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Original Article

Inflated medicine prices in Vietnam: a qualitative study

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Abstract

One third of the world's population lacks regular access to essential medicines partly because of the high cost of medicines. In Vietnam, the cost to patients of medicines was 47 times the international reference price for originator brands and 11 times the price for generic equivalents in the public sector. In this article, we report the results of a qualitative study conducted to identify the principal reasons for inflated medicine prices in Vietnam.

Between April 2008 and December 2009, 29 semi-structured interviews were conducted with staff from pharmaceutical companies, private pharmacies, the Ministry of Health, and the Ministry of Finance of Vietnam. Study participants were recruited using a combination of purposive and snowball sampling techniques. Interviews were recorded, transcribed and coded using NVivo8® software and analyzed using a framework of structure-conduct-performance (SCP).

Participants attributed high prices of originator medicines to a monopoly of supply. The prices of generic medicines were also considered to be excessive, reportedly due to the need to recoup the cost of financial inducements paid to prescribers and procurement officers. These inducements constituted a dominant cost component of the end price of generic medicines. Poor market intelligence about current world prices, as well as failure to achieve economies of scale because of unwarranted duplication in pharmaceutical production and distribution system were also factors contributing to high prices. This was reported to be further compounded by multiple layers in the supply chain and unregulated retail mark-ups.

To address these problems a multifaceted approach is needed encompassing policy and legislative responses. Policy options include establishing effective monitoring of medicine quality assurance, procurement, distribution and use. Rationalization of the domestic pharmaceutical production and distribution system to achieve economies of scale is also required. Appropriate legal responses include collaborations with the justice and law enforcement sectors to enforce existing laws.

Keywords: Informal payments, Medicine prices, Qualitative, Vietnam

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Key Messages

- In Vietnam, originator medicines were expensive, reportedly due to a monopoly of supply. By contrast, informal payments were a main driver inflating generic medicine prices.
- In an imperfectly competitive market, where the quality of generic medicines is not assured or standardized, financial inducements rather than reduced medicine prices become a significant strategy to gaining market access and retaining market share.
- Redressing the problems of appropriate access to affordable medicines in Vietnam requires a multi-faceted approach including both policy and legal responses.

Introduction

Cooperation with pharmaceutical companies to provide access to affordable essential medicines in developing countries is Target 8E of Millennium Development Goal 8 (United Nations 2008). Although some progress has been made, regular access to essential medicines is still out of reach of one third of the world's population (WHO 2004). In many countries, particularly resource poor settings, consumers pay the full cost of the medicine, commonly referred to as consumer out-of-pocket payments, which contributes significantly to the problem (WHO 2004). More recent data from household surveys and studies confirm the estimate (Cameron *et al.* 2009; Hogerzeil and Mirza 2011) .

Not an exception, Vietnam was also reported to have problems with access to affordable medicines (Nguyen *et al.* 2009). In Vietnam, major reforms in the health sector were initiated in 1989 following the 1986 economic reform 'Doi Moi' (renovation). As part of the reforms, market-oriented measures were implemented; user fees were introduced and private health sector legalized (WHO 2007). Medicines in the public sector were no longer free (Larsson 2003). Strict medicine price controls prior to 1989 were removed and the shift to free pricing (Nguyen *et al.* 2010) led to sharply increased medicine prices overall (Inspectorate of the MOH of Vietnam 2007).

To curb price rises, Vietnam has introduced several regulations since 2003. Using the mechanism of price declaration and the publication of price information, Vietnam aimed to improve transparency of medicine prices along the supply chain. The initiatives, however, have not been successful as expected. Because of the suboptimal regulation content, the pharmaceutical industry was able to declare and publish the highest price as the market would bear. Ineffective enforcement of the regulations further compounded the problem (Nguyen *et al.* 2010).

In Vietnam, medicine prices have been excessively high. Results of a medicine price survey using the World Health Organization/Health Action International (WHO/HAI) methodology showed that adjusted for Purchasing Power Parity, prices for outpatients in the public sector in 2005 were 47 times the international reference price for originator brands and 11 times for the lowest-priced generic equivalents (Nguyen *et al.* 2009). In addition, in contrast to other countries in the Western Pacific Region (Cameron *et al.* 2009), medicine prices were higher in Vietnam's public sector (i.e. public hospital pharmacies) than in private pharmacies (Nguyen *et al.* 2009). Another unusual finding was that in the public sector some so called 'lowest-priced' generics were more expensive than their corresponding originator brands (Nguyen 2011).

These findings suggest anomalies in the medicine price structure in Vietnam, especially in the public sector. To better understand the results from the quantitative medicine price survey (Nguyen *et al.* 2009), a qualitative method was adopted. Interviews with key stakeholders were conducted to investigate (1) the medicine price-setting behavior in the public and private sectors in Vietnam, (2) the main medicine price components and (3) the factors influencing medicine prices.

Methods

Context

In Vietnam, increased reliance on market mechanisms has resulted in a diminished role for the public sector in supplying medicines to the population. State-owned pharmaceutical enterprises and public medicine outlets are no longer the sole provider of medicines in the country following the introduction in 1989 of the Public Health Protection law, which for the first time allowed private medical and pharmaceutical practices. Subsequently, the protectionism afforded to State-owned pharmaceutical enterprises by Directive No. 03/1997/BYT-CT[1] was phased out. The liberalization of the pharmaceutical production and distribution and legalization of private pharmacy and medical practices (WHO 2007) has created a complex pharmaceutical supply system in Vietnam.

Locally produced medicines can be distributed directly by their Vietnamese producer to retailers and healthcare facilities or indirectly through wholesalers or distributors. Vietnamese manufacturers can also supply medicines directly to end users if they hold a retail license. Foreign entities that directly invest in local manufacturing, known as Foreign Direct Investment (FDI) producers are classified as domestic pharmaceutical producers, thus being able to distribute directly the products that they manufacture in Vietnam (Nguyen and Roughead 2015). By contrast, medicines produced overseas from international manufacturers have to be distributed by a local company (MOH of Vietnam 2006).

With regard to market share, domestically produced medicines, produced by some 180 domestic manufacturers, account for <50% of the market share (MOH of Vietnam 2013), and this is mostly for low-cost and low-technology generic products (BMI 2009).

Challenges exist for local producers to be competitive in the market place. Apart from 22 FDI factories (DAV 2009b), most locally-owned producers have limited capacity in research and development (R&D), capital and business administration. In addition, about 90% of the raw materials used in domestic production have to be imported (Cao 2008), of which 95% focus on a limited therapeutic groups such as antibiotics, vitamins, antipyretic, analgesics and antispasmodic drugs (MHBS 2010). This has led to a proliferation of similar products from local manufacturers who are then competing for a very limited market share. For example, in 2011 locally produced medicines included 13 268 brands for 524 active substances, averaging 25 brands per substance. At the extreme end of the range were 1,044 locally produced brands containing paracetamol (MOH of Vietnam 2013).

Medicines imported into Vietnam are generally specialized products. In 2011, the range of imported products included 15 552 brands for 971 active substances, averaging 16 brands per substance. Similarly to locally produced products, trading duplication also exists with imported medicines. For example, for the active substance, cefixim, there were 458 imported brands (MOH of Vietnam 2013). Trading duplication of imported medicines has also led to fierce competition for a limited market.

There are 90 Vietnamese pharmaceutical importers, most of which are State-owned or equitized companies that have been privatized from State-owned ones. About 81 of these importers compete against each other for one-quarter of the total imported medicines market share. The remaining 75% market share of imported medicines is accounted for by the nine biggest importers (VCA 2009). Nevertheless, importers' earnings are limited to their mandated import fee, ranging from 1% to 3% of the import value. Foreign manufacturers, of which there are 438 who distribute via the importers, account for the majority of the earnings, as they set both the imported price and the selling price of their products (VCA 2009).

There are three international distributors who play an important role in the distribution of imported medicines in Vietnam. Because foreign distributors are prohibited from direct medicines distribution in Vietnam, these distributors have established their FDI entity and registered for logistics services only (DAV 2009a). However, they just need to pay an import fee for their Vietnamese counterpart to import medicines into Vietnam and legally issue the invoice to their customers. All other tasks of the medicine distribution within the country from taking the orders to delivery of medicines to customers have been being undertaken by them.

The within country pharmaceutical distribution network also include about 800 domestic private wholesalers and distributors (DAV 2009a). They are often small in scale and limited in a financial capacity. These companies mainly distribute branded generic medicines imported from major generic manufacturers in Asia, Eastern Europe or South America.

Two main players in the pharmaceutical retail sector are retail medicine outlets and hospital pharmacies. Most medicines are purchased via the hospital pharmacies, of which there are >1000 and which accounts for 60% to 70% of the retail pharmaceutical market share. The remaining 30% to 40% of market share is accounted for by private pharmacies and other retail medicine outlets (Thanh Hải 2008). Imported medicines account for a dominant market share in the hospital market, being 94%, 77% and 39% for central, provincial and district hospitals, respectively (MOH of Vietnam 2013).

Data collection and interview instruments

In-depth interviews, guided by a prepared index of topics (c.f. Patton 1990) were adopted in this study. The index reflected two frameworks: the stages of the pharmaceutical supply chain (Table 1) (WHO & HAI 2008) and the pharmaceutical management cycle (Figure 1) (MSH 1997). Focus was on different price components incurred as a medicine moves along Vietnam's pharmaceutical supply chain. The impact of the Vietnam pharmaceutical distribution network, pharmaceutical production, and government controls on medicine prices was also explored to identify factors influencing medicine prices. Correspondingly, informants from pharmaceutical industry and government pricing authorities were recruited using a combination of purposive (c.f. Patton 1990) and snowball sampling techniques (c.f. Hendricks and Blanken 1992, Faugier and Sargeant 1997). Ethics approval was obtained from the University of New South Wales.

After each audio-taped interview, the record was transcribed *verbatim* in Vietnamese. The main topics discussed in the interview and emerging themes were summarized in a one page summary sheet (c.f. Miles and Huberman 1994). This preliminary analysis guided the data collection process and the emerging themes were further addressed in subsequent interviews. The combination of the transcript, summary sheet, and field notes from the interview formed one interview record for final analysis.

Table 1. The staged approach to price components

	Imported medicines	Locally produced medicines
Stage 1: Manufacturer's selling price (MSP); Cost, insurance and freight (CIF) price	MSPs Insurance Freight	MSP
Stage 2: Landed cost	Inspection Banking fees Port fees Customs fees Import tariff and importer's fees Storage Insurance Local transport	Local transport
Stage 3: Wholesale cost	Overhead costs: rent, salaries, electricity, security . . . Warehouse mark-up Government stores charges Local transport	
Stage 4: Retail cost	Overhead costs: rent, salaries, electricity, security . . . Health centres charges or retail mark-up	
Stage 5: Dispensed cost	Dispensing fee Sale tax Value Added Tax (VAT)	

Source: World Health Oganization & Health Action International (2008).

Data analysis

Final interview records were analyzed using a framework of structure-conduct-performance (SCP) to identify possible factors influencing and contributing to high medicine prices in Vietnam. Specifically, the SCP framework adapted by Palafox *et al.* (2015) for analyzing factors influencing prices of antimalarial medicines was adopted and adapted to guide the development of a coding system in our analysis. Under this framework, market performance outcomes such as the price, availability and quality of medicines are determined by factors associated with provider conduct (e.g. pricing and price competition, product differentiation and non-price competition, vertical restraints and response to regulation). Those factors in turn both influence and are influenced by factors related to market structure (e.g. range and characteristics of sellers, distribution chain structure and vertical integration, regulatory system and barriers to market entry) and consumer demand (e.g. information on product characteristics and prices). For between-countries comparisons, these inter-relationships need to be examined within the context of national features such as the socioeconomic situation and the health system to understand inter-countries differences (Palafox *et al.* 2015).

A hierarchy of codes (i.e. coding trees) was initially built with three broad categories of 'market structure', 'consumer demand' and 'provider conduct'. As the coding progressed, the coding structure was further developed by adding sub-categories under each main category in light of the SCP framework (Palafox *et al.* 2015). Connections across sub-categories were identified through constant comparisons of codes and those connected in a broader concept across sub-categories were grouped together to develop new sub-categories. QSR NVivo Version 8 software (c.f. Bazeley 2007) was used to support coding and analysis.

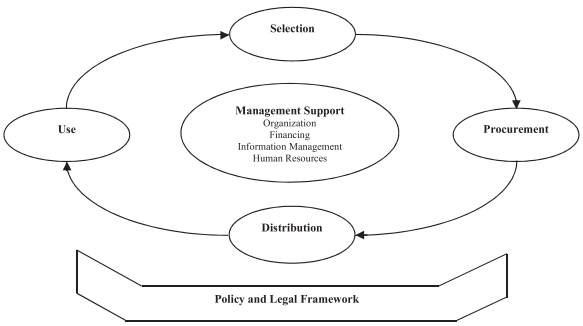

Figure 1. The pharmaceutical management cycle.
Source: Management Sciences for Health (1997).

Results

Participant characteristics

In total, 27 individual interviews and two group interviews were conducted, involving 35 participants from pharmaceutical companies, private pharmacies, Ministry of Health and Ministry of Finance of Vietnam. Some informants participated in both individual and group interviews. Detailed participant characteristics are presented in Table 2. The iterative sampling with preliminary analyses indicating the need to focus on the practices of private pharmaceutical companies led to a skewed final sample towards this group.

Market structure

Different factors related to market structure were identified when interview participants discussed the impact of the Vietnam pharmaceutical distribution network, pharmaceutical production, and government controls on medicine prices.

Range and characteristics of sellers

Interview respondents first commented on the lack of economies of scale among local pharmaceutical manufacturers as reflected in the following quote.

> Vietnam is not a big pharmaceutical market, with a market size of around USD 1 billion. It would be relevant to Vietnam if we had about five manufacturers big enough to produce medicines for the whole market. Currently, we have hundreds of factories so the capacity of each factory is not high, leading to higher costs of production and higher prices. (A private pharmaceutical company manager)

Respondents from private pharmaceutical distributors also asserted that their '*small-scaled business*' on the one hand deprived them of obtaining lower prices from international pharmaceutical producers due to lack of capacity for bulk purchase. On the other hand, it made them less attractive to originator brand manufacturers from '*Western Europe and North America*'.

> European partners don't want to trade with small companies. They often ignore small orders of USD 20,000 to 30,000. That is why small domestic companies have to buy Indian and Korean products, since Indian producers are willing to supply to orders of around USD 10,000. In contrast, European producers never reply to the orders of USD 10,000 to 20,000. That is why, although we like to trade European medicines, we can't buy them. (A manager of a pharmaceutical importer)

Table 2. Characteristics of participants

Participant group	Total Number	Sector			Gender	
		Public	Private	Foreign	Male	Female
Pharmaceutical Industry	**28**	**3**	**18**	**7**	**16**	**12**
Pharmaceutical company managers	18	3	12	3	15	3
Medical representatives	6	0	2	4	1	5
Private pharmacy owners	4	0	4	0	0	4
Policy makers	**7**	**7**	**0**	**0**	**4**	**3**
Ministry of Health officials	5	5	0	0	3	2
Ministry of Finance officials	2	2	0	0	1	1
Total	**35**	**10**	**18**	**7**	**20**	**15**

Range of products available

Interview respondents often distinguished originator brand medicines from their generic equivalents when talking about the range of pharmaceutical products. While generic medicines were distributed by an array of small scaled domestic distributors, market power was reportedly highly concentrated on the three FDI logistics companies that are multinational distributors in the originator brand submarket. This was said to result in a supply monopoly of originator brand medicines enjoyed by these three FDI logistics companies and their originator brand manufacturers and *'a monopoly automatically leads to high prices'*. Other factors contributing to high prices of originator brands included *'costly R&D [research and development] expenses'* and the global pricing policy of monopolistic originator companies.

> You cannot interfere with the price of originator brands at this stage. Originator companies have a global pricing policy, which is very clear. If they cannot have an expected profit, they will withdraw their products from this small market [...] (A foreign company manager).

Distribution chain structure and vertical integration

Respondents from domestic pharmaceutical distributors said that they could not *'negotiate with producers of originator brands'* to distribute originator products. They referred to the vertical integration in the supply chain of originator brand medicines where *'originator brand companies have their own distribution channels already'*, thus ostensibly leaving domestic distributors to be *'only able to import generics'*. A plethora of small domestic distributors also reportedly created a multi-layered pharmaceutical distribution network in which each layer factored a mark-up into the final medicine price to patients.

In contrast, lack of backward vertical integration was also reported to influence prices of locally produced medicines in Vietnam. Respondents from both the pharmaceutical industry and the Ministry of Health admitted that *'Vietnam's pharmaceutical market is heavily dependent on imports'*. The inability to control subsidiaries that produce active pharmaceutical ingredients (API) and associated raw materials together with reliance on the international market for API made the production cost of locally produced medicines fluctuated with imported API prices. The recent devaluation of the Vietnam currency against international currencies further compounded the problem given that API importation needed to be financed from foreign exchange funds.

Regulatory system and government restriction on market entry

Suboptimal regulation was reported to inflate prices of imported medicines. Respondents first remarked on the effect of the importation tariff such as *'a preferential importation tariff of 15%'* for *'oral ampicillin'*. Incurred early in the medicine supply chain, this tariff had a multiplying effect on the final medicine price when later percentage mark-ups added along the way. The Value Added Tax (VAT) was also reported to contribute to the final price of medicines. While the VAT of 5% for medicines was applicable for all customers, respondents discussed the poor enforcement of the law resulted in a disadvantage for hospital pharmacies (requested VAT invoices, thus having to pay the 5% VAT) against private pharmacies (did not require VAT invoices and did not have to pay the VAT). This was alleged to contribute to a higher final medicine price in public hospital pharmacies than in private pharmacies.

Government restrictions on the entry of FDI logistic companies and foreign pharmaceutical firms into the pharmaceutical distribution chain meant that these companies had to pay domestic importers to deliver their products, adding one more layer of costs into the distribution chain. Similarly, many domestic pharmaceutical companies without an import-export license wanting to supply imported medicines had to pay the licensed importer a mandated importation fee, as reflected in the following quote.

> [...] you have to pay a mandated importation fee if your company doesn't have an importation license. It is about 1.5 to 3%, [...] 2% on average depending on the value of the shipment. (A private pharmaceutical company manager)

Market intelligence and flow of market information

Respondents from both importers and private distributors considered that inadequate market intelligence (i.e. knowledge of the pharmaceutical manufacturers, products availability and prices) limited their ability to import medicines at the cheapest price. This also limited the ambit of their price negotiations; being able to choose only the cheapest medicines among what they knew. The most well-known markets among participants were *'some traditional markets such as India, Korea and selected Eastern European countries'*. Respondents claimed that limited knowledge of the available choices contributed to high imported prices and subsequently inflated final medicine prices in Vietnam.

The inadequate market intelligence was also reported to add unnecessary costs to the final price of medicines. For imported medicines, there were three main sources of market intelligence: 1) local importers, 2) an intermediary, the so-called *'consultant'* who could be *'a mandated importer, but more often was a representative from a foreign office'* and 3) the foreign manufacturer. Respondents indicated that private wholesalers often relied on a third party rather than directly contacting foreign manufacturers to negotiate prices and buy medicines. Consequently, they had to pay add-on costs, either in the form of *'a medicine seeking fee'* for the consultant or from the importer's mark-up, ranging from *'1.5 to 3%'* of the value of the shipment.

Consumer demand

Information asymmetry regarding product characteristics and prices

The information asymmetry between patients and medicine suppliers was emerged as a dominant theme discussed by respondents from the private pharmacy group that allowed them to set a high retail price to patients. Pharmacy owners reportedly preferred to have some medicines with an *'uncommon trade name'* that prevented patients from comparing prices between pharmacies. The resulting lack of price competition enabled private pharmacy owners to sell these medicines, even locally produced ones, *'with a price even higher than that of the originator brand'*.

Also exploited was the lack of patients' knowledge of the product characteristics and prices. Because of this, retail pharmacists could set a retail mark-up as high as 400%, especially in the absence of regulation on retail mark-ups in private pharmacies, as reflected in the following quote.

> [...] with not-too-expensive medicines [often locally produced medicines] we have a higher mark-up [...] for example, the sale is only USD 0.5 but our profit is as much as USD 0.4. Almost

> 50% of patients who come to my pharmacy are sold one medicine of this type. (A private pharmacy owner)

Provider conduct

Market segmentation, pricing and price competition

Interview respondents spoke of two relatively divided submarkets, where domestic wholesalers and distributors used different pricing strategies. The first was termed the *'free market'*, which included *'chợ thuốc'* (pharmaceutical wholesale market) and private pharmacies. In this submarket, all types of medicines were sold without 'detailing' to prescribers. Instead, a competitive, low selling price was set to influence customers.

The second submarket, where medicines were sold with the support of medical representatives detailing to prescribers, was termed the *'hospital market'*. This submarket included hospital pharmaceutical departments (serving inpatients and insured outpatients) and hospital pharmacies inside the hospital (serving uninsured outpatients). This submarket was further classified into public hospital and private hospital submarkets. Participants from private domestic distributors said that because private hospitals were new in the field (i.e. most private hospitals were recently established) and privately owned, *'they [private hospitals] have to buy good quality products with reasonable prices [to attract more patients] to maintain their own hospitals'*. Therefore, *'they [private hospitals] bargain directly to have a lower price for quality medicines'*. As a result, Vietnamese distributors competed by price to sell their medicines to private hospitals.

By contrast, public hospitals were established in the market, which was *'always overcrowded'*. This, together with the fact that public hospitals were publicly owned, reportedly resulted in no motivation for public hospitals to attract more patients by having lower prices of quality medicines. Therefore, pharmaceutical distributors responded to public hospitals differently. Instead of lowering the price of their medicines, in fact they inflated their medicine prices in the public hospital submarket.

> A tablet of cefixime, a third generation cephalosporin, which is imported from India, for example, and sold with the INN [International Non-proprietary Name] name of cefixime in the 'OTC' [Over The Counter] market[2] without detailing to physicians, had a price of USD 0.11 – 0.125 per tablet. However, this medicine, also from [the same] Indian [manufacturer], imported with its own brand name by another company to sell in [public] hospitals with detailing to doctors, is sold at USD 0.5 – 0.6 per tablet. (A private pharmaceutical company manager)

Product differentiation

A culturally embedded link between the quality and price of the pharmaceutical products emerged as a dominant theme. Participants' responses suggested that the medicine source was related to the medicine quality, hence price. Originator brand medicines often from Western countries were believed to be of higher quality and better efficacy than their generic versions, thus having highest prices. Among generic medicines, the quality was believed to go down from Western Europe or North America to Eastern Europe to Asia. Consequently, the generic price was set highest for Western European products and lowest for Asian medicines.

The following quote also illustrates that medicine prices were subject to the perceived quality of the raw materials.

> Our Indian business partners said that the price of a medicine made from Indian sourced active pharmaceutical ingredients (API) was USD 1 but if I accepted the medicine made from Chinese API they could sell it to me for half the price, only USD 0.5. Therefore, the price will go with the quality [...] they could offer me a cheaper price but I have to accept the API of the medicine is from lower quality sources [...]. The API of cefixime from Austria or Italy has a current price of USD 700 to 1,200 per kg. However, if we buy it from China, the price is only USD 200-300 while from India it is USD 400-500. (A private pharmaceutical company manager)

Non-price competition and informal payments

Interview respondents from local manufacturers spoke of the lack of availability of routine bioequivalence (BE) testing[3], which *'has just been done for very few medicines'*. This together with the misconception of generic medicines among health care providers reportedly disabled Vietnam distributors to compete against originator products based on quality and reputation. The cultural belief of *'you get what you pay for'* also prevented domestic private distributors to compete by price in the public hospital submarket where *'what is in it for me'* was reportedly a substantial motive for procuring and recommending a specific product. Offering material benefits and inducements (informal payments) to procurement officers and prescribers in this submarket was the only choice left for local private distributors to gain market access for their perceived lower quality generic medicines. To recoup the additional costs of the inducements, they inflated the selling prices, which were set at *'80% of the originator brand price for European generics and 60–70% for Asian products'* or by *'multiplying the procurement price by 2.5 to 3 times for European medicines and by 3.5 to 4 times for Asian products'*.

> People using generics assume that the products are cheap, but in fact they are paying an extremely high price against the real value of the medicines. They have to pay for the commission that pharmaceutical companies give to physicians. If this type of medicine had not had a commission, nobody would have prescribed these 'lởm khởm' [bad quality] products. These medicines would surely have not been able to be sold. (A manager from a foreign pharmaceutical company)

Informal payments were the reason most frequently cited by respondents for high priced generic medicines in Vietnam. A typical situation was that *'patients have to pay a virtual price [the price that does not reflect the real value of the product] that includes informal expenses of up to 40–60% of this price'*, involving *'informal payments to authorities, commissions for prescribers, and kickbacks to hospital pharmaceutical departments'*.

Managing expired products

Interview respondents from pharmaceutical distributors repeatedly distinguished the pharmaceutical market from other commodity markets by emphasizing the importance of the medicinal products' expiry date. They stated that unlike many other commodities, medicines often had an expiry date and had to be disposed of upon expiry. Some expired medicines were even required to be destroyed in a special way, which incurred further costs. In response, companies had to factor these expenses into the final price of medicines as noted below.

> Another issue is expired products. If we cannot win a tender after one year, the medicine will expire and we have to destroy it. How are we to be reimbursed for this loss? [...] We have to calculate it as an expense contributing to the final price of the medicine. (A private pharmaceutical company manager)

Managing marketing costs

Distinguishing the marketing practice for medicines from that of other commodities, respondents from pharmaceutical distributors suggested that unavoidable high pharmaceutical marketing costs inevitably led to a high final medicine price.

> Marketing cost is huge [. . .].The expenses for doctors, for holding conferences, seminars or even for printing promotional leaflets are very high. We have to pay high salaries to our promotional staff since they are pharmacists. We also do clinical trials, providing samples for free. All these expenses cost a great deal. (A private pharmaceutical company manager)

Different price components, derived from data provided by a private distributor respondent, for a typical generic medicine their company imported from Asian countries and sold into the public hospital submarket are presented in Figure 2.

Response to regulation

Factors contributing to high prices of generic medicines were reportedly attributed to a lack of effective government controls. Respondents sometimes discussed issues regarding the lack of controls such as lack of regulation on retail mark-ups in private pharmacies. More often they talked about the problems of lack of transparency, accountability and enforcement of existing regulations that led to '*nobody follows rules and regulations*'. For example, they said that '*one of the weakest points in governance in Vietnam*' was a lack of transparency both in regulations' content and the implementation of regulations. Some regulations were said to contain ambiguous provisions, which not only caused difficulty for pharmaceutical companies to follow but also enabled the authorities to act at their own discretion. One pharmacy owner said *'with our [ambiguous] regulations, anywhere the authorities look; they will find alleged breaches of regulations'*.

Vietnam's financial system with dominant cash-only transactions was reportedly another source of lack of transparency. A manager from a State-owned pharmaceutical company commented: *'In Vietnam, all financial activities are done with cash-in-hand so we cannot control corrupt practices. We need to do transactions through bank accounts. In an economy without a transparent financial system, we cannot control corrupt practices'*.

Accountability refers to the obligation of individuals or agencies to inform other actors about their decisions and actions, to justify or explain them, and to suffer sanctions and punishment for non-performance, misconduct or corrupt behaviors (Brinkerhoff 2004). The expected magnitude of any applicable punishment and sanctions for misconduct 'gives teeth to accountability'. Referring to the fine for breaching the pricing regulation of not selling medicines at a higher price than the published price, one manager from a foreign company said that *'a fine of [VND-Vietnamese currency] 300 000 [equivalent to USD 12.5] is not enough to even threaten a kid in year three'*.

Brinkerhoff (2004) states that 'sanctions without enforcement significantly diminish accountability'. Poor enforcement of regulations was reported to be a big problem in Vietnam. A foreign company manager said *'if they [the authorities] really want to control [the market], they can. However, the concern is whether they want to control [the market] or not'*. Most participants believed that *'at least in the next 10 years, Vietnam will still not be able to address the corrupt practices in the health sector.'* In fact, participants were so convinced of the lack of any consequence that they said: '*We dare to tell you all our secrets because when you are able to address the problem [using informal payment to gain market access], our hair will have turned white. This problem has existed for many years'*.

Figure 3 provides a summary of the components of the structure, conduct, performance framework identified in this study.

Discussion

Our study provides rich qualitative evidence on the failure of a sharply deregulated medicines market to deliver price competition and affordability in Vietnam. Study participants attributed the increased prices of originator medicines to a monopoly of supply. Prices of branded generic medicines were also considered to be excessive, at about 80% of that of originator brands or even higher. This effect was reportedly because of the need to recoup the cost of financial inducements paid to prescribers, procurement officers and

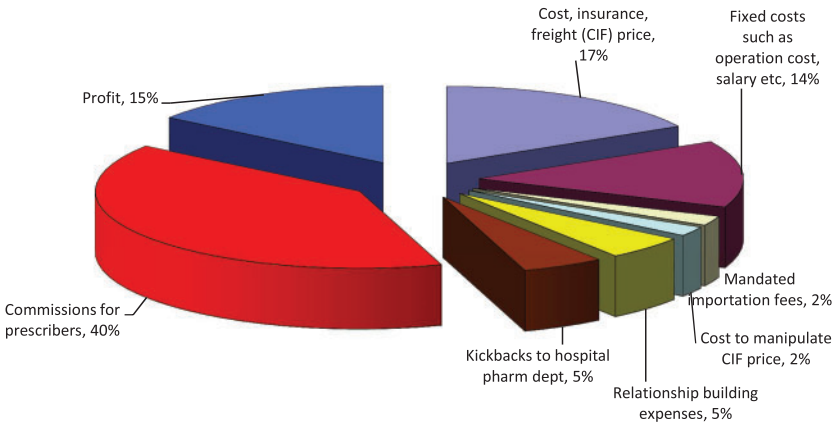

Figure 2. Example of the price structure of an imported medicine sold in the public hospital market.
Note: All the price components were re-calculated as a percentage of the end sale price.

supply authorities. Inducements constituted a dominant cost component of the end price. Poor market intelligence about current world prices, as well as failure to achieve economies of scale because of unwarranted duplication in pharmaceutical production and distribution were also factors contributing to high prices. This was reportedly further compounded by multiple layers in the supply chain and unregulated retail mark-ups.

Using the established analytical framework of SCP (Palafox *et al.* 2015), we were able to link the market performance outcome of high medicine price in Vietnam to different factors related to provider conduct in response to factors associated with market structure and consumer demand. The most critical themes emerging from this study were the culturally embedded link between quality and price across the market (i.e. you get what you pay for), and the use of informal payments. This effect is a result of a combination of interconnected factors related to market structure. They include the failure of the regulatory system to ensure the quality of generic medicines, the plethora of small scale domestic distributors competing against one another but unable to compete based on product quality or price, and the monopolistic position of the originator brand producers and distributors.

Another dominant theme that emerged was the negative response by providers to regulation due to the failure of the regulatory system. Lack of transparency, accountability and enforcement of medicine pricing regulations was reported to make the regulations less of a deterrent. This in combination with a lack of regulation of generic medicine prices or market regulation ensuring a fair price competition led to undesirable conduct where inflated generic medicine prices were set, sometimes at prices even higher than the originator brand price. Disturbingly this became the norm as a means to fund inducements considered necessary to enter the market and retain market share. While informal payments and undesirable forms of competition were found in this study to be the main reason for high prices of branded generic medicines sold into the public hospital market, the existing medicine pricing regulations were not considered sufficient to address these problems. Our study sheds some light on the failure of the medicine pricing regulations in Vietnam (Nguyen *et al.* 2010), showing that effective regulations addressing upstream determinants of high medicine prices and regulatory capacity enhancement are needed.

Unlike Vietnam, more developed markets have achieved better performance on prices of generic medicines. In the USA medicines prices are not regulated. However, the regulatory system including competition regulations is strong enough to ensure significant price competition. As a result, at the time of the launch of first generic medicine the average generic price is about 75% of the originator brand price and is further reduced to about one-fifth of the initial average generic price when more generics enter the market (Kanavos *et al.* 2008). In some European markets, generic medicine prices are directly regulated to be only a fraction of the originator brand price (Vogler 2012; Nguyen *et al.* 2014). For example, in France, generic medicines are required to be priced at <50% of the off-patent originator price to be listed for reimbursement (OECD 2008).

Other components of the SCP framework identified in this study include market intelligence and flow of market information, economies of scale, monopoly and taxation on medicines. These findings are corroborated by other studies. For example, poor market intelligence and failure to obtain economies of scale have been reported to increase medicine prices in developing countries (Levison 2003). Inadequate regulations on price mark-ups, taxes and tariffs on medicines have been documented in other Western Pacific regional countries (WHO-WPRO 2005) and across the globe (Levison and Laing 2003) as being associated with high medicines prices. A previous study in Vietnam also showed the virtual monopoly of multinational companies in the distribution of off-patent originator medicines through the three major FDI logistics companies that are dominant in Vietnam's specialized medicine market (VCA 2009). The position of market power allowed multi-national manufacturers to enter into various price maintenance arrangements with the distributors to artificially inflate medicine prices and reduce competition (VCA 2009).

In Vietnam there is an interconnection between market structure, consumer demand and provider conduct, influencing high medicine prices. To fix the problem of the high prices of originator brand medicines greater collaboration is needed between the Ministry of Health and the Ministry of Industry and Trade. This would assist authorities in the two ministries to identify poor practice in the pharmaceutical industry so that relevant legal tools and resources could be used to deter inappropriate pricing practices and competition restriction activities (Forzley *et al.* 2013). Compulsory licensing, stipulated in Vietnam's Intellectual Property law, can be used to

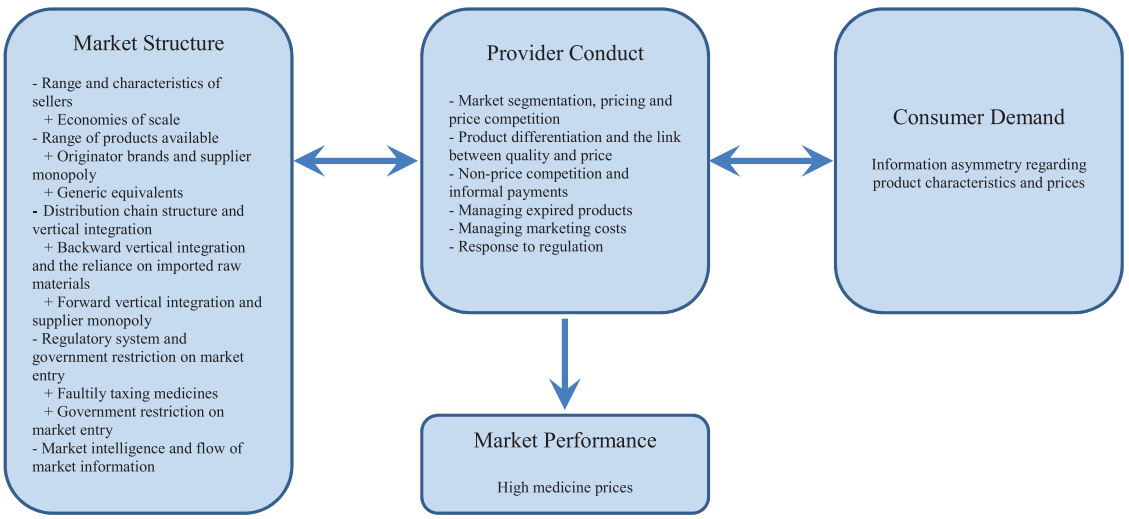

Figure 3. Components of structure, conduct, performance framework explaining high medicine prices in Vietnam.

remedy anti-competitive practices. Using other WTO/TRIPS compatible safeguards such as parallel importation can promote a competitive generic medicines market (Correa 2000).

To lower generic medicine prices, the dominant informal payments component needs to be eliminated. For this to occur, both actual quality and culturally perceived quality of generic medicines need to be addressed. The former can be achieved through strengthening the national medicine regulatory system with bioequivalence assessment being compulsory in registering generic medicines, except those with stable compounds in the waiver list (Nguyen *et al.* 2013). Effective communication that generic medicines have met the registration requirement of bioequivalence testing from the regulators can help to address the latter. Also, health professionals and the public will need to be educated about the generic medicines (Nguyen *et al.* 2013).

Ensuring the actual quality and culturally perceived quality of generic medicines is necessary but not sufficient for a low price of generics. Effective and efficient competition, produced by the existence and adequate enforcement of core regulations such as pharmaceutical sector regulation, criminal law, contract law, competition law and anti-corruption law, is needed. Pharmaceutical pricing and reimbursement policies including reference pricing and tendering may also be needed to ensure low generic medicine prices (Nguyen *et al.* 2014).

Conclusion

Monopoly of supply was reported by participants in this study to be the determining factor of high wholesale prices of originator brand medicines in Vietnam. Informal payments to prescribers and hospital procurement officers were reported to be the main component inflating wholesale prices of generic medicines. This was especially so for generic medicines of perceived low quality where the payment of inducements was a critical factor in gaining and retaining market share. In essence, inducements were considered a tradeoff for purchasing and prescribing medicines perceived to be of lesser quality. These factors, together with the absence of regulation on retail mark-ups and information asymmetry between patients and medicine suppliers, were reported to contribute to the high retail prices of medicines in Vietnam. Policy options to redress these problems include effective monitoring of medicine quality assurance, procurement, distribution and use. Rationalization of the domestic pharmaceutical production and distribution system to achieve economies of scale is also important. Legal remedies are required, especially collaboration with the justice and law enforcement sectors to enforce existing law. New legislation may also need to be enacted to define illegal and criminal behaviors such as bribery, unjust enrichment or other abuses of medicines pricing policy.

Ethics approval

Ethics approval for the study was obtained from the University of New South Wales.

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Conflict of interest statement. None declared.

Notes

1. Directive No. 03/1997/BYT-CT dated 25 February 1997 of the Ministry of Health (MOH) Concerning the Supply, Management and Use of Drugs at Hospitals directed that all hospitals under MOH management were required to purchase medicines from three central State-owned companies, each with its own regional responsibility (i.e. the North, Central, and South Vietnam). Reacting to this measure, provincial authorities implemented a similar scheme, that all provincial hospitals were required to purchase medicines from their provincial suppliers or distributors.
2. The terminology "OTC" here is not as it is commonly used, but the way participants classified a pharmaceutical submarket where they did not detail to prescribers. By law, antibiotic cefixime is a prescription-only medicine in Vietnam. However, if a pharmaceutical company sells it to private pharmacies and does not detail it to prescribers to promote its sale, these pharmacies are called an "*OTC*" market.
3. This test is used to assess the expected *in vivo* biological equivalence of two proprietary preparations of a medicine, often between a generic medicine and its originator brand. If two products are said to be bioequivalent, it means that they would be expected to be, for all intents and purposes, the same.

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