing program. Patients tend to buy prescribed medicines at hospital pharmacies rather than community pharmacies or drug stores[3].

The Office of Food and Drug Committee in cooperation with the Faculty of Pharmacy, Mahidol University, for the first time, conducted a nationwide study on prices of selected medicines in Thailand. The main goal of the study was to document medicine pricing situation in the public and private health sectors in Thailand.

Methods

The survey of the prices, availability and affordability of medicines in Thailand was conducted using the standardized World Health Organization/Health Action International (WHO/HAI) methodology. The WHO/HAI methodology is described in the manual "Medicine Prices: A new approach to measurement"

(WHO/HAI, 2003) and the document is publicly available on the HAI website [4]. Data were collected during October and December 2006. Pricing data were collected for 1. Public sector procurement prices 2. Public sector patient prices 3. Private sector procurement prices and 4. Private sector patient prices.

Selection of medicines to be surveyed

Among a total of 43 medicines included in the survey, 26 belonged to the Core List medicines suggested by WHO/HAI for international comparison, and 17 were added as supplementary drugs as requested by Thai FDA. For each substance, two products were monitored, namely: innovator brand (IB) and lowest price generic equivalent (LPG). Each medicine was strength and dosage-form specific. The medicine prices were measured centrally in health facilities and pharmacies in the capital city, Bangkok, and three randomly selected districts in each part of Thailand. The three randomly selected districts were *Phitsanulok* (North), *Suratthani* (South), and *Nakornrachaseema* (Northeast). Procurement prices and prices charged to patients were also recorded.

Selection of medicine outlets

The sampling method described in the WHO/HAI manual for selecting a representative number of public health facilities and pharmacies was employed. The samples in each province were: 1 central or provincial hospital, 4 community hospitals (not more than 3-hours driving distance from the central or provincial hospital), 5 (not more than 5 kilometers from the hospitals), and 1 Provincial Health Office.

Data collection

A standardized data collection form was used and data collectors were trained in a two-day workshop to ensure the reliability and reproducibility of the survey. Data collection was completed in six weeks by December 2006.

Data entry

Price data were entered into the pre-programmed MS Excel workbook provided as part of the WHO/HAI methodology. Data entry was checked using the 'double entry' and 'data checker' functions of the workbook. Erroneous entries and potential outliers were verified and corrected as necessary.

Data analysis

All data obtained were analyzed by the program designed by WHO/HAI. Availability was calculated as the percentage (%) of medicines found at individual sampling facilities. Data analysis is based on a total of 20 public sector health facilities (20 hospitals) and 21 pharmacies in Bangkok in three randomly selected districts.

For the price analysis, medicines were needed to be found in at least 4 pharmacies for their price data to be included. Medicine prices were expressed as ratios relative to a standard set of international reference prices:

$$\textit{Medicine Price Ratio (MPR)} = \frac{\textit{median local unit price}}{\textit{international reference unit price}}$$

An MPR of 2 would mean that the medicine price is twice than that of the international reference price. The reference prices used were the 2005 Management Sciences for Health (MSH) reference prices, taken from the International Drug Price Indicator Guide (2005) [5]. These are median prices of high quality multi-source medicines offered to developing and middle-income countries by different suppliers.

International reference prices were converted to local currency using the exchange rate (buying rate, Kasikorn Bank) on 2nd October 2006, the first day of data collection, at a rate of 37.78 baht per one US dollar [6].

Results

Public sector prices

Public sector procurement prices

Of the 35 medicines with an international reference price, price ratios were calculated for 8 innovator brands and 31 lowest price generics (when the products were found in 4 or more outlets). Overall the Median Price Ratio (MPR) was 1.46 for public sector generics while MPR for innovator brands was 3.3. The 25th and 75th percentiles for innovator brands were 1.65 and 7.68 MPR respectively. The 25th and 75th percentiles for lowest price generic equivalents were 0.80 and 2.26 MPR respectively.

Some innovator brands were being procured at very high prices, such as captopril (MPR 12.10), phenytoin (MPR 11.08), azithromycin (MPR 6.54) and carbamazepine (MPR 4.67). Some generic products were also being procured at high prices, such as the azithromycin (MPR 3.07), captopril (MPR 2.88), and nifedipine retard (MPR 2.6).

As a result of no medicine pricing policy in Thailand, the researchers found that different public hospitals procured the same product at different prices.

Public sector patient prices

Overall, the lowest priced generics were 2.55 MPR, and innovator brands were 4.36 MPR. The 25th and 75th percentiles of innovator brand MPRs were 2.03 and 9.86. The 25th and 75th percentiles of lowest price generic equivalent MPRs were 1.45 and 3.32.

Some innovator brands were sold to patients at very high prices in the public sector, such as phenytoin (MPR 15.82), captopril (MPR 15.63), azithromycin (MPR 7.94) and carbamazepine (MPR 6.11). The lowest priced generics were sold to patients at 0.49 to 6.79 MPR. High priced generics included glibenclamide (MPR 6.79), phenytoin (MPR 5.75), amitriptyline (MPR 4.05) and captopril (MPR 4.36).

It was found that among different public hospitals, the same products were sold to patients at different prices.

Table 1. Median MPRs for medicines found in the public sector; procurement prices and patient prices

Type and number of medicines	Median MPR Public procurement	Median MPR Public patient prices	Difference (%) Public sector patient prices to procurement prices
Innovator brand (n = 8)	3.3	4.36	32%
Lowest price generic equivalent (n = 31)	1.46	2.55	74.7%

Comparison of public sector patient prices with public sector procurement prices

Table 1 compares the price of medicines procured and then sold to patients in the public sector. For 8 innovator brands, patients paid 32% more than the government procurement price. Across 31 generics, patients paid about 75% more than the government procurement price.

Private sector prices

Private sector procurement prices

In the private sector, the lowest priced generic equivalents were procured at 1.48 MPR, and innovator brands at 9.67 MPR. The 25th and 75th percentiles for innovator brands were 4.36 and 18.32 respectively. For the lowest priced generics, they were 0.94 and 1.91 MPR.

Private sector patient prices

Overall, lowest price generic equivalents were sold to patients at 3.31 MPR, and innovator brands at 11.6 MPR. The 25th and 75th percentiles for innovator brands were 5.37 and 23.9 MPR respectively. The 25th and 75th percentile of the lowest price generic equivalent were 2.34 and 5.46 MPR, respectively.

Very high priced innovator brands included ciprofloxacin (MPR 72.64), diclofenac (MPR 30.54) aciclovir (MPR 29.71), atenolol (MPR 27.07), ranitidine (MPR 23.9) and glienclamide (MPR 20.36). High priced generics included hydrochlorothiazide (MPR 7.35), glibenclamide (MPR 6.79), nifedipine retard (MPR 6.16) and atenolol (MPR 6.02).

Comparison of private sector patient prices with private sector procurement prices

Table 2 compares the price of medicines procured and then sold to patients in the private sector. Across the 17 innovator brands, patients were charged about 20% more than the procurement price. Across the 22 lowest priced generics, the mark-up was about 124%.

Table 2. Median MPRs for medicines found in the private sector; procurement prices and patient prices

Type and number of medicines	Median MPR Private procurement	Median MPR Private patient prices	Difference (%) Private sector patient prices to procurement
Innovator brand (n = 17)	9.67	11.60	19.96%
Lowest price generic equivalent (n = 31)	1.48	3.31	123.6%

Comparison of prices in the public and private sectors

Table 3 compares procurement prices in the public and private sectors. As shown, overall the private pharmacies were buying innovator brand medicines at a price 67% higher than public sector facilities. Overall, lowest priced generics were being purchased by private pharmacies at 29% more than the public sector. Some generic products had large price differences, such as Atenolol 50 mg which was procured by the public sector at 0.95 MPR but by the private sector at 3.61 MPR (280%), Omeprazole 20 mg was procured by the public sector at 0.38 MPR but by the private sector at 1.29 MPR (239%).

According to table 4, overall patient prices in the private sector were approximately 43% and 37% more than patient prices in the public sector for innovator brands and lowest generic equivalents, respectively. Some generic products had large price differential, such as Atenolol 50 mg was sold to patients in the public sector at 3.01 MPR but in the private sector at 6.02 MPR (100%), Omeprazole 20 mg was sold to patients in the public sector at 0.72 MPR but in the private sector at 2.23 MPR (210%).

Table 3. Summary of procurement prices (median MPRs) for medicines found in both the public and private sectors

Type and number of medicines in both sectors	Median MPR Public sector procurement prices	Median MPR Private sector procurement prices	Difference (%) Private to public procurement prices
Innovator brand (n = 5)	4.67	7.79	66.9%
Lowest price generic (n = 22)	1.15	1.48	28.6%

Table 4. Summary of patient prices (median MPRs) for medicines found in both the public and private sectors

Type and number of medicines in both sectors	Median MPR Public sector patient prices	Median MPR Private sector patient prices	Difference (%) Private to public patient prices
Innovator brand (n = 5)	6.11	8.76	43.4%
Lowest price generic (n = 22)	2.42	3.31	36.6%

Comparing mark-ups in the public sector with those in the private sector for retail (procurement to patient price) of individual medicines found in both sectors showed that the median mark-up for innovator brands were similar i.e. 31% in the public sector and 22% in the private sector. The median mark-up for lowest priced generics were also similar; 80% in the public sector and 96% in the private sector.

Affordability

Table 5 illustrates the affordability of a 4 drug regimen when originator brands and lowest priced medicines are purchased in the private sector. The lowest paid government worker (211.5 baht/day) would have to work 0.98 days (207 baht) to be able to afford these medicines. In case, if the innovator brands were used, lowest paid government worker would have to work 4.17 (881 baht/211.5 baht) days to get all these medicines.

Table 5. Affordability of treatments for a family with multiple conditions, private sector

Condition	Treatment	Type	Median Treatment Price	Days' Wages
Hypertension	Hydrochlorothiazide 50 mg daily for 30 days	LPG IB	30 baht 57 baht	0.1 0.3
	Enalapril 20 mg daily for 30 days	LPG IB	75 baht 510 baht	0.4 2.4
Diabetes	Glibenclamide 5 mg*2 for 30 days	LPG IB	60 baht 180 baht	0.3 0.9
Resp. Infection	Amoxicillin 250 mg*3 for 7 days	LPG IB	42 baht 134 baht	0.2 0.6
Total		LPG IB	207 baht 881 baht	0.98 4.17

Discussion

The procurement prices in the public sectors were lower than the private sectors for both innovator brands and generic products as seen in table 3. This is due to public hospitals procuring through group purchasing mechanisms. It was found that public hospitals predominantly used generic products and lower price innovator brands (with median MPR = 3.3). The very high priced innovator brands such as ciprofloxacin (MPR 72.64), diclofenac (MPR 30.54) aciclovir (MPR 29.71), atenolol (MPR 27.07), ranitidine (MPR 23.9) and glibenclamide (MPR 20.36) were procured only in the private sectors.

The ranges of procured prices (percentile 25 and 75) for innovator brands were wider than the generic products both in the public and private sectors. This happens because of the high market competition among generic manufactures in Thailand, and the group purchasing system used by public hospitals tends to lower the procurement prices each year. This situation is good for the hospitals but not for the local pharmaceutical manufacturers. Regarding the innovator brands which do not have market competition, the prices tend to be high since the day of registration at the Thai FDA, because there is no organization to directly control the prices set by the pharmaceutical companies.

The paired analysis (only same medicines procured by both sectors) showed that the private sector procurement prices were 67% more than the public sector procurement prices for innovator brands, and approximately 29% greater for the lowest priced generics. This is the outcome of a no pricing policy, the result being that the pharmaceutical companies may set their selling prices on their own. Even among different public hospitals, medicines of the same generic names were procured at different prices.

The prices at which the medicines were sold to patients in the private sector were higher than in the public sectors. Differences in patient prices were found not only between public and private

sector but also among public hospitals and private pharmacies, the same products being sold at different prices.

The retail patient prices set in the public and private sector are not controlled by the government, only when the companies want to increase the prices; they have to notify the authorities. Different prices to patients create problems for the health insurance organizations in terms of reimbursement, and to patients in terms of fairness.

Mark-ups on the generic products were considerably higher than on innovator brands, however the prices of innovator brands were more than 4 times than that of generic drugs, thus making the profit much higher. Moreover, when looking at the percent mark-up of innovator brands in the public sector, it was found that the mark-up is higher than the private sector (45.95% to 25.02%) which shows that the public sector gains more profits by selling innovator brands. In order to tackle these issues, there is a need for regulations to control the percentage mark-up of drugs. High cost drugs should be marked up at a relatively lower percentage than low cost drugs. Results may be limited by the fact that data are inherently subject to outside influences such as market fluctuations and delivery schedules.

Conclusion and recommendations

There is no national pricing policy in Thailand to regulate medicine prices. Different prices for the same medicine were found, also high prices were observed for the innovator brand medicines.

These are some suggestions to overcome these issues:

At policy level, the government should include all stakeholders to participate in this matter, including decisions regarding pricing policy. Appropriate pricing strategies should be employed.

The price regulation system should be implemented at every level of drug supply chain: manufacturers to hospitals/drug stores and hospitals/drug stores to patients. Price regulations, such as maximum selling prices, or maximum wholesale/retail mark-ups, should be implemented and enforced.

There should be an organization responsible to set and monitor medicine prices.

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Medicine pricing interventions – the South African experience

Andrew Lofts Gray

Department of Therapeutics and Medicines Management, Nelson R Mandela School of Medicine, University of KwaZulu-Natal, Durban, South Africa

Address for correspondence: Andrew Lofts Gray, Nelson R Mandela School of Medicine, University of KwaZulu-Natal, Durban, South Africa. Email: graya1@ukzn.ac.za

Abstract

All countries face the challenge of finite health resources, and therefore the need to limit expenditure on medicines. Post-apartheid South Africa developed a National Drug Policy in 1996, which signaled a multi-faceted series of interventions to reduce medicines prices and also improve prescribing and dispensing practices. Implementing this policy has not been without challenges, including legal challenges by the pharmaceutical manufacturers, medical practitioners and pharmacists. While a policy of mandatory offer of generic substitution has been implemented successfully, improving the quality of medicines use in the private sector has not been as easily addressed. A single exit price mechanism for all medicines in the private sector has been introduced, with regulated maximal annual increases. However, the greatest difficulty has been encountered in determining a reasonable and enforceable dispensing fee. This element of the pricing intervention remains highly contested. South Africa's experience has also highlighted the need for clear legal drafting when attempting medicine pricing interventions. Other elements which still need addressing are the selection of medicines in the private sector, an enforceable code of marketing practice, and a more transparent way of indicating which medicines can be substituted, based on suitable bioequivalence and other data. South Africa's National Drug Policy is expected to be reviewed in the near future, and these issues will need urgent attention if the country is to realize its goal of introducing a National Health Insurance system.

Keywords: Medicine pricing, South Africa, policy reforms.

Introduction

Post-apartheid health policy discourse in South Africa has been dominated by the drive to improve equity in the health system as a whole, as well as to improve access to healthcare services for those citizens previously disadvantaged by racially-discriminatory policies and practices. In the immediate aftermath of the 1994 elections, new Ministers in the Government of National Unity embarked on wide-ranging policy reviews. The first post-apartheid Minister of Health, Dr Nkosazana Dlamini-Zuma, created 11 such policy review committees, one of which was tasked with developing a National Drug Policy. The process followed in the development and early implementation of this policy has been extensively reviewed[1]. The National Drug Policy was approved by the Cabinet and published in 1996[2].

This paper addresses just one element of the policy-that directed at reducing the prices of medicines.

Policy background

The issue of medicines prices had been addressed previously by the apartheid government on a number of occasions. Commissions of Inquiry were constituted in 1961, 1978 and 1985 to investigate the high costs of healthcare, including the costs of medicines. The responses by government to the recommendations from these three investigations – the Snyman[3], Steenkamp[4] and Browne[5] Commissions – are particularly instructive. All three Commissions identified patent legislation as contributing to high prices. The Snyman Commission (1961) recommended that the Minister of Health be empowered to issue compulsory licences for medicines. This was not implemented. The Steenkamp Commission (1978), a decade and a half later, also recommended that compulsory licences be used, as provided for in local patent legislation. None has ever been issued by a South African government. All three also identified generic medicines as important cost-savings mechanisms, and both the Snyman (1961) and Browne (1985) Commissions recommended that generic substitution be used. This only became legal in 2003, almost two decades later. The Syman Commission (1978) identified excessive promotion of all types of medicines as contributing to high expenditure, and recommended prohibition of the practice of free gifts and 'bonusing'[i] of medicines to pharmacists, medical practitioners and dentists. An enforceable code of marketing practice is not yet in place. Almost the only recommendation that was implemented in full was that made by the Browne Commission (1985) to establish a public sector tender process for the procurement of medicines.

[i] 'Bonusing' refers to the practice of giving free stock or reduced prices linked to volume purchases. A typical example would be a "buy 10 and get 2 free" offer.

The lesson learned from these decades of attention to medicines prices is simple – interventions are easily identified, but difficult to implement. The reasons for such difficulties varied from resistance from vested interests (both from manufacturers and healthcare professionals) to the political exigencies of the time (such as the sanctions imposed on apartheid South Africa in the 1980s).

Although some work had been done within progressive health circles and the African National Congress party prior to the change of government (and also by the apartheid Department of National Health and Population Development, in the early 1990s), the policy process undertaken in 1994-1996 was rushed and incomplete. The greatest challenges were encountered during implementation of the new policy. The 2002 review by the Centre for Health Policy concluded: "The challenge of implementation is less a matter of following blue-prints and recipes than of "learning by doing". This involves a high degree of organisational reflexivity – the ability to learn from experience. In the instances where the South African drug policy established processes that met these requirements, such as during the writing of the policy and the essential drugs list, outcomes were successful. Where these processes were not sustained, gains were not maintained or followed through. On the whole, the drug policy process in South Africa showed a high awareness of the actor environment, but only partial recognition of the fact that policy implementation is inherently a process of constant negotiation and renegotiation. Over time, the opportunities for negotiation have tended to diminish rather than expand. If future policy implementation is to be successful, mechanisms for organisational learning need to become far more institutionalised. Within government, this implies ensuring ongoing mechanisms to combine top-down, national with bottom-up, district and provincial planning. Also important are regular review and evaluation, creating opportunities for external actors to regularly interface with policy and legislative processes, and opening up public debate on measures that are likely to be controversial and elicit reaction from players with strong interests." South Africa's experience with implementing a medicines pricing intervention clearly demonstrates these points.

The policy options

Medicines are accepted as not being ordinary articles of trade, as their market is imperfect. Specifically, there is a three-tiered demand structure – with the prescribers as the actual demanders, the patients as the consumers and the health care system frequently the payer (both in the public and private sectors). There is also limited competition between suppliers, especially in the case of patented products. The information available to prescribers and consumers is often selective, unbalanced or incomplete. Medicines also have both positive and negative externalities. As a result, almost all governments regard medicines as "meritorious" goods, worthy of government intervention.

Intervening to reduce expenditure on medicines requires attention both to prices and to volumes. The policy options open to any government have been summarized as follows[6]:

- Producer price control measures – these include direct price controls, reference pricing systems, the practice of equity pricing, as well as generic-friendly policies
- Distribution chain cost controls – these include controls over mark-ups, fixed professional fees, limits or removal of value-added tax
- Bulk purchase measures – these include the use of tender and negotiation strategies, as well as regional initiatives
- International trade agreement relief measures – these include compulsory licensing and parallel importing
- Demand side measures – these include measures to ensure rational medicine use, as well as such tactics as co-payments that may limit demand by patients.

No single intervention is sufficient. For example, while generic substitution may reduce expenditure, this can be limited by prescribers choosing to prescribe patented medicines for which no generic versions exist.

The medicine pricing intervention – content and process

The policy committee charged with developing the National Drug Policy (NDP) was tasked "to develop a pricing plan for drugs used in South Africa in the public and private sectors". While the subsequent detail has been characterised as vague – "the policy instruments included in the NDP seem to vacillate between intervention and what has been termed "monitored freedom"" – the policy does seem to aim at addressing several points simultaneously[6]. The proposed pricing intervention was described as such:

- "A Pricing Committee with clearly defined functions to monitor and regulate drug prices will be established within the Ministry of Health. Committee members will include health economists, pharmaco-economists, representatives from the Department of Finance, the Department of Trade and Industry, the Procurement Unit of the Department of Health, the Department of State Expenditure, and consumer representatives. There will be total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals. A non-discriminatory pricing system will be introduced and, if necessary, enforced. The wholesale and retail percentage mark-up system will be replaced with a pricing system based on a fixed professional fee."

However, the overall policy stance incorporated other elements, and can be summarized as follows:

- A pricing committee, to "monitor and regulate drug prices"
- Total transparency in the pricing structure (at all points of the distribution chain)

- A non-discriminatory pricing system within the private sector
- Replacing the wholesale and retail mark-up system with one based on a fixed professional fee
- A database to monitor costs compared with other developing and developed countries
- Regulation of price increases
- Provision, in certain circumstances, of public sector stock to the private sector (e.g. supplying lower cost drugs bought by the State to private sector clinics in order to address a priority disease)
- Promotion of generics (multi-source pharmaceutical products, generally cheaper than the originator's branded products), including generic substitution, while maintaining a negative list (a list of drugs that could not be substituted by the pharmacist at the patient's request, but where the prescribed brand would have to be supplied)
- Measures to improve rational drug use, including establishing Pharmacy and Therapeutics Committees (PTCs) in all hospitals
- Control of pharmaceutical marketing practices.

Implementing some of these recommendations required changes to legislation. South Africa's medicines law, the Medicines and Related Substances Act (Act 101 of 1965), was amended in 1997, with the introduction of two inter-related sections. The first of these (section 18A) banned "bonusing"[ii] and the second (section 22G) created a "pricing Committee". It also provided for a "transparent pricing system", which would include a "single exit price" (SEP). It stated that "such price shall be the only price at which manufacturers shall sell medicines … to any person other than the State", but that pharmacists and licensed dispensing practitioners (nurses and medical practitioners) would be allowed to charge a "dispensing fee". These provisions only came into effect in 2003, once legal challenge to the legislation by the multinational pharmaceutical industry had been withdrawn.

As the details were not in the primary legislation, these had to be provided in the form of Regulations, issued by the Minister of Health (then Dr Manto Tshabalala-Msimang). The process of implementing has not yet been completed, because of repeated legal challenges. The necessary Regulations were published for comment in mid-January 2004, allowing barely enough time for the required 3-month comment period before the final versions were issued. This happened on 30 April 2004, and the scheme was intended to come into effect on 2 May 2004. Instead of the fixed professional fee envisaged in the policy, a capped fee (26% to a maximum of R26 per item[iii]) was prescribed. The single exit price was defined as the weighted average of 2003 prices offered to the private sector, thus locking in all volume discounts that had been offered before. An annual maximum percentage increase in single exit prices was to be published by the Minister thereafter. The prospect of a reference pricing system, or at least a one-off benchmarking exercise, was also signaled, but not described in detail.

The challenge to this intervention came from pharmacists in the community and private hospital arenas, and not from the pharmaceutical industry. The latter had succeeded in altering a draft regulation which sought to impose an immediate 50% cut in the factory gate price. As noted, the single exit price was initially cost-neutral, with the promise of annual review. Initially, two linked cases were heard by a full bench in the Cape High Court, and rejected by the majority (reported as New Clicks South Africa (Pty) Ltd v Tshabalala-Msimang and Another; Pharmaceutical Society of South Africa and Others v Minister of Health and Another 2005. (3) SA 231 (C)). The majority dismissed the challenges on all counts, and awarded costs to the State. In striking contrast, the dissenting judge found the Regulations to be contradictory (and in conflict with other legislation), and the dispensing fee based on "no more than a thumb suck". Immediately, the parties to the action sought leave to appeal this judgment. After more legal tribulations, the Supreme Court of Appeal came to a unanimous decision (reported as Pharmaceutical Society of South Africa v Minister of Health and Another; New Clicks South Africa (Pty) Ltd and Others v Minister of Health and Another 2005. (3) SA 238; 2005 (6) BCLR 576 (SCA)), overturning the Cape High Court decision with costs. The entire set of Regulations was declared "invalid and of no force and effect". They also found fault with the enabling Act, stating that "It will be extremely difficult, if not impossible, to draft sensible regulations unless the Act is amended" (at paragraph 95). This decision was immediately countered by the Minister of Health, who appealed to the Constitutional Court. The resultant findings (reported as Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others CCT59/04 2005 (2) SA 311 (CC) were complex, with a number of minority judgments in relation to certain points. In essence, the right of the State to intervene was upheld, but the Minister of Health was instructed to re-determine an appropriate dispensing fee for pharmacists. Importantly, the Chief Justice found that, while some evidence had been provided that the dispensing fee would result in damage to the viability of pharmacies (and in particular, rural pharmacies and courier pharmacies), the onus was on the Minister (as advised by the Pricing Committee) to show that their scheme would not have this effect: "Absent such explanation, there is sufficient evidence on record to show that the dispensing fee is inappropriate".

After the judgment, revised Regulations were issued, as instructed, and a process of determining a new dispensing fee was commenced. The revised fee was proposed to operate as follows:

- where the single exit price (SEP) was less than R75, the pharmacist would be allowed to charge up to R7 plus 28% of the SEP
- for an SEP between R75 and R150, the dispensing fee would be R23 plus 7% of the SEP
- for an SEP between R150 and R250, the dispensing fee would be R26 plus 5% of the SEP
- for an SEP of R250 or more, the dispensing fee would be R31 plus 3% of the SEP

[ii] Section 18A reads "No person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme."
[iii] At the time of writing US$1 is approximately worth R8

- all these fees would include value-added tax (14% in South Africa).

When announced, this fee was again found to be unacceptable by the pharmacists, and a renewed court challenge ensued in the Pretoria High Court. In an attempt to settle this matter, the Minister of Health published a new draft set of dispensing fees in June 2009. The details were as follows:

- where the SEP was less than R100, the dispensing fee would not exceed R6 plus 36% of the SEP
- for an SEP between R100 and R250, the dispensing fee would be R32 plus 10% of the SEP
- for an SEP between R250 and R1000, the dispensing fee would be R45 plus 5% of the SEP
- for an SEP of R1000 and more, the dispensing fee would be R65 plus 3% of the SEP
- all these fees would include value-added tax.

A similar contestation with dispensing practitioners has also been settled out of court, following a legal challenge.

Finality on this issue has not yet been reached, and assessing the impact of the proposed dispensing fee on the viability of different pharmacies, operating in very different communities, is extremely difficult. Modeling the effect on a "model" pharmacy of average size and average costs is possible, but may still pose problems. In principle, the fee needs to compensate the pharmacist for her/his professional service, while also covering the costs of maintaining an inventory of medicines and providing a suitable return on investment. The fee also has to be applicable to and practical for both community and private hospital pharmacies.

In a parallel development, the South African Pharmacy Council has published draft rules on which non-distributive services pharmacists can charge for, and what the basis of those fees should be. These include cognitive services as well as compounding services, and diagnostic tests. These fees have taken into account the methodology used by the National Health Reference Price List, a mechanism to exert pressure on the costs of all non-medicine healthcare services.

The extent to which the various pricing interventions have exerted downward pressure on medicines prices (and/or on medicines expenditure) in South Africa's private sector is challenging to depict. About 16% of South Africans are privately insured (are members or beneficiaries of a medical scheme). The Council for Medical Schemes Report 2007-2008 noted that expenditure on medicines dispensed by pharmacists and providers other than hospitals was R9.4 billion in 2007, accounting for 16.7% of scheme benefits[7]. Expressed in constant 2007 prices, medicines expenditure in this sector peaked in 2001, declined sharply until 2005, but was seen to be increasing again, albeit at a slower rate than had been seen between 1997 and 2001. The timing of these changes is interesting: generic substitution became legal in 2003, and the single exit price intervention was introduced in 2004, with schemes varying in how they paid dispensing fees thereafter. Medical schemes make use of intermediaries (administrators), and the reports of one of these (Mediscor) provide some insight into the changes seen over time. The Mediscor Medicines Review 2007 noted that "the use of generics is increasing steadily …. from 43% in 2005 to 46% in 2006 and to 47% in 2007"[8]. However, it also noted that "the average item cost for generic equivalents increased with 28% from 2005 to 2007". This administrator felt that the "increase in medicine expenditure between 2006 and 2007 is mainly driven by an increase in the average cost per claimed item (10.2%)" and that the "impact of new chemical entities with blockbuster potential and new generic equivalents for products that came off patent are clearly demonstrated".

Comparisons with private sector markets in other countries are possible, but strewn with methodological pitfalls. In 2008, it was reported that OECD countries spent an average of USD PPP 401 per person on pharmaceuticals in 2005[9]. However, these figures were skewed by the high expenditure in one country: "Per capita pharmaceutical expenditures were much higher in the United States (USD PPP 792) than they were in the next highest spending country, Canada, which spent USD 589 per capita". Other OECD countries were not as variable in expenditure on medicines: "The modest degree of deviation from the average is notable–half of all OECD countries have spending that deviates by less than 20% of the average – although three countries are outliers in this respect. At the other extreme, Mexico spent only USD PPP 144 per capita, about USD PPP 100 less per capita than Poland, the next lowest-spending country, and just 18% of the US spending level." Notably, it showed that "Prescribed medicines consumed outside the hospital setting account for the bulk of pharmaceutical expenditure". The following summary statements are worth considering: "In the vast majority of OECD countries, universal coverage schemes act as a combination pharmaceutical subsidy and *de facto* price regulation mechanism that is in effect for subsidised products (whether or not on-patent) nation-wide. This is the case, for example, in Sweden and Switzerland, where pharmaceutical firms submit their proposed ex-manufacturer prices to the pricing and reimbursement authority for consideration with supporting documentation. Once approved, the product is subsidised by the coverage scheme, but the manufacturer may not raise the price without approval; most OECD countries place restrictions on manufacturers' ability to increase prices. Products that are not proposed or approved for reimbursement, including most OTC products, may be sold to consumers in the country at any price. The US government employs *de facto* price regulation in the case of federal purchasers (*e.g.,* the Veterans Health Administration) and in the Medicaid social assistance programme– which provide coverage for about 20% of the US population. These schemes limit the prices manufacturers can charge, using the prices obtained by competing private plans as a benchmark."

Conclusions

South Africa's NDP is now overdue for re-evaluation and review. That process has recently started. The country has, however, attempted a number of interventions in relation to medicines expenditure, and its progress can be summarized as follows, by reference to the available options:

- Producer price control measures – while a policy or mandatory offer of generic substitution is in place, the single exit price (SEP) provides transparency at that level, and also limits annual increases to a set maximum
- Distribution chain cost controls – a single flat professional fee proved impossible, and finding a suitable dispensing fee has proven challenging; value-added tax remains in place
- Bulk purchase measures - the use of tender strategies, taking account of volume discounts, is limited to the public sector; no regional initiatives have yet been attempted
- International trade agreement relief measures – while the means to issue compulsory licences and the legal means to allow parallel importation are in place, these have not been used
- Demand side measures – while co-payments are routinely used in the private sector, there is evidence that prescribing of newly launched, expensive medicines may be reducing the impact of savings from generics.

The South African experience has demonstrated that clear legal drafting is a key element in the implementation of any intervention. The South African experience in the pricing case has also shown that, where policy implementation is challenged in the courts, there is a need for policy interventions to pass the test of reasonableness, based on the outcomes expected. The level of data required to satisfy a court is not easily predicted, but may be considerable.

Some elements remain unimplemented. Not only is a dispensing fee not yet in place and enforceable, but the ways in which wholesalers and distributors share in the SEP remain non-transparent. It has been suggested that further savings can be made by more closely aligning private sector medicines selection with the evidence based national Standard Treatment Guidelines/Essential Drugs Lists[10]. An enforceable code of marketing practice is also still recommended[11]. Increasing generic utilisation could also be strengthened if the Medicines Control Council moved from the non-substitutable "negative" list to a transparent Orange Book-like "positive" list. Finally, even though a benchmarking exercise has been repeatedly signaled, this has not yet been implemented. In time, as South Africa moves towards its goal of a National Health Insurance system, a more traditional reference pricing system, underpinned by rigorous pharmacoeconomic evaluation, may be possible. In order to do so, all actors in the medicines policy space will have to engage with the problem of medicine prices, and together find a way forward.

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Consumers' perception of generic medicines in community pharmacies in Malaysia

Raynu Thomas, Agnes Vitry

Quality Use of Medicines and Pharmacy Research Centre, Sansom Institute, University of South Australia, Australia

Address for correspondence: Raynu Thomas c/o Agnes Vitry, University of South Australia, Australia. E-mail: raynu_7@hotmail.com

Abstract

Objectives: This study aimed to assess Malaysian consumers' awareness of generic medicines, their willingness to use them and the reasons behind their choice.

Methods: A survey of consumers who had just visited a community pharmacy was undertaken using an interviewer-administered questionnaire. The survey consisted of 26 questions including questions about knowledge of generic medicines, past experience of generic medicines, willingness to try generic medicines and reasons behind this choice.

Results: In total, 203 consumers were surveyed in 10 pharmacies in Kuala Lumpur and Selangor, Malaysia. Overall, 137 consumers (67.5%) did not know what generic medicines were. Among the 86 consumers who had used generics before, most of them (79.0%) felt that generics worked well. For those who had not used generics or were unsure if they had, the majority felt that they would be unwilling to use them as they felt that they were not as effective or as safe as brand name products.

Conclusion: Awareness of generic medicines is lacking in Malaysian consumers although past experience with generic medicines may help form a favourable opinion of them. Development of consumer education on generics is required to support the implementation of the generic medicines policy in Malaysia.

Keywords: Generic medicines, consumers, perceptions, opinions, experiences, community pharmacy, Malaysia.

Introduction

The Malaysian healthcare system can be divided into the public and private sector. In the public sector, medicines are free to all patients in government hospitals and clinics whereas in university hospitals, patients pay a small co-payment fee[1]. Medicines dispensed in the government sector are mostly generic medicines[1]. In private hospitals, dispensing doctor clinics and community pharmacies, patients pay the full cost of their medicines[1]. Medicines dispensed in the private sector can be either generic or brand name medicines[1]. In Malaysia total expenditure on prescription medicines was estimated to be worth RM 2.24 billion (US$ 0.59 billion) in 2005[2]. This represents a significant burden to both government and individuals. On average, the affordability of an essential drug treatment in the private sector, expressed as the ratio of treating moderate pneumonia to the lowest government wage, was 3.7[3]. This indicates that the cost of drug treatment is more than the lowest weekly government wage.

A study found that generic substitution in community pharmacies could reduce consumers' overall expenses on medicines by a total of RM6137 (US$ 1615), a cost savings of 61.1%[4]. In 2006, Malaysia adopted a National Medicines Policy which aims to ensure continuous access and financial sustainability of essential drugs through a range of measures including a generic medicines policy. This policy intends to promote the procurement of generic medicines and give appropriate incentives to manufacture, prescribe, dispense and consume generic medicines[5]. However, specific measures or regulations that would encourage Malaysian community pharmacists and prescribers to do this have not been implemented yet. Therefore, consumers' knowledge of generic medicines and willingness to choose them is currently an important determinant of the success of the generic policy[6]. A study on Malaysian consumers' perceptions of the affordability of medicines found that more than 40% of respondents strongly agreed or agreed that there was a relationship between the price of medicines and their quality[7]. This suggests that some consumers may think that the cheaper generic alternatives are of lesser quality. The aims of this study therefore were to assess consumers' awareness of generic medicines, whether consumers would be willing to use generic medicines and the reasons behind their choice.

Methods

This study involved a survey of consumers who had just visited a community pharmacy using an interviewer-administered questionnaire. Consumers were approached as they entered the pharmacy and were given an information sheet in either Bahasa Malaysia or English that explained the research. The survey was administered in the pharmacy itself, normally in an area away from the flow of customers. It was conducted in 10 different pharmacies in Kuala Lumpur and Selangor, Malaysia that were randomly selected from the Malaysian Pharmaceutical Society Pharmacy Database (2007). Consumers were interviewed in May and June 2007 over a period of 9 days, with an average of 3 hours being spent at each pharmacy.

The questionnaire was designed specifically for this study after reviewing the literature in the area and consulting with experts. It consisted of 26 questions, including both selection from multiple choices and open ended answers. The English version was translated into Bahasa Malaysia (Malaysian Language) and when the questionnaire was administered, consumers were given the option of having the questions asked in Bahasa Malaysia or English, both of which the sole interviewer was fluent in. The survey included questions about knowledge of generic medicines, past experience of generic medicines, willingness to try generic medicines and reasons behind this choice. Data were analysed with SPSS Version 15.0. Descriptive statistics were generated for each question in the survey. This study was approved by the Divisional Human Research Ethics Committee of the Division of Health Sciences of the University of South Australia.

Results

Overall, 216 consumers were surveyed in 10 different pharmacies with an average of 22 respondents per pharmacy. Thirteen surveys were excluded from the analysis because the interviewer failed to ask one or more questions leading to incomplete responses. The consumers' characteristics are described in Table 1.

Sixty-six consumers (32.5%) said they knew what generic medicines were. Of this 32.5%, 15 consumers (7%) were unable to provide a description of a generic medicine. The most common descriptions given were "cheaper" (51%), being "non-original or non-genuine" (18%), "locally made medicines or made by a different company" (18%) and "a different brand of medicine with the same content" (13%).

All consumers were then given a description of what generic medicines were (a less expensive version of a medication made but with the same active ingredient and same effect) along with the example of paracetamol with Panadol® as the innovator and KKM paracetamol as the generic. Eighty-six consumers (42%) reported that they had used generics in the past, 27 (13%) did not know if they had and the remaining 103 (45%) had not. When surveyed, the majority of consumers (91%) did not purchase a prescription medicine that day, which could have meant that they did not know about generic medicines as they did not take medications. However 114 of them acknowledged purchasing a prescription-only medicine at some point in the past. Although 137 (67.5%) consumers initially did not know the term generic medicines, once they were given a description and an example, 43 (31%) of them acknowledged using generic medicines in the past. The 86 (42%) consumers who had used generic medicines were asked why they used generic medicines. They were allowed to choose multiple reasons from a list or could give other responses. Consumers gave various reasons for using generics: "know it is the same and will work the same" (40%), "cheaper" (36%), "were given at hospital" (21%) amongst other reasons (Table 2).

Table 1. Consumers' gender, age and educational level

Characteristics		No. (%) (n=203)
Gender	Male	87 (42.9)
	Female	116 (57.1)
Age (years)	18-21	6(3)
	21-30	41 (20.2)
	31-50	74 (36.4)
	50-65	64 (31.5)
	>65	18 (8.9)
Educational level	No schooling	11 (5.4)
	Primary school	6 (3.0)
	Secondary school	69 (34.0)
	Diploma	52 (25.6)
	University education	64 (31.5)
	Polytechnic certificate	1 (0.5)

Table 2. Consumers' reasons for using generic medicines.

Reason for using a generic medicine	No. (%) (n=86)
Know it is the same and will work the same	34 (40)
Cheaper	31 (36)
Given at hospital	18 (21)
Used before and it worked well	9 (11)
Just to give it a try	8 (9)
Recommended by someone	4 (5)
Other reasons	5 (6)

Of the 86 (42%) consumers who had used generic medicines, 79% felt that the generic medicine they had used worked well for them and/or was the same as the brand name, but some of them had reservations (i.e. 3 consumers felt generics could not be substituted for all medications, 2 consumers felt that generics were not for serious conditions, 1 consumer felt they took longer to produce an effect and another consumer simply still preferred the original). Eighteen consumers (21%) felt that the generic medicine they used did not work as well as the brand names or were unsure of how good they were.

A total of 117 consumers who had not used or did not know if they had used generics in the past were asked if they would be willing to use them. The majority (55%) said no, 23% said yes, and 22% were unsure. Of those consumers who had not used generics, 41% said the reason why they would be willing to use generics because they were cheaper. Those who were not willing to try generics had various reasons for their choice: 27% felt that generics were not as effective as the original, 27% would not use them because they did not think they were as safe as the original, 25% felt that because generics were cheaper they must be of inferior quality. Twenty-six people were unsure about using generics and the main reason was because they did not have sufficient knowledge about generics to make a decision.

Discussion

A majority of Malaysian consumers did not know what generic medicines were. This result differs from other international studies. In a German study, 63% of consumers had heard of the difference between generics and brand name medicines, mainly from the media and/or their doctor[8]. More than 70% of consumers in Brazil[9] knew that generic medicines were cheaper and of equivalent quality to brand name medicines. However, once the consumers in our study were given a description and an example of generic medicines, some of them acknowledged using generic medicines before. This result suggests that perhaps some people do not know the term 'generic medicines' as such but possibly are aware of or have had experience with a cheaper, equivalent alternative to a brand name medicine.

Most consumers in Malaysia who had tried generic medicines reported a positive experience. However, around a fifth felt that the generic medicines used did not work as well as the brand names or were unsure of how good they were. Among consumers who had never tried generic medicines, most declared that they did not want to use them in the future. This negative perception of generic medicines among non-users possibly indicates that past experience with generics help form a favourable opinion of them. Similar results were found in a survey on consumers' perceptions of generic substitution among 505 consumers in the United States[10] and in a study among 804 patients in Germany[8]. Consumers or patients who had had a past experience with generic medicines generally had a more positive perception of them.

The cheaper cost of generic medicines was found to be one of the factors for choosing them as 36% of the 86 consumers who had used generics before did so because they were cheaper. Also, among the 117 who had not used generics, 41% said they would try them because of their reduced cost. Similarly, consumers interviewed in Australia claimed the main reason for accepting generic medicines was their reduced cost [11].

Negative perceptions of generic medicines among Malaysian consumers could be due to a lack of knowledge about generic medicines and negative portrayals of generic medicines by the people around them. Among consumers who were unsure whether they would be willing to try a generic medicine, the main reason given was that they felt they had insufficient knowledge to make a decision. National information campaigns about generic medicines have been undertaken in several countries to support the use of generics. For example in the United States, the Food and Drug Administration (FDA) launched the "Generic Drugs: Safe. Effective. FDA Approved" campaign with the intention of promoting consumers' confidence in generic medicines[12]. The FDA has spread the word about generic medicines through magazines, newspapers, posters, public service announcements and advertisements. Similar campaigns need to be run in Malaysia to convince the public about the advantages of generic medicines, ensure the success of the generic policy and decrease national medicine expenditures. In Spain, a study was conducted on the effect that patient education had on acceptability of generic substitution[13]. This study found that the overall rate of generic prescribing was doubled in the people who had been educated on generic medicines, which illustrates just how important education can be. A recent US study has also established that health beliefs about generic medicines were associated with the use of generic medicines[14].

This study has some limitations. It was performed in two regions of Malaysia and results cannot be generalized to the whole of Malaysia. In particular, rural areas in Malaysia were not included in the study and hence the perceptions of rural communities were not assessed. Unfortunately, a response rate was not calculated when the study was conducted. It cannot be excluded that consumers who declined to answer the questionnaire may have had a different knowledge and use of generic medicines from respondents in this study. Consumers were questioned when they were exiting community pharmacies. Different results might have been obtained when questioning patients from public health clinics who are exclusively given generic medicines. Also, most of the participants who visited the pharmacies were not obtaining prescription medications. If they had been, they possibly may have had more experience with generic medicines, varying their responses.

Conclusions

Our study showed a lack of awareness of generic medicines among Malaysian consumers. However, consumers who had past experience with generic medicines use, generally had a positive perception of them and were more willing to use them. Consumers' main reasons for using generic medicines were because they knew they were the same and they were cheaper. Consumer education about generic medicines is important to correct misconceptions and to give consumers the knowledge that they need to make an informed decision about using generic medicines. Along with consumer education, the development and implementation of policies promoting generic use by health professionals and regulating medicine prices could help ensure the success of the generic policy in Malaysia.

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Generic medicines in Australia: business dynamics and recent policy reform

Hans Löfgren

School of International and Political Studies, Deakin University, Australia.

Address for correspondence: Hans Löfgren, Deakin University, Australia. Email: hans.lofgren@deakin.edu.au

Abstract

This article describes the role of generics in the Australian prescription drug market and patterns of business activity in this dynamic market segment. The Pharmaceutical Benefits Scheme (PBS) is the central mechanism for the supply of prescription medicines. PBS prices are arrived at through cost-effectiveness analyses comparing new products against already available products and therapies. In this system, prices do not operate effectively as incentives for consumers or prescribers to choose generics, and their market share was historically marginal. In recent years, generics suppliers achieved a growing market share through discounts (trading terms) to pharmacists. It is estimated that around 30% of PBS scripts, representing around 15% of PBS sales by value, are now filled with generics. Complex changes to the PBS were introduced in 2007, to be phased in over the period to 2012, aimed at increasing the scope for cost benefits to the government, and to lesser extent consumers, from the expanding availability of generic medicines.

Keywords: Australia, generic medicines, Pharmaceutical Benefits Scheme, pharmacies

Introduction

Prescription drug sales in Australia at around US$8 billion constitute a small share of the US$800 billion global market[1]. Yet Australia is a high income economy with strict regulatory requirements closely monitored by drug policy analysts and the pharmaceutical industry[2]. Prescription medicines are subsidized by the Commonwealth (federal) government through the Pharmaceutical Benefits Scheme (PBS). The PBS is designed to ensure 'timely access to the medicines that Australians need, at a cost individuals and the community can afford' and forms a central component of the National Medicines Policy[3]. Through the PBS the government exercises strong market power which has delivered, for decades, relatively low prescription drug prices[4]. The design of the scheme precludes effective price competition and generics prices historically approximated those of originator brands. Consequently the Australian market was until recently the almost exclusive preserve of the big brand companies. The generics sector remains small, in both value and volume terms, by comparison with economies such as the US and the UK, though policy changes and the increasing availability in international markets of cheap generics ensure an expanding role for generics also in Australia[5-7]. Recent assessments suggest that around 30% of PBS prescriptions are dispensed with a generic, representing around 15% of the value of sales[8]. In response to escalating health costs, and patents expiring on many big products, the Department of Health and Ageing (DoHA) has been searching for ways for tax payers and consumers to benefit, to a greater extent than hitherto, from low cost generics. The result is a major policy reorientation in 2007 aimed at driving down generics prices. This article briefly explains these changes, against the background of a sketch of regulatory arrangements and the business of generics in Australia. The focus is on the PBS market, which represents the bulk of prescription drug sales (public hospital tendering arrangements have long ensured a dominant role of generics in that sector)[9].

Prescription drug regulation and the role of generics

Australia's system of drug regulation encompasses two major steps. Medicines must first be entered on the Australian Register of Therapeutic Goods (ARTG) following approval by the Therapeutic Goods Administration (TGA) for acceptable quality, safety and efficacy. Generic products are assessed by the TGA for bioequivalence with the originator brand through a process of rigorous scientific evaluation normally completed within 45 working days[10,11]. For biosimilars, the TGA has adopted the guidelines of the European Medicines Agency (EMEA) and each submission is assessed on a case-by-case basis. Omnitrope (supplied by Sandoz/Novartis) was the first biosimilar introduced (in November 2005) to the Australian market[12]. Notwithstanding the efficiency and high reputation of TGA procedures, regulatory requirements are considered relatively inhospitable to the

generics sector. Patent rights extend beyond those mandated by the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS) to include a five-year data exclusivity period, precluding data submitted to the TGA relating to a pharmaceutical product from being used by another company in applying for marketing approval until five years after approval of the original product. Moreover, patent extensions of up to five years are available for pharmaceutical standard patents, under certain circumstances, to compensate for delays in the marketing approval process. Such extensions are not available in countries such as New Zealand, Canada, South Africa, China or India[13,14]. Mylan, the parent company of market-leading Alphapharm, considers consequent delays in patent expiries to be 'somewhat responsible for under-penetration of generic products' in Australia[15]. Generics can also not be produced for exports whilst patents still apply in Australia. This latter constraint "places Australian generic manufacturers at such a disadvantage, even relative to generic manufacturers located in the US, Canada or Western Europe, that global companies are actively choosing their non-Australian facilities to manufacture new products"[16].

Following marketing approval, companies in most cases apply for PBS listing. This is normally required for sales to be commercially viable, making the prescription medicines market to all intents and purposes synonymous with the PBS. This is an uncapped scheme introduced in the early 1950s to provide all residents, irrespective of financial circumstances, with timely access to necessary medicines[17]. More than 70% of all dispensed prescriptions are subsidized under the PBS, at a cost to tax payers of about AUS$7 billion in 2007-08[18]. In July 2008, 641 medicines, in the form of 2,995 branded products, were available through community pharmacies under normal PBS arrangements[19]. The government is responsible for approximately 85% of the total cost of the PBS, with the remainder paid through patient co-payments (complemented by safety net provisions)[20]. Co-payments in 2009 were AUS$32.90 for general patients and $5.30 for pensioners and other concessional categories. Many products, particularly generics, are priced (for general patients) below the co-payment, a trend reinforced by the 2007 changes described below. In these circumstances no subsidy takes effect, which gives pharmacists discretion to determine the price to the customer[21]. There are close to 5,000 community pharmacies, operated as small business enterprises, which draw for most of their revenue on fees and charges, negotiated with the government, for dispensing PBS products. The pharmacy owners are represented by a politically influential lobby group, the Pharmacy Guild of Australia (PGA)[22].

New PBS listings require a recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent statutory body, to the Minister of Health and Ageing. Before the listing of a new drug, a price acceptable to the government is negotiated with the supplier through the Pharmaceutical Benefits Pricing Authority (PBPA)[17]. The principle of reference pricing is central to the PBS, that is, products that (in the judgment of the PBAC) produce similar health benefits are subsidized at the same level. In other words, the government subsidizes 'each of the available brands to the level of the lowest priced brand[18]. The PBS listing and pricing process has delivered relatively favorable prices for patented drugs whilst 'in general, the prices Australian taxpayers pay for generic medicines are high compared to some other OECD countries'[18].

In therapeutic group (groups of non-identical drugs with similar safety and health outcomes) and multi-brand markets, companies are at liberty to charge a price higher than the lowest priced brand, with patients then paying, in addition to the co-payment, a brand or therapeutic group premium[21]. In 2008, 'the average brand premium was $3.03, and premiums ranged from $0.08 to $76.86. The majority of brand premiums were in the range of $1.00 to $4.00[18]. The brand premiums, often poorly understood by consumers, in conjunction with other changes explained below, provide a window of opportunity for generics suppliers. A space for the generics sector was first opened up with the introduction of brand substitution by pharmacists in 1994, and subsequent policy changes have progressively widened the commercial potential of consumers avoiding brand premiums by choosing a brand priced at the base rate. Where a prescription has been issued for a product with a price premium, the pharmacist can at the patient's request dispense another brand of the same medicine, unless the prescribing doctor has specifically indicated otherwise. About 55% of all PBS prescriptions are substitutable, yet only 33% are substituted – the difference points to the potential for further generics growth through substitution (even in the absence of additional medicines coming off patents)[23].

A conundrum for the government which was only marginally mitigated by the brand premium policy (introduced in 1990) and the therapeutic group premium policy (in 1998) is the absence of incentives for PBS suppliers to compete on price, with reference pricing ensuring that any price cuts offered to the PBS flow through to all other suppliers of the same or similar products[5]. Rather than competing on price, generics suppliers in the past decade gained access to the PBS market though discounts or trading terms to pharmacists, typically around 30% and often 50% or more. In other words, pharmacists have been reimbursed by the government at prices well above the prices actually paid. From a pharmacy perspective, such trading terms came to be considered standard business deals rewarding efficiencies and scale[22]. With weak incentives for prescribers and consumers to choose generics, the discounts served as an incentive for pharmacists to drive generic substitution. That the cost benefits of cheaper generics were flowing to pharmacists, while PBS prices continued to approximate those of the originator brands, became increasingly unpalatable to the government. This formed the context for recent changes to the PBS, which radically extend an earlier policy measure (introduced in 2005) which mandates that the first new generic brand of a medicine

already listed on the PBS must be priced at least 12.5% below the current lowest priced brand. Reference pricing then ensures that the price cut flows through to other brands of the same product and to products linked in Therapeutic Groups.

The generics business in Australia

It is estimated, as noted, that around 30% of PBS prescriptions are dispensed with a generic, representing between 10% and 15% of the value of PBS sales[24,25]. But reliable market information is not readily available. The detailed data on the community pharmacy market collected by the PGA is not publicly released, but used selectively for lobbying purposes. For their part, generics suppliers share with the PGA an interest in withholding information about market shares and pharmacy trading terms. The lack of transparency is reinforced by increasingly blurred lines globally and in Australia between the originator and generics sectors[26]. Several leading brand companies are also major generics suppliers, most significantly Novartis through its Sandoz division. The use of authorized or pseudo-generics is common practice, that is, products cross-licensed by a brand company to a specialized generics supplier, or marketed by an originator company by a subsidiary under a different name[27]. Around 20% of all generics available in Australian community pharmacies are estimated to be in this category, which includes re-packaged versions of major products such as Ventolin, Losec, Valium, Normison, Augmentin and Prozac. Repackaged is the key term – pseudo-generics are not bioequivalent, alternative brands but by definition identical to the originator product, typically from the same production line[28]. The extent of this practice can be gauged from the estimate that 'of the 300-plus products sold by Alphapharm, the nation's biggest generic drug company … a quarter is made by other companies'[29]. Pseudo-generics are the subject of legal and political controversy in the USA but in Australia it is a phenomenon yet to be systematically investigated[30].

There are around ten companies supplying generics to the PBS, with two firms dominating. The Generic Medicines industry Association (GMiA) claims its six member companies supply 98% of generic prescriptions. Alphapharm has a market share of around 60% and Sigma about 20%[15]. Only three firms – Alphapharm, Sigma and Hospira – undertake manufacturing or R&D associated with manufacturing in Australia, the others are engaged solely in the marketing of imported final drugs[16].

The member firms of the GMiA can be briefly characterized as follows. **Alphapharm®** is a subsidiary of US-based Mylan Pharmaceuticals, ranked 29 on PharmExec's list of global pharma companies[1]. Alphapharm has made 'branded generics' the dominant business model, that is, its products are marketed through the advertising of the company name. **Sigma Pharmaceuticals®** forms part of an Australian-owned health care company, headquartered in Melbourne, which is also a leading full-line wholesaler and the operator of a number of pharmacy retail brands (including Amcal, Guardian, and Amcal Max). It claims to be the Australian generics company with the largest manufacturing capability, and expanded its market position through acquisition of Herron in 2003 and a merger with Arrow Pharmaceuticals in 2005. **Ascent Pharmahealth®** was established as Genepharm Australasia in 2003. It is a distribution-only firm which claims the number three position. Following a merger in 2008 with the Indian firm Strides Arcolab it now operates also in Asian markets including Singapore, Hong Kong, Malaysia, Thailand and Vietnam. **Apotex®** is a subsidiary of the global Canadian Apotex group, a specialized generics company, with about 6,800 employees globally. **Hospira Australia®** was established in Australia through the acquisition in 2007 by the US-based global 'specialty pharmaceutical and medication delivery company' of the same name (with more than 14,000 employees) of the Australian firm Mayne Pharma, the leading Australian supplier of injectable generic pharmaceuticals. **Sandoz®**, as noted, is a division of Novartis, one of the world's largest pharma companies. Non-GMiA members supplying generics in the PBS market include Ranbaxy and Pharmacor. Ranbaxy, India's largest drug company, which established Australian operations in 2004, was acquired in 2008 by the Japanese multinational Daiitchi Sankyo. **Pharmacor®** is an Australian firm established in 2006 which markets 'small niche products where it's not worthwhile for the larger companies to focus[23].

Generics suppliers in Australia operate in a growing and dynamic market but one characterized by lack of transparency and distortions such as dominance by a few major players and shadowy cross-licensing arrangements. Consolidation is happening in the international generics sector at a rapid pace and most firms in Australia are now linked into global corporations drawing on manufacturing in locations such as India[26]. The government is presently seeking to address some of the problems of the generics market through major changes to the PBS.

PBS reform

The key premise of the complex reform legislation introduced in 2007 is that generics prices have been too high and the aim of is to ensure better value for taxpayers[31-33]. The importance of this policy shift is highlighted by the looming expiry of patents on more than 100 PBS drugs in the next decade. In 2006 the government foresaw PBS savings from these changes of AUS$3 billion over ten years, but a recent estimate suggests that savings may exceed AUS$7 billion over that period[25]. Prices of generic drugs will be cut, pharmacy trading terms will be scaled back, and real prices paid by pharmacies made transparent through the phasing in of price disclosure requirements. The legislation was preceded by negotiations with the different sections of the industry behind closed doors. The gain for Medicines Australia, representing originator companies, is a weakening of the reference pricing system, a concession made by the government in exchange for the brand industry's acceptance of measures ensuring lower generics prices and incentives for greater uptake of generics by pharmacists. This

is achieved through the de-linking, for PBS pricing purposes, of patented products from generics, even where delivering similar therapeutic benefits, unless deemed 'interchangeable at the patient level'[33,34].

This delinking is brought about through the break-up of the PBS into two formularies (from August 2007): F1 encompassing single brand drugs, in most cases under patent, and F2 comprising drugs with multiple brands (and single brand drugs in a Therapeutic Group with a drug that has multiple brands). Until December 2010, F2 is divided into F2A (products discounted by less than 25% as at 1 October 2006) and F2T (products then discounted by more than 25%) with different pricing arrangements and different implementation dates for price disclosure. Mandatory price cuts were imposed on all F2 drugs on 1 August 2008: F2A prices were cut by 2% cut (to be followed by additional 2% cuts in 2009 and 2010) while a 25% price cut was imposed on 99 F2T drugs. The 12.5% price reduction imposed at the time of listing of the first generic brand of a drug will continue to apply. While the market impact of price disclosure arrangements, to be phased in over several years, is difficult to assess, they have commenced taking effect: in August 2009, price reductions were applied to four PBS drugs following the first round of the price disclosure system[35]. In the meantime, newspaper reports suggest that high trading terms continue for some products, with the government 'paying between 50 per cent and 80 per cent more for generic drugs [under the PBS] than the pharmacists are paying for the medicines themselves'[36].

Prescribers figure only peripherally in the present drive for greater uptake of cheaper generics, while the government has allocated some additional resources to a campaign by the National Prescribing Service to inform consumers about generics[37]. But the reform emphasis is squarely on the mandatory price cuts and associated measures to achieve greater generics pricing transparency and on changes in incentives for pharmacists. The community pharmacy sector is very sensitive to its dependence on regulatory protection and the volume and value of PBS products dispensed. The PGA viewed with apprehension the prospect of lower generics prices and the scaling back of trading terms and is perennially concerned about the possibility of more far-reaching regulatory changes[24,38]. But community pharmacy reform has been deferred by the government, possibly to be revisited in context of negotiations with the PGA about arrangements to follow the Fourth Community Pharmacy Agreement, which expires in June 2010[39]. The 2007 reform included a favorable compensation package for community pharmacy

- An incentive payment from 1 July 2007 of 40 cents for each prescription processed with PBS Online.
- A payment of AUS$1.50 from 1 August 2008 for the dispensation of substitutable, premium free PBS-subsidized drugs.
- A 15% increase in dispensing fees and adjustments to pharmacy mark-ups from 1 August 2008.(25)

It was reported in March 2009 that generic substitution had increased by around 20% following PBS changes coming into effect in August 2008 'with 29% of pharmacists increasing their substitution to some degree'[8]. Recent changes also includes the establishment of an industry-government Access to Medicines Working Group, to provide an avenue for direct communications between Medicines Australia and DoHA, to consider issues related to the PBS, including matters such as the future of pharmacy compensation arrangements and consumer education programs to promote generics[31].

It is too early to assess the implications of the F1-F2 reform and related PBS changes for different industry segments. The PGA remains uneasy about the future of community pharmacy while Medicines Australia appears broadly satisfied with recent developments. For its part, the generics sector reports declines in revenues and profitability as a result of price cuts. Yet medium and long term prospects for generics suppliers remain positive as PBS reforms and patent expiries accelerate the growth of the market share of generics[15]. According to Ascent Pharmaceuticals "The one-off effect of the PBS reforms will allow the industry to grow profitably going forward from these new price levels. This along with increased generic substitution and the introduction of new generic medicines is expected to bring strong margin value growth to the sector. The market outlook for generic pharmaceuticals remains strong with generic substitution in Australia expected to grow strongly over the next few years"[40].

Concluding remarks

The generics sector is an established and growing segment of the Australian drug market and the PBS changes initiated in 2007 will accelerate this process. Following the introduction in 1994 of brand substitution, the major impediment to the growth of the generics sector, due to small price differentials, was the absence of incentives for doctors, pharmacists and consumers to choose generics. Recent changes do not significantly address the role of prescriber and consumer incentives, but will make dispensing pharmacists more inclined to support generic substitution. However the direct cost benefits to government are arrived at through mandatory price cuts and price disclosure requirements. These steps in conjunction with coming patent expiries will significantly increase, over the next decade, the market share of generics from the present level of around 30% of dispensed PBS drugs. But the brand industry remains strongly entrenched, as reflected in intellectual property rights legislation unfavorable to the generics sector and the design of the F1/F2 reform. Moreover, the generics market is distorted by the dominance of a small group of suppliers and cross-licensing (pseudo-generic) arrangements with the major brand companies.

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Antiretroviral therapy in a South African public health care setting – facilitating and constraining factors

Karine Wabø Ruud[1], Sunitha Chandrasekhar Srinivas[2], Else-Lydia Toverud[1]

[1]*Department of Social Pharmacy, School of Pharmacy, University of Oslo, Pb1068 Blindern, 0316 Oslo, Norway.*

[2]*Pharmacy Administration and Practice, Rhodes University, Grahamstown 6140, South Africa.*

Address for correspondence: Karine Wabø Ruud, Department of Social Pharmacy, School of Pharmacy, University of Oslo, Pb1068 Blindern, 0316 Oslo, Norway. E-mail: karine.ruud@farmasi.uio.no

Abstract

Objective: The objective of the study was to identify and document facilitating and constraining factors in the antiretroviral therapy (ART) programme in a public health care setting in the Eastern Cape, South Africa.

Method: Observations for the study were carried out in a district hospital and two down-referral clinics in Makana Local Services Area in the Eastern Cape Province. Two discussion groups with key stakeholders were conducted to gather information about opinions and experiences among the health care providers (HCPs).

Results: It was found that the operating ART programme in this setting has been integrated in the existing down-referral health care system, based on follow-up in primary health care (PHC) clinics. Treatment is provided free of charge. The treatment programme provides the patients with access to counselling, nutritional assistance, psychosocial support and social welfare evaluation. However, increasing patient numbers and lack of human resources leads to a heavy workload for the HCPs involved with the ART programme. The need for additional, educated health workers is a major constraint for progress in provision of health care to patients who have accepted their HIV status, and are enrolled, or waiting to be enrolled, on the ART. However, delegation of work tasks among available HCPs and good communication between HCPs in the different clinics is a facilitating factor that ensures efficient use of the human resources available.

Conclusion: Taking into account the challenges in a resource-constrained setting, this programme shows potential for functioning well as a provider of ART for those who are able and willing to access it. Considering an already heavy workload for HCPs, limitations and challenges still exist in reaching out with adequate treatment to a greater number of people who need ART.

Key words: ART programme, down-referral, HIV/AIDS, primary health care, public health, resource-constrained settings.

Introduction

Sub-Saharan Africa is the region that is most greatly affected by HIV/AIDS in the world. South Africa is one of the countries with the highest prevalence of HIV in the sub-Saharan region, and has the highest number of people infected with HIV in the world (5,7 million people)[1]. Sub-Saharan Africa also suffers from a shortage of skilled health care providers (HCPs)[2], which is one of the basic needs in a health care system. A previous study from South Africa has found that HCPs in South Africa have stressful working environments due to increasing numbers of patients together with staff shortages[3]. Triple combination antiretroviral therapy (ART) for treatment of HIV became available in 1996. Although the access to this treatment has been very limited for HIV patients in low and middle income countries[4], it is now growing steadily[5]. The goal of the United Nations (UN) is to come as close as possible to universal access for all who need it by 2010[6].

In November 2003 the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa (The Comprehensive Plan)[7] was approved. This plan, now supplanted by the National Strategic Plan 2007-2011, promoted distribution of antiretroviral therapy (ART) through the public sector. The public health care system in South Africa is based on primary health care (PHC) principles, with PHC clinics offering first-level care. In 2004, the national ART programme was introduced in the public PHC setting. The ART programme provides the following two ARV treatment regimens in the public sector: 1a/b. Stavudine + Lamivudine + Nevirapine or Efavirenz and 2. Zidovudine + Didanosine + Lopinavir/Ritonavir.

The criteria for treatment initiation as given by the national antiretroviral treatment guidelines are: CD4<200 cells/mm^3 or World Health Organization (WHO) stage IV AIDS defining illness[8]. This is also the criteria for HIV patients to qualify for a disability grant (DG), which is intended for people who are unable to work and support themselves due to their disease.

South Africa has a large inequity in the distribution of human and financial resources between the public and the private health sector[9]. The population in the country is about 48 million people, and medical scheme coverage is only 14%[10]. Despite its low share of beneficiaries, the private sector employs more than 70% of the country's health care specialists, and accounts for more than 60% of the total South African health care spending[11].

Objective

The present study was carried out in a public health care setting in the Eastern Cape province of South Africa. The aim of the study was to identify and document facilitating and constraining factors in the operating ART programme.

Methods & results

Study setting

The study was conducted in a public health care setting in Makana Local Services Area (LSA) in the Eastern Cape Province of South Africa. The public health system in the area of Makana LSA consists of two district hospitals, 20 PHC clinics, seven mobile clinics and three specialized hospitals[10]. During the time of the study there were seven down-referral clinics in the sub-district where the present study was conducted. These clinics received patient-specific ARVs pre-packed from the district hospital. The PHC clinics operate mostly without doctors, and patients are referred to the district hospital for initiating therapy and monitoring during the early stages. When stabilised on treatment, the patients are down-referred to the clinic closest to their home for continued follow-up and monthly refill of prescriptions. The same down-referral system has been utilised to implement the ART programme. The estimated ART coverage for South Africa is 28 % (2007), and since Eastern Cape is one of the poorest provinces in the country, one can assume that coverage of ART is even lower in this province than the country estimate[12].

The ART programme in the health care setting we studied was implemented in May 2004, and after two years 687 patients had been enrolled. Seventy percent of these were women, and 52 patients in total had died while on treatment. Since initiation of the programme, 210 patients had been down-referred to PHC clinics. The remaining patients were in their stabilising stage, receiving medication at the district hospital.

Study participants/centres

The healthcare providers (HCPs) were mainly from one district hospital and two down-referral clinics in the public health in Makana LSA. The HCPs included in these clinics were all those who were involved in the work with HIV patients, and varied between four and ten among the different clinics. The HCPs from the remaining down-referral clinics in the area, who attended mutual ART meetings at the district hospital during the study period, were also included in the study.

Participant observation was carried out at the three public treatment sites between February and April 2006. Table 1 shows the elements of observations included at each treatment facility. Two group discussions were held in August 2006 with key stakeholders, of whom the majority had participated in preparing the launch of the ART programme in 2004 in Makana LSA. Communication between the researcher and HCPs was carried out in English. Field notes were made by the researcher during the observations. For the group discussions an assistant conducted field notes for cross checking results. Data containing information about number of clinics providing ARVs, provision of ARVs and movement of patients within the system were extracted from the field notes to create a flow chart of the down-referral health care setting.

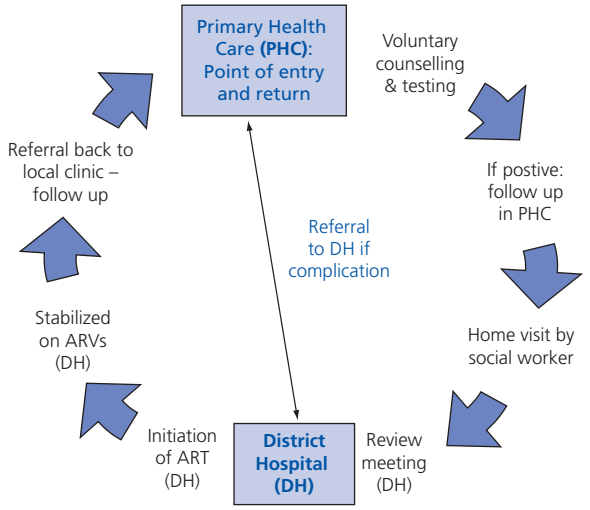
Permission to conduct this study was obtained from Rhodes University Ethical Committee, Makana Municipality Department of Health and Eastern Cape Department of Health. Access to health care facilities for observational studies was allowed by the local authorities.

The HIV patients in this health care setting enter the ART programme via voluntary counselling and testing in a primary health care clinic. Patients who test positive are followed up in the same PHC clinic until eligible for treatment initiation. When ready for treatment, the patients are initiated and stabilised on ARVs at the district hospital, and then referred back to the local PHC clinic for continued follow-up and care. The structure of the ART programme is shown in figure 1.

Table 1. Observations

Referral site (District hospital)	Dispensing of ARVs Consultation (patient/doctor, patient/support staff) Adherence counselling (patient/pharmacist) Mutual meetings
Down-referral site 1 (Primary Health Care Centre)	Patients' ARV collection (patient/pharmacist)
Down-referral site 2 (Primary Health Care Clinic)	VCT (nurse/patient/support staff) Consultation (patient/nurse) ARV collection (patient/nurse)

Figure 1. Patient Flow Chart



Facilitating factors

Financial aspects

Voluntary counselling and testing (VCT) and ART are provided free of charge in the public health facilities. The HCPs informed that some patients received a state-provided disability grant (DG) due to their health status. It was the HCPs' impression that the HIV patients were very concerned about their own ability to apply for the DG, and therefore asked questions regarding how to apply for DG. However, the HCPs' experiences were that not all patients who were eligible to apply for a DG were given such financial support. The HCPs also expressed that patients who already received DG were concerned about the risk of losing their DG.

Accessibility and proximity of testing and treatment

VCT and ART follow-up are available at the patients' local PHC clinics. VCT is carried out at the patients' requests on specific days. To ensure that the patients are ready to undergo HIV testing, special counselling is provided by a community health worker right before the testing. HIV testing is carried out by a registered nurse, and the results are available after 5-10 minutes. In order to give the patients appropriate support and advice according to their HIV-status, all patients receive personal post-test counselling together with their test results. Both individual support and educational material (posters, brochures, and leaflets in the three main languages) are available in the clinics.

Follow-up and monitoring of patients

All patients who test HIV-positive are entitled to receive follow up in their local clinic. HCPs reported that both CD4 and viral load counts are done every six months after a positive HIV test. This provides indicators for monitoring of a patient's disease progress prior to initiation of ART. During the period when patients are prepared for ART, either a social worker or a community health worker visits the patients at home. A standardised scheme is used for these visits to gather information about the patients' families and economic situations. These home-visits may provide the HCPs with information about the patients' probable ability to cope with the treatment and the disease.

To ensure that patients are stabilised on ARVs before down-referral to the PHC clinics, the patients are followed up at the district hospital for three to six months after treatment initiation, depending on their condition. It was observed that the down-referral PHC clinics keep records on when the patients are expected to return, and annotations are made when patients do not appear as scheduled. Some patients need to be seen by a doctor after they have been down-referred to the PHC clinic. Various reasons for this are: when patients complain about their health, or there is a suspected adverse drug reaction or a suspected poor response to ARVs. In such cases, patients are either referred to the district hospital, or they can return to the clinic on a specific date when the doctor is scheduled to make a visit.

HCPs promoting treatment adherence

It was pointed out by one of the HCPs that patients whose disease state has progressed to the WHO stage II are given antibiotic prophylaxis (Co-trimoxazole). By taking antibiotics regularly, patients are also trained practically on adherence. This is part of a patient readiness programme, to ensure that patients are not initiated on ART without being adequately prepared for adherence. To encourage correct drug use, it is also required that patients appoint a personal treatment supporter (usually a friend/family member) prior to treatment initiation.

Communication and cooperation between HCPs

HCPs have weekly meetings within and between the different health facilities. The major gathering point for HCPs from different health facilities is the weekly review meeting at the district hospital. This meeting provides an opportunity for HCPs to discuss all the new patient cases thoroughly. A nurse from each PHC clinic provides information about new eligible patients' disease states and their treatment readiness, and brings a report from the home-visit. Based on this information, the HCPs discuss appropriate time for treatment initiation. The weekly meetings are, on some occasions, used to provide the HCPs with informal training on topics related to ART. It was also reported by HCPs that they provide in-service training for staff members who are unable to attend workshops/training sessions. The HCPs communicate and make use of each other by referring patients to other HCPs when there are problems beyond their competence.

Constraining factors

HCPs are carrying the burden of a heavy workload

A heavy workload combined with lack of human resources is a challenge in this health care setting. It was reported by HCPs that the programme was operating at its maximum during the time of the study. The programme is growing continuously and according to HCPs from the different health care facilities, extra staff has not been provided as promised after implementation of the ART programme in 2004. One of the HCPs explained

that because of an increased workload at the district hospital after implementation of the ART programme, all non-HIV out-patients are managed at the largest PHC facility. In the study area this facility is referred to as a PHC centre due to additional medical support provided here compared to the other PHC facilities in the study area.

Limited number of highly qualified HCPs

Few doctors and pharmacists are available in this health care setting, so nurses and support staff are given major responsibility regarding treatment and follow-up of HIV patients. During the time of this study, responsibility for adherence counselling shifted from the pharmacist to a nurse, due to heavy workload for the pharmacist. Because of the high pressure on the ARV clinic, there are several weeks' waiting from the time when a patient's case is presented on the weekly review meeting until an appointment with the doctor for treatment initiation. However, it was observed that special arrangements are made for patients whose need for treatment is considered more urgent than the average.

Few ARVs are available

The limited selection of ARVs available in the public sector does not allow for individualised treatment, and if both regimens fail there are no further treatment options. HCPs reported that there had been very few defaulters in the programme so far, and ARV resistance was not yet a problem in this setting. Fixed dose combination of ARVs was not available for patients on this programme during the time of the study.

HCPs dealing with complicated patient cases

Observations in the clinics and discussions during the weekly meeting showed that many of the patients enrolled on the ART programme have special needs, due to their medical condition and the emotional pressure that accompanies the disease. Common challenges for the HCPs are: patients with tuberculosis co-infection or severe disease progress, patients with fear of stigmatisation, patients with complicated family relations or unstable situations at home, and patients with insufficient food and money. One of the HCPs reported that there had been a few situations with patients who found it very difficult to disclose their HIV-positive status to a friend or a family member, with the outcome that treatment initiation had been delayed due to lack of treatment support.

Discussion

A primary health care based ART approach

The ART programme in our study was integrated in the existing down-referral health care system, based on follow-up at PHC level. This is in accordance with WHO recommendations[4] and directions in The Comprehensive Plan[7], which specifies that PHC clinics and community health centres be the primary sites for diagnosis, staging and routine follow-up of HIV-positive patients. Previous studies conducted in other African countries have shown that both referral and non-referral approaches have been adopted for implementing ART programmes in a public health sector[13-17]. However, the advantage of PHC involvement on a local level has been emphasised lately in resource-constrained settings. Some ART programmes, e.g. in Botswana[17] and Malawi[18], have shifted from an initial, hospital-based follow-up for all ART matters, to involve more down-referral PHC clinics. It has been stated that provision of ART in central hospitals without strong links to community outreach or PHC services weakens the link between prevention and care[19]. The close co-operation and communication between the district hospital and the down-referral clinics in our study is in line with intentions in The Comprehensive Plan that there should be ongoing communication between PHC facilities and the district hospital HIV/AIDS specialty clinic.

Making the most out of the available resources

Due to the low number of highly educated HCPs, a system for delegation of work tasks has been adopted. This is in line with WHO recommendations of making optimal use of available human resources. Despite this, there was still great pressure on the available doctors, and patients who were ready for treatment had to wait several weeks before treatment could be started. It is of concern that the programme is growing without further allocated resources. This means that patients may have to face longer waiting times before treatment is initiated. According to the treatment guidelines, the majority of the patients who are eligible for treatment have a CD4 count less than 200[8]. Since late presentation for HIV care is one of the major reasons for morbidity and mortality in HIV patients[20], any treatment delay may lead to a further impaired immune system, which ultimately may increase the probability of severe disease progression or even death[21-23].

Stabilising patients on treatment before down-referral ensured that prospective complications at an early stage could be identified by HCPs with the highest competence available in the system. Intentions in the South African Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment is that provision of HIV/AIDS care should not be at the expense of quality of other health care services provided in the clinics. According to the South African Health Review 2008, the number of medical practitioners and professional nurses varies in the nine provinces from 14.1-37.9 and 94.5-155 respectively per 100 000 population. This is much lower than the number needed to achieve the millennium development goals. Eastern Cape has among the lowest rates of HCPs/100 000 population of the nine provinces[10]. There is already a heavy workload and the ART programme is growing with more and more HIV patients who require treatment, follow-up and care. Therefore, with the current workforce, it is hoped that a situation will not arise where ART services are provided at the expense of other health care services.

As suggested by the WHO, decisions regarding treatment selection were simplified by defined first- and second-line treatment options in the National ART guidelines. Such standardisation is essential due to the limited selection of medicines in resource-

constrained settings[24]. Unfortunately, the current limited selection of ARVs leaves the physician with no choice for further options if the second line treatments fail. For such cases the guidelines instruct that the second line treatment be continued until there is no longer clinical benefit from the treatment[8].

Focus on adherence and the individual's needs

There was great emphasis on the importance of treatment adherence in this programme. Previous research has shown that important factors for long-term adherence to ART are: an 'easy to take' regimen, dispensing health facilities within easy reach of the patients, individual support and educational material[25]. Fixed combination tablets were not used in this health care setting, but collection points were those clinics which were within the easy reach of the each patient. Although educational material was available, written material is of limited value unless there are sufficient HCPs available to explain the meaning of its contents.

HCPs in the present study had experienced that the patients were concerned about the disability grant (DG). Previous research from South Africa has found that the DG is an important contributor to the income of households receiving this grant, and removal of this may be a serious threat to the household[26]. Since patients may loose their grants once their health condition improves, this may lead to a conflict between improving their health by being adherent or discontinuing treatment in order to qualify for the grant. The importance of understanding each individual's situation and needs was addressed to some extent by the social assessment carried out prior to ART initiation. Bringing these aspects into the mutual discussion about appropriateness of treatment initiation shows good communication and cooperation among different HCPs for the patient's benefit.

Limitations

Because this was a multilingual study setting (Xhosa, Afrikaans, English), there were a few situations where the researcher needed translation and explanation from the HCPs. This was particularly to understand what was communicated between the patients and the HCPs. A limitation to the study is that conversations, group discussions and observations were not audio or video recorded. Therefore it was not possible with a full transcription to provide verbatim quotations. Due to language barriers, patients' perspectives and satisfaction with the treatment programme could not be studied. Hence the facilitating and constraining factors identified came from data gained by observations at public health facilities and conversations with health care providers.

Conclusion

HCPs with extremely diverse educational backgrounds work together to provide health care for HIV-positive patients enrolled on the ART programme in this Makana LSA health care setting. Delegation of work tasks, availability of guidelines and close contact between HCPs facilitate the efficient use of the human resources available. Equity in treatment access is addressed by the opportunity for patients to receive treatment and counselling free of charge, and to become enrolled in the system at the clinic closest to their home. Major challenges were identified with respect to heavy workload, time constraints and the limited number of highly educated HCPs. When considering both facilitating and constraining factors, this programme shows potential for functioning as a successful provider of ART for those who are able and willing to access it. Limitations and challenges still exist in reaching out with adequate treatment to a greater number of people who need ART.

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Legislation, regulation, and consolidation in the retail pharmacy sector in low-income countries

Richard Francis Lowe, Dominic Montagu

Global Health Group, Global Health Sciences, University of California, San Francisco

Address for correspondence: Dominic Montagu, Global Health Group, Global Health Sciences, University of California, San Francisco.
Email: montagud@globalhealth.ucsf.edu

Abstract

Formal pharmaceutical retailing in most countries in the world is governed by regulations concerning ownership, staffing, medicines, prescriptions and prices. However, in most low and middle-income countries regulatory enforcement of these regulations is difficult or impossible constrained by limited government capacity, and complicated by the fragmented nature of pharmaceutical retail markets.

This paper documents the current status of private-sector retail pharmacy legislation and regulation in the low-income countries where private financing of healthcare is most important. We look at regulatory frameworks in 25 countries, what legislative and market forces are causing changes in the practice of retail pharmacies, and what the effects of these changes have been in recent years.

In most countries studied, pharmacy legislation and regulation is fragmented and there is sporadic and limited enforcement of regulations. Market consolidation through shared ownership, franchise arrangements, or formal collaboration, is usually impeded by ownership laws. Consolidation in South Africa has resulted from a recent legislative change, while in India it has been driven by refinement of existing legislation and changing market forces. In these two countries recent changes have permitted rapid expansion of pharmacy chains. The early effects of these chains appear to be lowered prices, greater competition, and an initial balance between newly opened stores in shopping centers and the closure of independent pharmacies.

Four main factors determine the extent to which consolidation is possible in the private pharmacy sector: 1. Legislation on ownership, 2. Regulation, licensing and registration of pharmacies, 3. Availability of qualified pharmacists, and 4. Access to finance to set up a pharmacy.

Keywords: Legislation, retail pharmacy, regulation, low-income countries.

Introduction

Most health delivery in low-income countries occurs in 'mixed market' systems, with care delivered by both government and private sector providers[1,2,3]. Within this larger category of 'private providers', cost, access, speed, anonymity, and other motivations drive patient selection of provider. Private pharmacies, drug stores and drug sellers are often the first point of contact for healthcare[4,5,6,7,8,9].

Formal private sector pharmaceutical retailing in most countries, including low-income countries is governed by regulations that prescribe ownership, staffing, acceptable medicines along with sources and quality standards, and pricing and prescription practices[10]. There is considerable variation between countries in the way retail pharmacies operates. While retail chains such as Boots, Walmart, Watsons, Farmacias Similares, and Payless are common in Canada, the US, the UK, and across much of Latin America and East Asia, many countries in Europe, Asia, and Africa impose regulatory limits on pharmacy ownership, prohibiting chains and discouraging franchises.

The great difference between the market for pharmaceuticals in Europe and the market for pharmaceuticals in low-income countries is regulatory capacity. German oversight of the country's 21,500 pharmacies is effective at assuring that medicines are dispensed by qualified and registered pharmacists and the sale of illegal, out-of-date, or non-prescribed medicines is prevented. In most low- and middle-income countries, regulatory oversight is constrained by governments which lack the enforcement staff, budgets, or efficient regulatory and judicial framework that exists in developed countries[11,12]. Regulatory inspections are few, enforcement is weak and infringements common[13,14,15,16]. Enforcement is made particularly difficult because the pharmaceutical retail market in most low-income countries is highly fragmented: the number of formal pharmacies is small compared to the many different types of retailers, such as dispensing doctors, medicine sellers, drug sellers and general stores that also sell a variety of drugs and healthcare remedies[13].

The result is widespread unregulated and sometimes illegal sale of restricted medicines, often without prescription and often by

unqualified staff [17,15,18,16,19,20]. In most low-income countries there is little, if any, quality control and retail prices are inflated and highly variable according to what each patient will pay[21,22,23]. Pharmacists working in these countries often complain that they are not viewed or valued as health care providers but merely as retailers or businessmen[24,25,26]. All of these factors are especially detrimental to the poor who, due to limited access and information, often have few choices when buying medicines.

This paper documents the current status of private-sector retail pharmacy legislation and regulation in those low-income countries where private healthcare plays a particularly important role. We look at regulatory frameworks in these countries, what legislative and market forces are causing changes in the practice of retail pharmacies, and what the effects of these changes have been in recent years.

Focus of study

We focused this study on 24 low- and middle-income countries (LMIC) having the highest private expenditure on health (PHE) as a percent of total health expenditure (THE) in 2003. The 23 countries were examined and South Africa was included because of recent legislative changes in its retail pharmacy regulation. South Africa ranks 36th in terms of PHE as a percentage of THE.

Average PHE as a percent of THE for the 24 countries was 74% and average expenditure on pharmaceuticals as a percent of THE was 35% (Table 1). Private expenditure on pharmaceuticals was almost five times greater than government expenditure on pharmaceuticals, likely indicative of both higher volumes purchased with private funds and higher prices in the private sector where such purchases mostly take place.

Table 1. Twenty-four selected countries and indicators for expenditure on health

Country	Rank	Private expenditure on health (PHE) (% of total expenditure on health) [1]	Out-of-pocket expenditure on health (% of private expenditure on health) [1]	Total expenditure on pharmaceuticals (% of total expenditure on health) [2]
Guinea	1	83.4	99.4	21.3
DR Congo	2	81.7	100.0	19.9
Cambodia	3	80.7	86.2	36.7
Myanmar	4	80.6	99.7	16.0
Armenia	5	79.8	80.6	52.6
Tajikistan	6	79.2	100.0	13.4
Burundi	7	76.7	100.0	29.8
Azerbaijan	8	76.2	96.8	7.8
Georgia	9	76.1	98.2	39.1
India	10	75.2	97.0	14.5
Togo	11	75.2	88.0	36.8
Nigeria	12	74.5	91.2	18.2
Uruguay	13	72.8	25.0	17.1
Côte d'Ivoire	14	72.4	90.5	17.5
Pakistan	15	72.3	98.0	27.1
Nepal	16	72.2	92.2	29.9
Vietnam	17	72.2	74.2	41.0
Cameroon	18	71.1	98.3	44.5
Lebanon	19	70.7	79.4	21.2
Uganda	20	69.6	52.8	15.4
Bangladesh	21	68.7	85.8	37.9
Paraguay	22	68.5	74.6	38.9
Ghana	23	68.2	100.0	32.8
South Africa	36	61.4	17.1	12.3

[1] Data from World Health Report 2006. Annex Table 3 Selected national health accounts indicators: measured levels of per capita expenditure on health, 1999–2003. World Health Organization, 2006, Geneva.

[2] Data from the World Medicine Situation 2004 Report, World Health Organization, 2004, Geneva

Table 2. Retail Pharmacy Legislation in a selection of low- and middle-income countries

Country	Ownership / Practice Legislation	Pharmacy Registration / Licensing	Drug sales / Prescription Legislation
Cambodia	Law on the Management of Pharmaceuticals 1996	Ministry of Health	
India	Pharmacy Act 1948 Food and Drug Administration India (FDA)	Food and Drug Administration India (FDA) (licensing). State Pharmacy Councils (Registration) reporting to National Pharmacy Council	Pharmacy Act 1948 Drugs and Cosmetics Act 1940
Nigeria	The Pharmacists Council of Nigeria Act 1992. Registration of Pharmaceutical Premises Regulations, 2005	Pharmacy Council (Registration)	National Agency for Food and Drug Administration and Control (NAFDAC)
Côte d'Ivoire	Pharmacy in Public Health of Cote d'Ivoire, "Draft of the Manual of Procedures of System of Management and Quality of Pharmacy in Public Health, February 2007. Directorate of Pharmacy and Medicaments	Administration of Pharmacies and Medicines, Ministry of Health. Order of Pharmacists. Syndicate of Pharmacists	
Pakistan	Pharmacy Act XI 1967	Pharmacy Act XI 1967	Drugs Act 1976. National Drugs Policy State regulations (Northern Area Drug Rules, Punjab Drug Rules)
Nepal	Drug Registration and Regulation	Department of Drug Administration	Drug Act 1978
Vietnam	Law 34-2005-QH11 of the National Assembly14 June 2005 on Pharmacy Ordinance on Private Medical and Pharmaceutical Practice 2003	Provincial-level Departments of Health issue "eligibility" and "practicing" certificates	Vietnam Drug Policy. Ministry of Health
Cameroon	Drug Law 1980	Administration of Pharmacies and Medicines, Ministry of Health	Republique Unie du Cameroun (RUC). 1980. Law No. 80/ 10 of 14 July 1980: To Regulate the Practice of Pharmacy
Lebanon	Law No. 367 1st August 1994 on the practice of the profession of a pharmacist	Directorate of Pharmacy, Ministry of Health	Law No. 367 1st August 1994 concerning the practice of the pharmacy profession
Uganda	National Drug Policy and Authority (Issue of Licenses) Regulations 1995 Pharmacy and Drugs Act 1971	National Drug Authority (Licensing) Pharmaceutical Society of Uganda (Registration / Certification)	National Drugs Policy and Authority Stature 1993. Pharmacy and Drugs Act 1971 (to be replaced by Pharmacy Profession and Pharmacy Practice Bill 1999)
Ghana	Pharmacy Act 1994	Pharmacy Council (Registration)	Pharmacy Act 1994 (also referenced in National Drugs Policy (2nd ed.) 2004)
South Africa	Pharmacy Act 153, 1974. Amended 1997, Enacted 2003	Director General of Health, Department of Health (Licensing) Pharmacy Council (Registration)	National Drug Policy 1996 Medicines and Related Substances Control Act 1965 (amended 1997)

Methods

Information on countries' retail pharmacy legislation, regulation and practice was collected through multiple sources. Peer-reviewed articles were sought through searches of academic databases including PubMed, ISI Web of Knowledge, and the International Pharmaceutical Abstracts using keywords on pharmacy-related terms[i]. Gray material and non-peer reviewed articles were obtained through online searches using the search engines Google and Google Scholar with the same terms used for the databases. The websites of the World Health Organization and the International Pharmaceutical Federation were searched for relevant information and reference publications. Government, Ministry of Health, Pharmacy Council or Association or drug regulatory authority websites in each of the 24 countries were searched and where appropriate contact information was available these agencies were also contacted by either e-mail or fax. Published experts in the field were asked for additional information, both general and country-specific, and requests for information were posted on the Essentialdrugs.org website.

Much of the information included in this paper is derived from personal interviews and gray matter publications such as online newspapers and pharmacy business websites. This is a reflection of the limited peer-reviewed research regarding pharmacy legislation and regulation in low to middle income countries.

Findings

Most of the information on legislation, regulation and pharmacy practice was obtained from national Pharmacy Council or Association websites, contact with officials in those councils or in Ministries of Health, or from websites that aggregated country legislation data[27]. A complete set of information on three areas of retail pharmacy – legislation, regulation, and practice – was only found for 12 countries, 11 of these low-income, and one, South Africa, a middle-income country. One country had data on two of these areas. Four countries, Armenia, Georgia and Uruguay, and Bangladesh, had information on only one area. We found insufficient information to draw conclusions about legislation, regulation, or practice of retail pharmacies in seven countries: Guinea, DR Congo, Myanmar, Burundi, Paraguay, Tajikistan and Togo.

Legislation and regulations

We collected information on legislation pertaining to the practice of pharmacy in 12 countries (Table 2). Columns one and two list legislation pertaining to practice and ownership, and prescription and drug sales respectively. Column three indicates which agencies are responsible for pharmacy registration and licensing.

All of the 12 countries studied have an Act or Law relating to Pharmacy or Drugs. This legislation determines who is allowed to practice pharmacy, the conditions under which a pharmacy may operate, and sets out rules for prescription and sales of drugs. In almost all countries prescription medicines and restricted medicines (such as psychotropic or narcotic drugs) can only be sold or dispensed at a pharmacy by a registered and qualified pharmacist upon presentation of a prescription. In some countries ambiguous legislation permits pharmacists to treat simple and common ailments with antibiotics dispensed without a prescription[5]. Over the counter and non-prescription medicines are sold at pharmacies and a variety of drug sellers or chemical shops, and may be sold by pharmacy assistants and staff with little or no formal training.

Registering and licensing of qualified pharmacists is usually the responsibility of a national or state Pharmacists' Association or Society, or a department within the Ministry of Health or government but may also be controlled by more than one entity. The Pharmacy Act often stipulates the conditions and legal structures under which these bodies can operate.

Ownership rules and restrictions

From legislative documents and articles about pharmacy we compiled information on ownership rules, restrictions and required qualifications of pharmacists for 12 countries (Table 3). In most of these 12 countries only qualified and registered pharmacists who hold a bachelors degree or pharmacy diploma are allowed to own pharmacies and can do so as individuals or sole proprietors. Ownership is often limited to one pharmacy per pharmacist.

In a small number of countries, a partnership or corporation is permitted to own a pharmacy but with the requirement that at least one, and sometimes all, of the partners are qualified pharmacists. These corporate entities may be allowed to own more than one pharmacy, provided again that a registered pharmacist manages each store.

Of the 12 countries studied, very few countries have retail pharmacy chains. The few chains in Nigeria, Pakistan, Uganda and Ghana are small, consisting of three to six stores each. Only two countries in our study are exceptions to this rule: India and South Africa. Both have seen tremendous growth in the number and size of chains in the past five years. In South Africa, this growth stemmed from a legislative change in 2003 that permitted corporate ownership of pharmacies for the first time. In India, liberal interpretation of laws on pharmacy licensing together with explosive growth in the retail sector opened the door to chain growth beginning in 2000, first within hospital chains, but since 2004 increasingly through stand-alone pharmacy chains and outlets located in grocery or general retail stores.

In Nigeria, ownership of more than two retail pharmacies by a corporation is permitted, provided that the partners are registered pharmacists and a licensed and registered pharmacist manages the store at all times. In Ghana, legislation permits multiple pharmacies to be owned by non-pharmacists, and a

[i] Search terms used: pharmacy, drug, medicine, chemical, seller, shop, store, retail, community, chain, private, practice, legislation, regulation.

Table 3. Ownership rules, restrictions and qualifications required for pharmacy staff

Country	Who can own	Ownership restrictions	Qualifications	Retail chains
Cambodia	Pharmacist only. Pharmacist without sufficient funds may own with another non-pharmacist	Must be Khmer. Maximum one pharmacy per pharmacist license. Locations based on commune needs	Diploma recognized by MOH. In pharmacist absence, someone who has attained suitable qualifications approved by MOH	Not permitted
India	Individuals, Partnerships or Body Corporates	Individuals must be pharmacists. Partnership and Body Corporate-owned stores must have a supervising pharmacist, often a *"signature pharmacist"*	B.Pharm (4 year degree) or D.Pharm (2 year diploma course from an approved institution followed by 500 hours of practical training over 3 months)	>10
Nigeria	Individuals or partnership	Individual must be registered pharmacist. Partnership must be with other pharmacists. Owner can register as superintendant in only one pharmacy. All stores owned must employ a pharmacist	B.Pharm, followed by 1 year internship	3-5
Côte d'Ivoire	Individuals only.	Must be registered pharmacist and be Ivorian. One pharmacy per pharmacist. Non pharmacists may not own (or manage)	Pharmacy Assistant may manage a store under responsibility of owner	Not permitted
Pakistan	Individuals and corporations	Individuals must be a pharmacist. For non-pharmacist owners (individuals and corporations), drug sales must be under continuous supervision of a pharmacist	Pharmacist (B.Pharm). Pharmacy Assistant (diploma). Persons who pass an examination in pharmacy held by a Provincial Council	2-5
Nepal	Individuals. A "legal person" (defined as 'Private Limited' or 'Public Limited' or 'cooperative organization' or "not-for-profit organization")	Individuals must be a pharmacist. "Legal person" owners: must have full-time pharmacist managing	Pharmacist (4 yr B.Pharm), Pharmacy Assistant or Technician (1.5 yr Certificate in Pharmacy), Professionalist or *Vyawasayi* (3 month course approved by Drugs Advisory Committee)	Not permitted
Vietnam	Individuals and organizations	Individual must be a pharmacist or has 5 years of professional practice	Pharmacy diploma from university, intermediate pharmaceutical school or primary pharmaceutical school, depending on pharmacy type	Not permitted
Cameroon	Individual	Individuals must be a pharmacist. Maximum of 1 pharmacy per pharmacist	B.Pharm	Not permitted
Lebanon	Individual	Must be registered pharmacist. Additional requirements for non-Lebanese	Diploma in pharmacy, over 20 and has part 2 baccalaureate	Not permitted

Country	Who can own	Ownership restrictions	Qualifications	Retail chains
Uganda	Individuals, Partnerships or Body Corporates	Individual: must hold a pharmacist license and be a Uganda resident. Partnership or Body Corporate: one partner or director must be pharmacist and Uganda resident	B.Pharm, followed by a pre-registration examination	3-5
Ghana	Sole proprietors or corporate entities	Pharmacists and non-pharmacists permitted to own. Must be a supervising pharmacist but can be part-time	B.Pharm, 1500 hours internship (480hrs in a recognized Community Pharmacy), pass in professional exams	3-5
South Africa	Individuals and Body Corporates	Individual must be a registered pharmacist in all stores. Must satisfy a need for a new pharmacy in that area	B.Pharm (4 yr), 12 month practical training period, pre-registration evaluation, 12 months public sector community service	>7

qualified and licensed supervising pharmacist need not always be present, meaning that the store can be managed by staff with lower-level qualifications. Ugandan law permits corporations to own a pharmacy, provided that at least one partner is a pharmacist, but ownership is still restricted to two pharmacies, thus restricting any broader market consolidation. In Pakistan chains are permitted, but have not developed. Chain formation in the remaining countries in our study, Cambodia, Cote d'Ivoire, Nepal, Vietnam, Cameroon and Lebanon, is prevented by one-pharmacist-one-pharmacy laws.

Legislative change and market consolidation

South Africa

The Pharmacy Act of 1974 only allowed for a pharmacy to be owned by an individual licensed and registered in one of four categories prescribed in the Act[28]. The Act was amended in 1997,[29] and the amendments ratified in 2003. The new statute allows non-pharmacists to own pharmacies, provided that a registered pharmacist is employed to run them at all times[30,31].

Since the legislative changes a number of pharmacy chains have appeared in grocery outlets. Clicks, a large retailer focused on health, beauty, entertainment and home furnishings, began opening in-store dispensaries in some of its 700 existing stores soon after deregulation[32]. It now has over 130 such dispensaries and is adding additional services such as screening and basic health care in some of its stores. The 30 year old company Dis-Chem, the second largest pharmacy group in the country announced in June 2008 that it was planning to expand through franchising in an attempt to speed up growth in the smaller cities and retain young pharmacy graduates[33]. Franchises would not be limited to pharmacists but would also be open to retailers, in recognition of the fact that the bulk of revenues from Dis-Chem stores are derived from retail and not the pharmacy sales. A number of other grocery and general retail chains such as *Pick n' Pay* and *Shoprite* have also opened in-store pharmacies. *Pick n' Pay* has also experimented with in-store pharmacy-clinic in one store, which provides basic health care diagnostics along with full pharmacy services[34].

The change in legislation and subsequent entrance of chain stores in the retail pharmacy market has added pressure to small retail pharmacies that were already struggling[35]. It is not clear if the addition of corporate chain pharmacies has led to the closure of independent pharmacies, but it seems likely. Despite this, overall pharmacy numbers are increasing: in the first four years after ownership deregulation the total number of pharmacies in South Africa increased by 15%[36].

India: Liberalization and competition

India's two main pieces of legislation that pertain to retail pharmacy are the Drugs and Cosmetics Act of 1940 and the Pharmacy Act of 1948. The Act requires individual States to create Pharmacy Councils, responsible for keeping a register of pharmacists and information relating to their qualifications and place of practice. A comprehensive revision of the Pharmacy Act was initiated by the Pharmacy Council in 2005 and is currently progressing through parliament[37].

Pharmacy licensing is controlled by the Food and Drug Administration of India which awards a license only to a qualified pharmacist to operate. However, many pharmacies set up by non-pharmacist businessmen are able to hire a *signature pharmacist* who works part time and fulfills the regulatory requirements. These pharmacies are generally staffed by pharmacy assistants or less well-trained staff[19].

Beginning in the mid-1990s hospital chains began to incorporate pharmacies into their facilities, creating de-facto pharmacy chains. Their success, combined with a growing urban middle

class market and greater access to financing as India's economy liberalized, led to the creation of independent pharmacy chains, the first around1997, expanding rapidly after 2000. As in South Africa, many of these chains have been located in grocery and general merchandise stores, but chains of stand-alone pharmacies are also developing. There are estimated to be around 1500-2500 pharmacies grouped in retail chains. Although this number is still very low when compared to the estimated 550,000 pharmacies and drug sellers countrywide, it is growing rapidly[38].

Retail prices for many medicines in India are set by the state. As a result, competition by chains has successfully emphasized discounting and delivery. Since 1997, one company, Subhiksha, has opened over 1000 stores in 90 cities and sells all medicines at 10% discount from the government set-prices.

Despite the tremendous interest in this area in the last five years, there is some evidence that expansion has slowed due to the rising cost of retail real estate, an overall shortage of qualified pharmacists and rising salaries. A comparison of the projections of five of the largest groups with the actual situation shows that by early 2008 none of them had come close to opening the number of stores initially projected (Table 4)[39]. Despite challenges, in 2007, more than a dozen other healthcare firms had plans for large-scale expansion into retail pharmacy[40].

The growth of retail chains has created friction with individually owned pharmacies, prompting the latter to organize against the perceived threat from large retailers. In June 2007, the All India Organization of Chemists and Druggists (AIOCD) launched an initiative to gather many of the country's 500,000 pharmacies and drug sellers into a single corporate entity, the All Indian Origin Chemists and Distributors Limited. The goal of creating this corporation is to coordinate direct purchasing from drug companies, standardize and share logistics, and to obtain supplies through a common system at lower costs. The new organization is to be formed in collaboration with State Chemist and Druggist Associations and planned to raise Rs 250 million ($5 million USD) through issuance of shares to members[41].

At the same time a smaller organization, the Retail and Dispensing Chemists Association (RDCA), is organizing 5000 individual pharmacies and drug sellers to adopt shared management practices, including customer loyalty schemes, and modernize stores with computerized dispensing records and air conditioning[42]. The organization is also working with wholesalers to prevent stock-outs in member pharmacies[43].

Normative countries: slow growth serving the wealthy and maintenance of the status quo

The remaining countries in our study have seen no changes in pharmacy retail practice or regulation and the few chains that do exist are small. In Nigeria, Medicines Plus is a wholesale, retail chain with 30 employees[44]. Their three stores are located in shopping malls in the Lagos area, cater to wealthy clientele, and are not representative of the pharmacies used by the majority of Nigerians.

In Pakistan, although permitted by law, chain stores are still rare. The largest chain in mid-2008 was Faizal Din's Pharma Plus group, founded in 1995, with eight pharmacies in Lahore. Larger chains, operating within the government hospitals, are planned but do not yet exist[45].

In Uganda there are at least two small chains of retail pharmacies, Vine Pharmacy,[46] and Gilead Pharmacy. Each has three to five stores. A third company, Abacus Pharma, has five branches and is also a wholesaler that has expanded into Kenya and Rwanda.

In Ghana, small chains of three or four retail pharmacies began to appear in the early 1980's. These have expanded to include some supermarket-based pharmacies, but the overall market is still dominated by independent stores. Early retail chains such as Ernest Chemists Limited, Kinapharma[47] and Kama Group[48] first became wholesalers and distributors before ultimately moving into manufacturing[49].

Discussion

Effective pharmaceutical policy is an essential piece of any country's legislation, particularly given the increasingly widespread availability of inexpensive prescription medicines. In many low-income countries, formulating policies to legislate and regulate the production, approval and sales of drugs remains challenging. Differences in legislation between neighboring countries, inadequate administration and enforcement, and a lack of qualified personnel, make this a particularly difficult area for many governments[50].

Table 4. Projected and actual retail pharmacy store openings in India

Healthcare Group	Projected stores	Projected date	Stores April 2008
Fortis Healthworld®	1,000	by 2012	45
MedPlus®	800	by early-2008	260
Lifeken®	700	by 2009	< 100
Medicine Shoppe®	500	by 2010	130
Cure & Care®	100	by 2008	2

This study found very little research on whether changes in pharmacy legislation and regulation in the context of increased privatization could improve the quality of practice, increase access to drugs, and lower the costs of medicines. We found few studies on the relationship between legislation and enforcement of regulations, and none that could be used as a guideline for low-income countries in the area of retail pharmacy specifically.

Consolidation has been a defining feature of the retail industry worldwide and pharmacy retailing is no exception. Chain stores are now common in the United States, the UK, and much of Asia and Latin America[51]. Even where chains are restricted, as is the case in much of mainland Europe, franchise contracts are being used to create de-facto chains[52].

Chain pharmacies have been evaluated by the Community Pharmacy Section of the International Pharmaceutical Federation (FIP),[53 54] and Australia's National Competition Council conducted a policy review on deregulation[55]. In Norway, the effects of total deregulation in the retail pharmacy industry in 2001 have been well documented[56 57]. Potential benefits and drawbacks of chain retailers highlighted by these articles are summarized in Box 1.

In comparison to high-income countries, the retail pharmacy sector in the countries examined has seen very little consolidation in recent years except for South Africa and India. Restrictive legislation, which includes allowing only pharmacists to own pharmacies and limiting the number of pharmacies that can be owned by each pharmacist, prevents consolidation in most low-income countries studies.

Where chains have formed they appear to have been facilitated by the existence of an urban middle-class market, but also by a legislative change, as in the case of South Africa, and by overall growth in the retail sector as in India. While we found no peer-reviewed research comparing the quality of services at chain pharmacies against that of independent retailers, reports from India do show that the appearance of the chains is stimulating competition, prompting some independent retailers to improve the quality of their stores and services in a bid to keep their existing customers.

Box 1. Benefits and drawbacks of chain retail pharmacies

Pros	Cons
Standardized quality	Profit driven and business focused
Improved efficiencies	Less personalized service – decrease in quality of care
Encourages effective competition	Opposition from Pharmacy Councils
Increased accessibility	Possible decrease in pharmacist accountability
Increase in pharmacies and pharmacists	Additional investment in infrastructure required
Expansion of new services	Potential loss of services in rural areas
Lower costs to consumers	

From our study, two other factors beyond ownership laws appear likely to effect consolidation where legislation allows it. First, there is a shortage of degree-level pharmacists in almost all the countries surveyed coupled with a universal requirement that professional pharmacists supervise pharmacies at all times – a law which is often flouted by 'mom-and-pop' pharmacies, but which corporate chains dare not disobey. This has almost certainly slowed pharmacy expansion in India and in many Sub-Saharan African countries. To address this, some researchers have proposed acknowledging the role that non-pharmacist drug sellers and dispensers play in the community by providing training to improve their skills[58] or by adapting legislation to match the country's enforcement capabilities[16].

The second factor which is limiting consolidation is the availability of financing for new pharmacies. This has been highlighted as a significant restriction for pharmacists in some countries[24]. Permitting non-pharmacist businessmen and corporations to own stores and employ pharmacists to manage them would appear to be an attractive option in these instances.

Conclusions

The private retail pharmacy sector is an important source of healthcare for millions of people in low-income countries. This study, although limited by the availability of data, shows that pharmacy legislation and regulation in many low-income countries is often inadequate, is largely un-enforceable, and in some cases, appears to work against the broader goals of the health system to assure affordable access to quality medicines.

Four main factors determine the extent to which consolidation occurs in the private pharmacy sector: 1. Legislation on ownership, 2. Regulation, licensing and registration of pharmacies, 3. Availability of qualified pharmacists, and 4. Access to finance to set up a pharmacy.

Experience from India and South Africa indicates that where legislation changes or where successful examples become known, market forces will quickly lead to growth in both chain and franchise operations for retail pharmacies. There remains very limited, and contradictory, evidence on the effects of this consolidation towards quality, pricing, enforcement of regulation, and responsiveness to patient needs.

Further detailed study and documentation of the impact of legislative and marketplace changes on the pharmacy sector in countries such as South Africa, India, Pakistan and in Latin America would be valuable in assisting low- and middle-income countries improve the quality of retail pharmacy.

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