Chapter 18
Pharmaceutical Pricing Policies in Vietnam

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Abstract This chapter discusses the pharmaceutical system in Vietnam and the mechanisms for pharmaceutical prices. We include an analysis of the legislative reforms and the impact of the reforms on pharmaceutical prices and accessibility.

Health sector reforms since 1989 have transformed Vietnam's health care system from a publicly funded and provided health care system to public-private mix. With the shift towards a market economy, Vietnam has allowed pharmaceutical companies to set prices of their products based on market forces, subject to stabilization by the State. A number of legislative and regulatory reforms have been introduced to regulate medicine prices in Vietnam, which were intended to ensure transparency of prices along the supply chain, through price declaration and publication of price information. The initiatives, however, have been less successful than expected because they did not address the need for reasonable prices or the need to differentiate between declared, published and selling prices. Further, provisions were not routinely monitored or effectively enforced.

18.1 Introduction

Health sector reforms since 1989 have transformed Vietnam's health care system from a publicly funded and provided health care system to public-private mix. With a shift towards a market economy, Vietnam has allowed pharmaceutical companies to set prices of their products based on market forces, subject to stabilization by the State. A number of legislative and regulatory reforms have been introduced to regulate medicine prices in Vietnam, which were intended to ensure transparency of prices along the supply chain, through price declaration and publication of price information. This chapter provides an analysis of the legislative reforms and the impact of the reforms on pharmaceutical prices and accessibility. It begins with an overview of Vietnam's health care and pharmaceutical systems. A section follows

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Z.-U.-D. Babar (ed.), *Pharmaceutical Prices in the 21st Century*,
DOI 10.1007/978-3-319-12169-7_18

on drug regulatory authority, highlighting the function of Vietnam's single drug regulatory authority and its component of drug pricing authority, as well as the timeline for marketing authorization approval for pharmaceuticals. The chapter continues with sections that are devoted to the mechanisms for pharmaceutical prices, including drug pricing set-up, how prices are set and who is involved in price setting, with a focus on the legislative reforms on pharmaceutical pricing. The impact of the reforms on pharmaceutical prices and accessibility is then reviewed, as is an alternative strategy of promoting competition by increasing use of generic medicines in Vietnam. The chapter ends with conclusions and recommendations for future research.

18.2 Vietnam Health Care System

Vietnam's health care system has evolved from health systems established separately in North and South Vietnam. During the war period (1945 to 1975), North Vietnam established an extensive network of primary health care facilities with the aim of achieving universal health care coverage. In urban areas nearly 100 % of the population were covered, as were 75 % of the population in rural areas (Witter 1996). In South Vietnam, a strong private health sector dominated until, upon unification with the North in 1975, private enterprises were banned (Larsson 2003).

Post 1975, Vietnam suffered severe financial pressures, including costly post war reconstruction, an economic blockade by the United States, withdrawal of aid from the former Soviet Union and a rising inflation rate (Chalker 1995; Wolffers 1995; Witter 1996). This had significant impacts on the health care system. The expansion of the network of free public health services that had been set up in North Vietnam to include the South added further economic strain, resulting in poor maintenance of health care facilities and lack of basic equipment and medicines in many health stations and hospitals (Witter 1996). At this time the domestic pharmaceutical industry was only able to meet 30 % of the population's demand for medicines and most essential medicines had to be imported as there was not capacity to manufacture in country (Wolffers 1995).

The economic reform process known as "Doi Moi", initiated in 1986, led to important policy shifts in the health care system in the late 1980s and early 1990s. A number of market-oriented measures were implemented, including the introduction of user fees at public health facilities, legalization of private pharmacy and medical practices, and liberalization of the production and sale of pharmaceuticals (WHO 2007). Free access to health care was gradually replaced by a system of direct payment by patients (Larsson 2003). The provision of free medicines dispensed through the public health system was also discontinued (Larsson 2003). As a result, Vietnam's near universal, publicly funded and provided health services were converted into an unregulated public–private mix (Sepehri et al. 2008).

One result of the country increasing its reliance on market mechanisms was substantial increases in consumer out-of-pocket (OOP) health expenditure (World

Bank 2007). Between 1995 and 2008, OOP expenditure ranged from 55 to 66 % of total health expenditure (WHO 2010). The rising household OOP spending on health was partly because of increasing user fees in public hospitals (MOH of Vietnam, Health Partnership Group 2008). Increases in medicine prices also contributed to the growing magnitude of absolute household OOP expenditure on health.

To address the growth in OOP payments that placed financial barriers to health care access, the government issued a national Health Insurance Decree in 1992, introducing compulsory health insurance for people in salaried employment. Since then, health financing from social health insurance as a percentage of public health expenditure has risen, from 7 % in 1995 to 32 % in 2008 (WHO 2010). In 2008, the Health Insurance Law was passed and came into effect in July 2009. The law stipulated that the government was responsible for fully subsidizing health insurance for children less than 6 years of age, the elderly, and the poor, and for partially subsidizing health insurance for the near-poor and students. The law also provided a roadmap for universal health coverage. By 2011, health care coverage in Vietnam exceeded 64 % of the population (Somanathan et al. 2013). Medicines eligible for public health insurance reimbursement are limited to medicines listed on the schedule issued by the Ministry of Health (MOH). The current schedule comprises 900 western medicines and 57 radioactive substances and marking compounds (MOH of Vietnam 2011). The public health insurance scheme does not cover medicines that are purchased at private retail pharmacies.

18.3 The Pharmaceutical System

The health sector reforms, introduced since 1989, have also impacted on Vietnam's pharmaceutical supply chain, shifting it from a centrally controlled system to a market-oriented system (Larsson 2003). The opening of the country to foreign trade and the liberalization of rules governing pharmaceutical manufacture, sale and distribution led to a 300 % increase in medicine production and a tenfold increase in importation of medicines between 1988 and 1992 (Witter 1996). To improve coordination of pharmaceutical policies the National Drug Policy was promulgated in 1996, with two basic goals; ensuring regular and adequate supply of good quality medicines at affordable prices, and ensuring rational use of medicines (Government of Vietnam 1996b).

To facilitate the implementation of the National Drug Policy, the Drug Administration of Vietnam (DVA) was also established in 1996 with responsibility for state management of pharmaceuticals (Government of Vietnam 1996a). The DVA adopted a roadmap of good practices to ensure the quality of medicines across all aspects of the supply chain. In Vietnam, manufacturers have to comply with the code of Good Manufacturing Practice (GMP), importers with Good Storage Practice (GSP), distributors with GSP and Good Distribution Practice (GDP) and

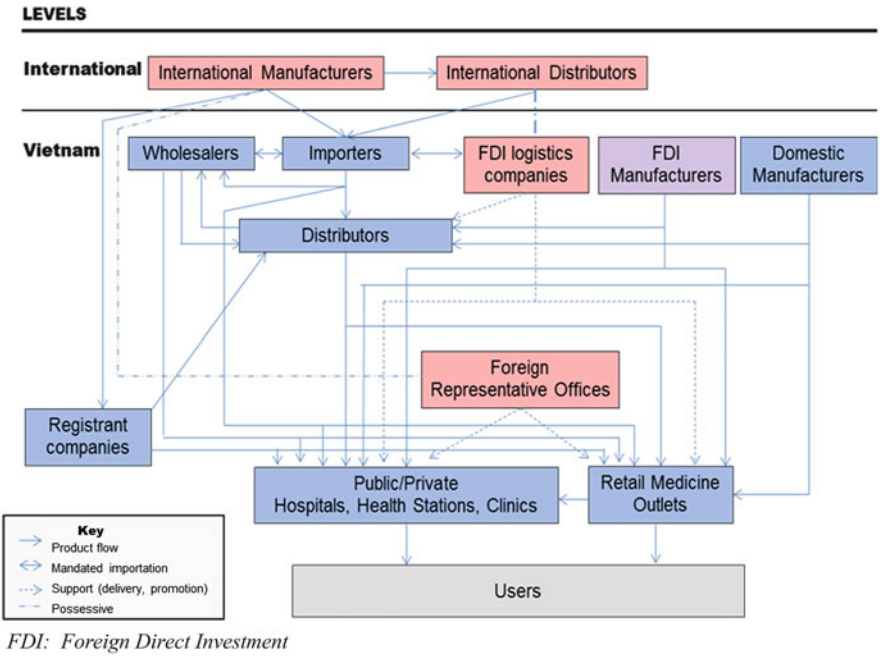


Fig. 18.1 The pharmaceutical supply chain in Vietnam. *Source*: authors' analysis. *FDI* foreign direct investment

retailers with Good Pharmacy Practice (GPP). Figure 18.1 shows a schematic representation of the current pharmaceutical supply chain in Vietnam.

Vietnam's pharmaceutical market is, however, heavily dependent on imports. Imported medicines account for approximately 50 % of the market share, focusing on specialised products. By the end of 2008, there were 10,339 imported medicines covering 909 active substances, averaging 11 brands per active substance (DAV 2009a). The range of imported products is wider than those locally produced, and there is trading duplication of some active substances. For example one substance, cefixime, had 458 imported brands with a valid registration number in Vietnam (MOH of Vietnam 2013).

Domestic medicine production accounts for an increasingly growing market share, rising from 36 % in 2001 to 50 % in 2008 (DAV 2009b). However, the domestic pharmaceutical industry is characterized by limited R&D facilities, insufficient financial capacity and poor management (BMI 2009). Most local pharmaceutical manufacturers comprise small-scale operations with outdated manufacturing technology and duplicated production processes. About 90 % of the raw materials used in domestic production are imported (Cao 2008), thus making domestic medicine prices subject to price fluctuations in international prices, as well as fluctuations in the exchange rates. Nearly 95 % of imported active pharmaceutical ingredients are antibiotics, vitamins, antipyretic, analgesics and

anti-spasmodic drugs (MHBS 2010), reflecting a concentration of domestic pharmaceutical production on only some therapeutic classes. By the end of 2008, there were 9,727 locally produced medicines, representing 491 active substances registered for sale in Vietnam, averaging 20 locally produced brands per active substance. Thus, local manufacturers compete for a very limited, and often uneconomic, market share.

Pharmaceutical distribution in Vietnam is a complex activity which involves a number of intermediaries from manufacturers to consumers including:

- 180 domestic pharmaceutical manufacturers (including 22 Foreign Direct Investment (FDI) producers), 90 importers, and 800 domestic wholesalers/distributors (DAV 2009b);
- Three FDI enterprises investing in drug logistics (DAV 2009b);
- 438 foreign pharmaceutical companies (DAV 2009b);
- 39,172 retail medicine outlets, including 9,066 private pharmacies (DAV 2009b);
- 13,460 public health care facilities, including 974 hospitals, 781 regional polyclinics and 10,917 commune health stations (GSO 2009b);
- 74 private hospitals and more than 30,000 private health clinics (MOH of Vietnam, Health Partnership Group 2008).

Locally produced medicines from Vietnam's pharmaceutical manufacturers can be distributed directly to retailers and health care facilities or indirectly through wholesalers or distributors. Vietnamese manufacturers holding a retail license are able to supply medicines directly to end users. Classified as domestic pharmaceutical producers, Foreign Direct Investment producers can directly distribute the products that they manufacture in Vietnam.

Foreign Direct Investment logistic companies and foreign pharmaceutical companies are not permitted to distribute pharmaceutical products directly in Vietnam. Their products have to be sold to domestic pharmaceutical distributors for distribution. Foreign distributors are only permitted to supply their medicines to a local importer. Foreign pharmaceutical manufacturers with a trading license in Vietnam who are not established in Vietnam as an Foreign Direct Investment producer can supply their medicines via their local registrant company or a local importer (MOH of Vietnam 2006) (see Fig. 18.1).

In the retail sector, patients can buy medicines from retail medicine outlets or hospital pharmacies. Accounting for 60–70 % of retail pharmaceutical market share was more than 1,000 public hospital pharmacies and the rest 30–40 % belongs to private pharmacies and other retail medicine outlets (Hải 2008). Pharmacists with a university degree and 5 years of experience can be licensed to operate private pharmacies. In remote areas, assistant pharmacists are able to apply for licenses. By law, licensed pharmacists must always be physically present when the pharmacies are open for business. In practice, licensed pharmacists are not always on duty (Chuc 2002).

The current pharmaceutical distribution network needs reorganisation. The many layers within the distribution network, each contributing a compounding

mark-up along the supply chain, serve to inflate the final price of medicines to patients. Unnecessary duplication in manufacturing, importing and trading medicines leads to fierce counterproductive competition for an uneconomic share of an increasingly shrinking market (Nguyen 2011).

18.4 Drug Regulatory Authority

The Drug Administration of Vietnam (DVA) on behalf of the Ministry of Health (MOH) is the pharmaceutical regulatory authority in Vietnam. Most medicines must have product registration, as indicated by a valid registration number prior to marketing in Vietnam. The MOH can allow medicines without a registration number to be marketed on a case-by-case basis, to avoid shortage of medicines. By law, within 6 months from the date of receiving complete and legitimate registration applications, the MOH shall issue medicine marketing authorization for the medicine. To ensure the quality, efficacy and safety of medicines marketed, the pharmaceutical manufacturer must meet the GMP standards and the products must pass laboratory quality testing and clinical trials either in Vietnam or in exporting countries. Where applications fail to meet relevant requirements, the MOH will release written reasons for refusing registration (MOH of Vietnam 2009). By the end of 2011, there were 28,820 medicines registered in Vietnam (MOH of Vietnam 2013).

In 2006, the MOH assigned the DVA to be responsible for assisting the Minister of Health to regulate medicine prices. Accordingly, the Drug Price Management Division was established with four staff. The Drug Price Management Division faces difficulties in the management of prices for medicines, especially because the medicine pricing policies are in the start-up phase and there is currently no requirement for Health Technology Assessment to support medicine pricing.

18.5 Drug Pricing Set-Up

In Vietnam, pharmaceutical pricing policies are classified as public policies, which are developed and implemented to achieve pre-set goals of the government. Therefore, pharmaceutical pricing policies are disseminated in the form of legal documents (Ministry of Health Vietnam and Health Partnership 2011), which can be either legislative or sub-legislative regulatory documents.[1]

[1] Legislative documents comprise the Vietnam Constitution, Laws or Law Sets, and Resolutions of the National Assembly. The sub-legislative regulatory documents include Ordinances, Resolutions of the Standing Committee of the National Assembly (SCONA); Decrees of the government (often issued to elaborate laws/ordinances); and Ministerial Circulars (to guide implementation of Decrees).

Prior to 1989, a strict medicine price control strategy was in place (Simonet 2001). Medicines were sold only via the public sector with one uniform price set by the State Pricing Commission and the MOH (The Council of Ministers 1987; Ministry of Health of Vietnam 1987). Losses in pharmaceutical production and trading due to the one price mechanism were subsidized by the government. In 1987, joint Circular No 28-TT/LB of the State Pricing Commission and the MOH introduced flexibility into medicine pricing by permitting domestically produced medicines to have a different designated price level which was within a price bracket set by the MOH.

In 1989, following the health sector reform, there was a shift to free market pricing for medicines. Joint Circular No 440-TT/LB of the MOH and the State Pricing Commission allowed medicine prices to be set by demand and supply. The change meant government would no longer set prices of medicines and no subsidies would be provided to cover losses in production, trading, importation or exportation. Competition and competitive tendering would be applied with market protection for domestically produced medicines (MOH of Vietnam and State Pricing Commission 1989).

Subsequently, a number of legal instruments and policies were introduced by the Vietnam government, all explicitly referring to free pricing for medicines (i.e. pharmaceutical prices may be freely set by the manufacturers). The legislation and policies could be classified into three groups: (1) the general management of prices of most goods including medicines, (2) the state management of medicine prices, and (3) the state management of medicine prices in public health facilities (see Table 18.1). The next section of this chapter focuses on the key ordinances, decrees and circulars that have been used to influence and control medicine prices in Vietnam.

Table 18.1 Main legislative and sub-legislative documents from January 1989 to December 2013 influencing medicine prices in Vietnam

Groups	Promulgator	Name of regulatory documents	Date of issuance
The general management of prices	NA	Ordinance on Prices No 40/2002/PL-UBTVQH10	26/4/2002
	Gov't	Decree No 170/2003/ND-CP, detailing the implementation of a number of articles of the Ordinance on Prices No 40/2002/PL-UBTVQH10	25/12/2003
	Gov't	Decree No 75/2008/ND-CP, amending and supplementing some articles of Decree No 170/2003/ND-CP on 25 December 2003, detailing the implementation of a number of articles of the Ordinance on Prices	9/6/2008
	NA	Law on Prices No 11/2012/QH13	20/6/2012

(continued)

Table 18.1 (continued)

Groups	Promulgator	Name of regulatory documents	Date of issuance
The state management of medicine prices	MOH and MOF	Circular No 08/2003/TTLT/BYT-BTC guiding the declaration and publication of prices of preventive and curative medicines for human use	25/7/2003
	Gov't	Decree No 120/2004/ND-CP on management of prices of preventive and curative medicines for human use	12/5/2004
	NA	Pharmaceutical Law No 34/2005/QH11	14/6/2005
	Gov't	Decree No 79/2006/ND-CP regulating in detail the implementation of a number of articles of the Pharmaceutical Law	9/8/2006
	MOH, MOF, and MOIT	Joint Circular No 11/2007/TTLT-BYT-BTC-BCT guiding the State management of prices of human-use medicines	31/8/2007
	MOH, MOF, and MOIT	Joint Circular No 50/2011/TTLT-BYT-BTC-BCT guiding the State management of prices of human-use medicines	30/12/2011
The state management of medicine prices in public hospitals	MOH	Decision No 3016/1999/QD-BYT regulating the organisation and operation of hospitals' drug stores	6/10/1999
	MOH and MOIT	Joint Circular No 20/2005/TTLT-BYT-BTC guiding the implementation of bidding for the purchase of medicines in public medical establishments	27/7/2005
	MOH and MOIT	Joint Circular No 10/2007/TTLT-BYT-BTC providing guidance on bidding for the purchase of medicines in public medical establishments	10/8/2007
	MOH	Decision No 24/2008/QĐ-BYT regulating the organisation and operation of hospitals' drug stores	11/07/2008
	MOH	Circular No 15/2011/TT-BYT regulating the organisation and operation of drug retailers inside hospitals	19/04/2011
	MOH and MOIT	Joint Circular No 01/2012/TTLT-BYT-BTC providing guidance on bidding for the purchase of medicines in public medical establishments	19/01/2012

NA National Assembly, *Gov't* Government, *MOH* Ministry of Health, *MOF* Ministry of Finance, *MOIT* Ministry of Industry and Trade

18.6 How Prices Are Set

18.6.1 Free Pricing Principle and State Stabilization of Prices of Essential Goods

In 2002, Ordinance on Prices No 40/2002/PL-UBTVQH10 (Ordinance 40) was issued confirming the free pricing principle for most goods including medicines. It stipulated that "The State respects the right of organisations and individuals involved in production or trade to set prices and compete based on price according to law". The ordinance also stated that the State could implement price stabilization for essential goods by adjusting supply and demand of domestically produced goods, exported and imported goods. Other price stabilisation measures included use of national reserves of goods, controlling inventories, setting maximum or minimum prices, or price brackets, and controlling factors determining price. Goods or services paid in full or partly by the State are subject to State price assessment if they are not purchased via tendering. Price publication at each point of sale along supply chain was also stipulated to increase price transparency, with the ordinance indicating the published price must be the selling price.

The implementation of a number of articles of Ordinance 40 was detailed in subsequent Decrees. Decree No 75/2008/ND-CP (Decree 75) stipulated that the schedule issued by the MOH of medicines used in public health facilities would be subject to State price stabilisation. In addition, prices of all medicines paid by the State or public health insurance would be set by the State. Decree 75 added the requirement of price declaration to the MOH and price publication at each point of sale for medicines subject to State price stabilisation. In 2012, the Law on Prices No 11/2012/QH13, which replaced Ordinance 40, was passed and came into force at the start of 2013. The law reasserted the principle of free pricing and State stabilisation of essential goods. It also stipulated that goods, including medicines under the national reserves scheme, one of the price stabilisation measures regulated in Ordinance 40, would have prices set by the State.

18.6.2 Contextual Development of Medicine Pricing Regulations

In the first quarter of 2003, Vietnam faced a surge in medicine prices. The Drug Price Index (DPI), a component of the consumer price index (CPI) increased by 8.6 %, more than five times the CPI (GSO 2009a). In response, the Vietnam government requested the MOH, in cooperation with the Ministry of Finance, to issue a joint Circular intended to guide the management of prices of essential medicines. The objective was to stabilize medicine prices at a reasonable level (Văn phòng Chính phủ 2003). Subsequently, Circular No 08/2003/TTLT/BYT-BTC (Circular 08) was issued and came into force in August 2003. The regulation

broadened the scope of medicines covered beyond essential medicines to include all preventative and curative medicines marketed in Vietnam. Constrained by the free pricing principle, Circular 08 used price declaration and publication as the main mechanism to improve price transparency. Pharmaceutical companies were requested to declare an official wholesale or retail price for their medicines to the MOH. At the point of sale, the companies had to publish their prices for customers' reference. Retail prices were required to be published on the medicine pack and wholesale prices on a board or papers that makes it easy for customers to see. The actual transaction prices must not be higher than the published prices. However, the Circular did not explicitly stipulate that the price to publish is the declared price. Exploiting this regulatory loophole, pharmaceutical companies often published a different price for customers' reference from the price they declared to the MOH.

Despite Circular 08 requirements for price transparency medicine prices kept increasing (GSO 2009a). The circular did not require the declared and published prices to be reasonable or fair prices. Thus, pharmaceutical suppliers declared and published medicine prices as high as the market would bear, resulting in sharp increases in the price of many medicines and another jump on DPI in September and October 2003 (GSO 2009a).

To address this issue government Decree No 120/2004/ND-CP (Decree 120) on the management of prices of preventive and curative medicines for human use was promulgated in June 2004. The Decree included for the first time external reference pricing as the basis for price declaration. Decree 120 also regulated maximum mark-ups for pharmaceutical wholesalers and retailers. Further controls were implemented for medicines directly ordered and purchased by the State without a tender and for medicines purchased by hospitals and other health care institutions that were paid for by the State or by public health insurance. The prices of the former were directly determined by the Minister of Finance and those of the latter were controlled by a tendering process. Subsequent Decrees and Circulars reinforced these approaches included Decree No 79/2006/ND-CP (Decree 79), Joint Circular No 11/2007/TTLT-BYT-BTC-BCT (Circular 11) and Joint Circular No 50/2011/TTLT-BYT-BTC-BCT (Circular 50). Table 18.2 presents a summary of the characteristics of the declaration and publication mechanism used in the pricing regulations of interest.

18.6.3 Ensuring Reasonable or Fair Declared Prices and Published Prices

In this section, we review the effectiveness of the regulation in ensuring reasonable or fair medicine prices and highlight areas where the regulation failed or could have been improved.

Table 18.2 Summary of preconditions of declaration and publication mechanisms used in Vietnam pricing regulations

	The reasonableness of declared prices				Declaration and publication provisions		
	External reference pricing: international comparison standard		Cost plus pricing	Wholesale/ retail mark-ups	Selling prices or published prices not being higher than declared prices	Re-declaration for price increases	Selling prices not being higher than published prices
Circular 08 (2003)	No		No	No	No	No	Yes
Decree 120 (2004)	Highest price	Category base	No	Yes	No	No	Yes
Decree 79 (2006)	Highest price	Category base	No	No	Partly	Yes	Yes
Circular 11 (2007)	Average price	Medicine-to-medicine base	Yes	No	Yes	Yes	Yes
Circular 50 (2011)	Yes but no further information provided		Yes	Yes[a]	Yes	Yes	Yes

[a]Only for medicines sold in retail facilities inside hospitals

18.6.3.1 External Reference Pricing

Decree 120, Decree 79, and Circular 11 all employed external reference pricing as a means of price stabilisation. External reference pricing attempted to ensure that the prices of medicines in Vietnam were reasonable in relation to comparable countries. One of the challenges of implementing external reference pricing came from the fact that no regulations explicitly defined the type of prices for international comparisons (i.e. ex-factory price, wholesale price or retail price, before or after taxes). As price varies along the supply chain (Mossialos and Mrazek 2002), a valid comparison is only achieved when prices are compared at similar levels of the supply chain.

The use of non-specific language also created challenges. Decree 120 and Decree 79 required the price of a medicine sold in Vietnam "*to be not higher than*" prices of medicines of "*the same categories*" sold in comparable countries. This is known as *the highest price* comparison standard, which proved problematic. A strict interpretation of the comparison "*not higher than*" implies that the price in Vietnam could be as high as the highest price among the comparator countries. Using this approach, the Vietnam government could create an opportunity for pharmaceutical suppliers to set *the highest price* from the comparable countries for each medicine, potentially resulting in higher average prices in Vietnam than in the comparator countries. Taking the lowest price in the set or averaging the prices of the medicine among comparator countries is much more commonly used by other countries with experience in external reference pricing system (Nguyen et al. 2014; Espin et al. 2011). In addition, the use of *category* comparisons could also pose dilemmas of definition. Category comparisons mean that comparisons could be applied to different levels of medicine groups such as those that have identical bioactive ingredients, a group of medicines from the same class (i.e. chemically slightly different but related medicines with comparable or identical indications), or a group of medicines used to treat the same condition (Dickson and Redwood 1998; McLaughin 1997; Ioannides-Demos et al. 2002). Other countries only compare the prices of identical medicines in their external reference pricing system (Espin et al. 2011; WHO/HAI 2014).

To overcome these problems, Circular 11 stated *the average price* standard should be used and employed a *medicine-to-medicine* (identical bioactive ingredients) comparison base. The Circular stated that the declared price of a medicine imported into Vietnam was not to be higher than the "*average CIF [Cost, Insurance and Freight] price*" of "*this medicine*" sold in comparator countries. Therefore, the imported medicines were compared to identical products in comparator countries to ensure the price in Vietnam was the average level in comparator countries. One limitation that could arise with this approach is that if the comparator countries include one country with unreasonably high price, the outlier price would affect the mean resulting in a higher average price. Using the *median price* standard would reduce the influence of outliers. An alternative approach is using a larger number of reference countries and taking the average price in the three lowest-priced

countries. This approach is employed in Columbia and the Slovak Republic (KEL 2010; OECD 2008).

Decree 120 specified comparator countries as those having similar medical and commercial conditions as Vietnam. It did not, however, nominate the comparator countries, nor specify selection criteria. It was not until Decree 79 that specific criteria were nominated, with statistical indices similar to those of Vietnam. The indices included: (1) per capita gross domestic product (GDP) per year; (2) per capita GDP at purchasing power parity (PPP) per year; and (3) networks of providing services for preventive medicine, medical examination and treatment, functional rehabilitation, and health improvement and medicine supply. Guiding the implementation of the Decree 79, Circular 11 required the government to decide and announce the list of comparators annually. In 2008, the MOH proposed for the first time a list of comparator countries: Thailand, Malaysia, Indonesia, The Philippines and Cambodia. This feature, however, has yet to be implemented due to a number of challenges including lack of resources and difficulty in collecting medicine price information in comparator countries. Another challenge is that, unlike most OECD or European countries that restrict their external reference pricing to on-patent products (WHO/HAI 2014), Vietnam attempted to apply it to all medicines, thus adding further burden on policy implementation and enforcement. Consequently, the external reference pricing system was only included in the legislation and not applied in practice.

18.6.3.2 Cost Plus Pricing

In addition to external reference pricing, Circular 11 and Circular 50 used cost plus pricing techniques to ensure the reasonableness or fairness of declared prices. The circulars stipulated that pricing authorities could use importation or production costs, distribution costs and changes in factors that determine price, including active ingredient costs or exchange rates, to determine if the declared prices were reasonable. No specific formula for calculating the declared price from costs were provided, which made compliance difficult for suppliers.

18.6.3.3 Maximum Distribution Margins

Decree 120 employed maximum distribution margins to ensure the reasonableness of wholesale and retail prices. The decree stipulated that the Ministry of Finance would be responsible for specifying the maximum wholesale and retail mark-up. However, no specification took place because the Ministry of Finance could not issue a subsequent Circular to guide the implementation of Decree 120. As a result, wholesale or retail margins were not effectively regulated.

Maximum retail margins for medicines sold in retail facilities within hospitals were regulated in Circular 50. Circular 50 requested these margins to be compliant with the regulation of Circular No 15/2011/TT-BYT which regulated the

organisation and operation of drug retailers inside hospitals. Regressive mark-ups where the percentage mark-up decreases when medicine prices increase were used. A limitation of this approach is that the use of maximum retail margins is only be effective to control retail prices if the wholesale price is also reasonable or fair (Nguyen et al. 2014).

18.6.4 Declared or Published Prices as a Cap for Actual Selling Prices

18.6.4.1 Relationship Between the Declared Price, Published Price and Actual Selling Price

All pricing regulations stipulated that pharmaceutical suppliers must not sell their products at a price higher than the published price. This has enabled the published price to be a ceiling to control the actual selling price. The success of this mechanism has depended on the accuracy or reasonableness of the published price. However, no pricing regulations explicitly stipulated the prices declared to the MOH should be the price to publish for customers' reference. This means that there was no mechanism to ensure a fair or reasonable published price.

To overcome this problem, Circular 11 and Circular 50 directly regulated the relationship between the actual selling prices and the declared prices. The Circulars required medicine producers and importers to declare the final wholesale price of medicines for the entire wholesale chain and wholesalers were not permitted to sell medicines to retailers at prices higher than the declared price. If the declared wholesale price was reasonable, this provision would ensure a fair actual selling wholesale price. To ensure a fair, reasonable retail price retail margin must be regulated. However, the maximum retail margin regulation has not been fully implemented (Decree 120), or regulated (Decree 79 and Circular 11). Circular 50 did regulate retail margins but this provision was for medicines sold in retail outlets inside hospitals only.

18.6.4.2 Re-declaration

Prior to marketing in Vietnam, a medicine must be registered with the MOH with a declared price nominated by the registrant company. The Ministry issues a marketing authorisation, usually valid for 5 years, after which the product must be re-registered. In accepting the declared price, Circular 08 and Decree 120 did not take into account the life-span of the marketing authorisation. The regulations failed to provide for the re-declaration of prices in response to changed economic circumstances, such as adjustments for inflation over the life of the license. Thus, registrants were implicitly encouraged to declare the highest possible price at time of first marketing to accommodate future cost fluctuations.

Overcoming shortcomings of previous pricing regulations, Decree 79, Circular 11 and Circular 50 allowed producers or importers to declare increases in prices with an explanation for the increase prior to their application for re-registration. This provided a legal framework for monitoring increases in medicine prices, as well as ensuring medicine prices remained reasonable throughout the license period. The regulations also permitted suppliers to change their prices after the declaration, thus removing the cost pressure associated with having a fixed price for the entire 5-year approval cycle.

18.6.5 Other Pricing Provisions

Except for Circular 08, all pricing instruments proscribed additional price controls for two targeted medicine groups. The first group included medicines directly ordered and purchased by the State without a tender process. The prices of these medicines were determined directly by the Minister of Finance. The second group comprised medicines purchased by hospitals and other health care institutions that were paid for by the State or health insurance. The prices of these medicines were controlled by a tendering process, first regulated in Joint Circular No 20/2005/TTLT-BYT-BTC in July 2005 and subsequently by Joint Circular No 10/2007/TTLT-BYT-BTC in August 2007 and then Joint Circular No 01/2012/TTLT-BYT-BTC from January 2012. The Circulars stated the successful tender prices were not allowed to be higher than the latest maximum price, which had to be announced every 6 months by the MOH. While proscribed, the MOH has yet to develop a way of determining the maximum price. Thus, currently, tender prices are evaluated against the previous year's prices or previous winning-bid prices (WHO-WPRO 2009). The limitation of this approach is that the previous prices may not have been assessed as reasonable or fair.

While tendering is the main pricing mechanism in public hospitals, tender practices can be problematic in Vietnam. Discriminatory terms and conditions for market entry that favours particular tenderers are sometimes applied in return for gratuities or bribes, all of which confound the free market tender system (Nguyen 2011). The scope of this practice is widespread and can result in significantly inflated tender prices. The successful tender prices are, therefore, often higher than the prevailing market retail price (Pham 2010).

Another confounder is the lack of regulation for the Vietnam Social Insurance (VSI) agency, which is responsible for the reimbursement of medicine costs via public health insurance, Joint Circular No 10/2007/TTLT-BYT-BTC, did not regulate the role of the VSI in the tendering process. As a result, VSI is constrained in its ability to use its purchasing power to negotiate medicine prices. The current tendering regulation Joint Circular No 01/2012/TTLT-BYT-BTC stipulates representatives of VSI participate in the whole tendering process, from planning to approval. However, VSI is yet to establish a decisive role in determining reimbursement prices (Nguyen 2011).

18.7 Who Is Involved in Setting Prices?

Pharmaceutical suppliers and distributors are the primary party involved in setting medicine prices in Vietnam. Subject to the stabilization regulations highlighted in the previous section, pharmaceutical companies set the prices of their products. The pharmaceutical pricing authorities (DAV) do not approve the medicine prices declared by pharmaceutical companies. Instead, they monitor the declared prices as a measure of price stabilization. If they find the declared prices unreasonable, the pharmaceutical pricing authorities will provide pharmaceutical companies with their assessment and request the companies revise the declared prices. Assisting the DVA in assessment are representatives from the Ministry of Finance and Ministry of Industry and Trade.

18.8 Official Prices Are Not the Actual Transaction Prices

Price declaration is the main mechanisms for stabilizing pharmaceutical prices in Vietnam. However, the declared prices may not reflect the selling price. Declared prices are usually maximum prices that can be established within the constraints of the legislation, but companies are free to sell at prices lower than this. The declared prices is sometimes 200 % more than the selling prices (Inspectorate of the MOH of Vietnam 2007).

The shortage of personnel and resources for assessing the reasonableness of declared prices of medicines marketed in Vietnam means that most of the information on medicine prices declared by pharmaceutical companies has not been validated. This was sometime exploited by pharmaceutical companies, also resulting in discrepancies in declared and actual transaction prices as illustrated in the following example (Table 18.3).

The actual transaction CIF price of an imported Celecoxib brand as recorded by the General Department of Vietnam Customs was USD 4.5/box of 100 capsules. However, the declared CIF price was USD 34.4/box, 764 % higher than the actual transaction CIF price (USD 1 = VND 15,700). Without validation from the DAV,

Table 18.3 Price declaration provided to the Drug Administration of Vietnam by a registrant company for a brand of Celecoxib 200 mg

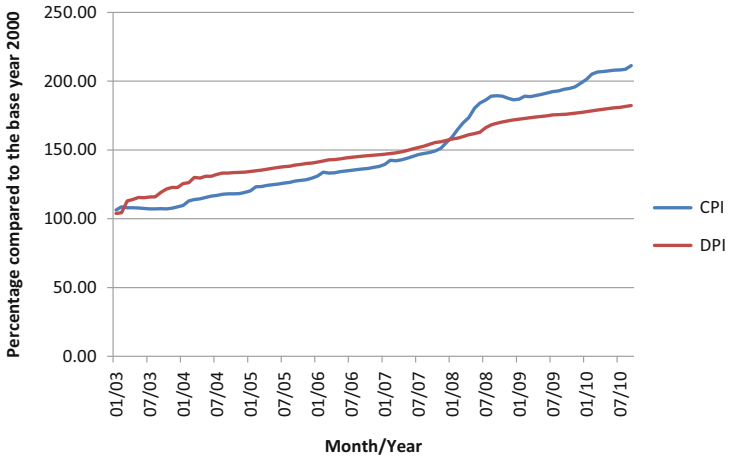
Medicine	Strength	Dosage form	Packing	Declared price in India	Declared CIF price	Declared retail price in Vietnam
Celecoxib	200 mg	Capsule	Box of 10 Strips × 10 capsules	51.0 (USD)	34.4 (USD)	44.6 (USD)

the declared CIF price establishes a declared retail price of USD 44.6/box (approximately 30 % higher than the declared CIF price and still lower than the price in India, which was also declared by the pharmaceutical company and unchecked by the DAV). The officially declared retail price establishes a lower actual selling price of USD 41.4/box to end users in Vietnam, but 920 % higher than the actual transaction imported price (CIF).

18.9 Medicine Prices Change Over Time

Prior to 1989 when strict price controls were in force, medicine prices remained stable over time. The relative stability of medicine prices continued after the market reforms until 2003. Between 2003 and 2004, prices of some medicines soared fourfold (Bộ Tài chính 2004), and the Drug Price Index increased by 13.8 %, almost double the CPI (GSO 2009a). Rising medicine prices have been reported to account for most of the threefold increase in total pharmaceutical expenditure in Vietnam between 2000 and 2005 (World Bank 2007).

In addition to price stabilization, pharmaceutical pricing authorities do use price freezes to slow down price increase of medicines although no legislation stipulated a price freezes provision. The combined effect of all these strategies appears to be having some impact, the DPI after being higher than the CPI for the 5 years (2003 to 2008) has since been kept below the CPI (Fig. 18.2).



CPI: Consumer Price Index, DPI: Drug Price Index

Fig. 18.2 Drug price index in comparison with consumer price index over time. *Source*: Authors' calculation based on data from the General Statistics Office of Vietnam. *CPI* consumer price index, *DPI* drug price index

18.10 The Impact of Pricing on Public Health

Health care in Vietnam is often less affordable and less accessible for poorer households (Segall et al. 2002; Ladinsky et al. 2000). In order to meet health care costs, many poorer households reduce consumption of essential goods, sell assets and incur debt or fail to use health facilities because of cost barriers (Ensor and Pham 1996). With pharmaceutical expenditure accounting for a large component of total health care costs (Nguyen et al. 2009), the cost of medicines plays a role in impoverishing the poor in Vietnam.

While strategies are now in place to influence medicine pricing in Vietnam, there is evidence that further work needs to be done to make medicines affordable for the population. In assessing the affordability of a standard treatment for pneumonia (using the average retail price of a basket of food sufficient to feed one person per day as the benchmark), Falkenberg et al. (2000) found that the medicines cost people the equivalent price of 2 days of food. Ait-Khaled et al. (2000) also showed the challenges of affordability of inhaled corticosteroids 1 year of treatment for a case of moderate persistent asthma in 1998 was reported to cost a nurse in Vietnam 1.7 months of salary. In Turkey and Algeria however, the same treatment apparently cost a nurse 0.4 months (Ait-Khaled et al. 2000).

A recent study assessing medicine prices, availability and affordability in Vietnam compared the prices of 42 medicines to international reference prices of the same products. The international reference prices were the median of actual procurement prices offered by not-for-profit suppliers or international tender prices to developing countries for multi-sourced products (MSH 2008). Results showed that the procurement prices of the lowest priced generic medicines in the public sector were two times the international reference price and for originator brand medicines they were eight times. Adjusted for purchasing power parity, the prices to patients in the public sector were 11 and 47 times the international reference price for the lowest priced generics and originator brand medicines, respectively. Assessing affordability using the number of days' wages needed by the lowest paid unskilled government worker to purchase a course of treatment for an acute disease or a month's treatment for a chronic disease, the study found that the worker would have had to work 0.7 days to treat an acute respiratory infection with the lowest priced generic amoxicillin (250 mg three times daily in 7 days) but would pay 15.9 days' wages with lowest priced generic ceftriaxone (1 vial 1 g daily in 7 days) in the public sector. Compared to countries in the Western Pacific Region, medicines in Vietnam were much less affordable. The study concluded that medicines were unaffordable for the lowest paid unskilled government worker, and even less so for the population who earned below this benchmark (Nguyen 2011; Nguyen et al. 2009).

18.11 The Case of Generic Medicines

Increased use of generic medicines represents another key strategy used by governments and third party payers to contain medicines costs and improve affordable access to medicines. Vietnam did not have a national generic medicines policy. While the National Drug Policy was adopted in 1996, there were no generic medicines provisions included (Nguyen et al. 2013). In 2009 an Aide Memoire on Strategic Collaboration in Pharmaceuticals was signed by WHO and the Ministry of Health of Vietnam, which included the need for a strategy to develop and promulgate a national generic medicines policy to ensure affordability of safe, high quality medicines (WHO-WPRO 2013). Prior to this, the regulations on prescription-only medicines did require physicians to prescribe using the International Non-proprietary Name (generic name) for "single component" medicines (i.e. one active ingredient medicine) and generic substitution was allowed if pharmacists obtained the acceptance from patients or prescribers (Nguyen 2011).

Barriers to increasing generic medicine use include mistrust in generic medicines in terms of quality, efficacy and safety among physicians, pharmacists and patients. Lack of an assessment of bioequivalence as a regulatory requirement in generic medicines registration and lack of appropriately skilled inspectors and monitoring to ensure the quality of generic medicine products contributes to this mistrust (Nguyen et al. 2013). Lack of knowledge of generic medicines and misconceptions that a cheaper price equates to poorer quality also contributed to low acceptance of generics. In addition, promotional incentives for prescribers from some pharmaceutical companies were reported to influence physician prescribing behaviour, leading to recommendations for more expensive branded products. Vietnam did not have any financial incentives to promote prescribing and dispensing of generic medicines (Nguyen et al. 2013). In addition, the sub-optimal pharmaceutical pricing regimes led to some generic medicines being more expensive than their corresponding originator brands (Nguyen 2011).

18.12 Conclusion

Vietnam has made important economic progress since initiating the Doi Moi reform in 1986 which has had a profound impact on the health care system. With a move towards a market economy, Vietnam promoted free pricing of medicines. Pharmaceutical companies are free to set prices of their products based on market forces, subject to stabilization by the State. Analysis of the vast number of legislative and regulatory reforms demonstrates that, in recent times, substantial improvements have been made in regulations of medicine prices in Vietnam. The legislative and associated instruments in Vietnam were intended to ensure transparency of medicine prices along the supply chain, through the mechanism of price declaration and publication of price information. The initiatives, however, have been less

successful than expected because they did not address all the preconditions necessary for the regulations to operate effectively in practice. Additionally, some provisions of the regulations were not monitored or effectively enforced. Consequently, medicine prices remain high in Vietnam and research demonstrates low paid workers would need to forgo more days of wages for courses of treatment for acute or chronic illness than in comparable countries.

While appropriate legislation is pivotal to control medicine prices, it is insufficient as the only means to achieve change. Also critical is the enforcement of legislation and ongoing monitoring. Further research is required to compare between the published prices and the declared prices and to establish the best mechanisms for government controls. The other challenge is the continual revision of legislation and enforcement to cope with changes in the market which can occur quite rapidly. Thus, more work is still needed to ensure reasonable medicines prices in Vietnam that will provide affordable access for the population.

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