



Drug Price Policy in Vietnam Letting the market set prices is not as easy as it seems

Mr. Cao Minh Quang, head of the Drug Administration of Vietnam and now Deputy Minister of Health, had learned a lot about drug markets and prices over the years. One thing was for sure, the invisible hand did not always work the way we wanted it to. Clearly, by 2012 there had been a huge improvement in the situation compared to the shortages and rampant speculation, black markets and counterfeit drugs that had characterized the central planning period. Now people could be pretty sure about the quality and safety of the drugs they used, and not have to worry so much about whether the drugs they needed were available. But high and rising drug prices were another story, and had given Mr. Quang endless headaches.

Drug prices were not only a problem for Mr. Quang. Mr. Pham Luong Son, head of claims processing for Vietnam's Social Health Insurance Agency, was also keen to reduce drug prices to reduce payments for pharmaceuticals that in 2010 had accounted for 61% of total health insurance reimbursements.¹ Patients were also concerned, especially those with chronic illnesses. One example reported in the local media was that of a Mr. Pham. He was 41 years old, and had undergone seven months of treatment for hepatitis C, but now he had to stop treatment because he was out of money. He had already used his house as collateral for a loan for treatment of his illness, and borrowed from his relatives, but after seven months of treatment, his illness was not responding well to the drugs. With no more money to pay for treatment, he lamented `I'll just have to trust in God come what may'.² Another example was the case of a woman who had been receiving treatment for breast cancer for nearly a year. Fortunately, she had health insurance and only had to pay 50% of the cost of chemotherapy and 20% for other drugs. Despite insurance, the total cost of treatment for the year was almost US\$ 5000, high for a country with a per capita GDP of only US\$ 1191 in 2011. Now the drug prices were going up, so she expected that she would have to sell her house in order to continue treatment.³

But there were also those who were happy to see high drug prices. Foreign drug companies enjoyed a revenue premium not only because of their patent protection giving them monopoly prices, but also because doctors believed that imported drugs were more effective and preferred

¹ Minh Bắc, "Cần cơ chế tham gia vào quá trình sản xuất kinh doanh thuốc," *Hanoi Moi Online*, March 1, 2011, http://bhxhlamdong.gov.vn/tin-bhxh-bhyt/478-cn-c-ch-tham-gia-vao-qua-trinh-sn-xut-kinh-doanh-thuc.html (accessed 15 January 2012).

² Gia Phú, "Khánh kiệt vì bệnh," *Bao Thanh Nien Online*, May 31, 2011, http://www.tienphong.vn/Page/PrintView.aspx?ArticleID=539888 (accessed January 12, 2012).

³ Thu Hang, "Khốn khổ vì giá thuốc leo thang," *Bao Hanoi Moi*, October 31, 2003, <u>http://hanoimoi.com.vn/print/6662/print.htm</u> (accessed January 15, 2012).

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to prescribe them. It was well known that under-the-table commissions for prescribing imported drugs were higher than for domestically produced drugs.⁴ For a cash-strapped hospital director trying to retain his underpaid staff, income supplements to his staff paid in the form of drug commissions could be easy to overlook. For those running a private pharmacy, the high price of drugs was not really a problem. Even consumer preference played a perverse role, as Vietnamese, over much of this period, tended to believe foreign brands were of better quality and more effective, and had little sense of benchmark prices, so it was easy to sell more expensive brand name drugs than the cheaper domestically produced or international generic drugs.⁵

The dilemma for Mr. Quang was to find a policy that could find a balance between the objective of ensuring that drugs were affordable to the people and social health insurance fund, promote and aid development of domestic drug production and not threaten the revenue generation activities of medical providers, while remaining consistent with macro-level policies of the Government.

Background

Before the *Renovation policy*⁶ had transformed Vietnam into a market economy, pharmaceuticals were being produced and distributed according to a central planning mechanism. Drug prices were set by the State Pricing Commission or the Ministry of Health. Many drugs were being imported from the Soviet Union to meet Vietnam's medical needs. But in the early 1980s, the Soviet Union had begun to go through its own transformation. Aid to Vietnam, including pharmaceuticals, had dropped sharply. This had led to severe shortages of pharmaceuticals while demand was growing. The result had been an increasing role for black markets, smuggling, speculation, counterfeit production and theft of drugs from public health services.⁷ The Government had tried to regain control over the production and supply in a setting with no incentives for production and low access to affordable pharmaceutical ingredients. Desperate calls for officials to have integrity in their pharmaceutical production, distribution and utilization activities seemed as ineffective as asking a child alone in a candy store not to eat any candies.

The failures of central planning had more widely culminated in the 6th National Party Congress in 1986, which had opened the way for a new paradigm – the so-called socialist-oriented market economy. According to the Resolution of the 6th National Party Congress (18 December 1986), all forms of direct subsidies that hindered business development were dropped, prices were set based on production costs and reasonable profit levels, and subsidies to producers were eliminated.

⁴ Tường Lâm, "Ngành được ì ạch, giá thuốc leo thang," *Saigon Giai phong Online*, March 24, 2011, <u>http://sggp.org.vn/ytesuckhoe/2011/3/253459/# (a</u>ccessed on January 15, 2012); Le Thanh Ha,"Giá thuốc tăng cao, vì sao nên nỗi?," *Tuoi tre online*, May 27, 2008, <u>http://tuoitre.vn/Chinh-tri-Xa-hoi/259727/Gia-thuoc-tang-cao-vi-sao-nen-noi.html</u> (accessed January 15, 2012).

⁵ Nguyen Huu Duc," Cần nghĩ đúng về thuốc nội." *Tuoi tre Online*, August 24, 2011, <u>http://tuoitre.vn/Tuoi-tre-cuoi-tuan/PrintView.aspx?ArticleID=452298</u> (accessed January 15, 2012).

⁶ The 'Renovation policy' began in 1986 and involved transforming the economy from central planning to the market mechanism.

⁷ Bộ Y tế, Bộ Nội vụ. Thông tư liên bộ số 14-TT/LB (April 20, 1983) về công tác bảo vệ thuốc, được liệu làm thuốc chữa bệnh: Chống tệ tham ô, trộm cắp, đầu cơ buôn lậu, làm thuốc giả, kinh doanh trái phép.

Drug prices continued to be set by the State Pricing Commission and the Ministry of Health until 1989. In August 1989, the State Pricing Commission and the Ministry of Health issued Circular No. 440, which could be considered Vietnam's first explicit drug price policy.⁸ According to this policy, drug prices would be set by demand and supply in the market in each locality and for each type of drug. No production subsidies would be provided to cover losses in production. Drug prices would be linked to their efficacy, quality and consumer preferences. Competition and competitive bidding would be applied and there would be market protection for domestic production of drugs, although precise measures were not mentioned in the national drug policy.

To increase competition, in the early 1990s, private pharmaceutical sales and imports of drugs were allowed and regulations put in place regarding the conditions to be met in order to register the business and obtain licences for drugs to be sold. Pharmacies were required to post prices of the drugs they sold. Efforts for inspections and penalties for violations of these regulations were introduced to reduce the nagging problems of smuggling, counterfeit and substandard pharmaceuticals in the market. Regulations on proper pharmaceutical labelling were put in place to improve the information available in Vietnamese to users of pharmaceuticals. Material and financial benefits to influence doctors or pharmacists to prescribe or sell particular drugs were strictly forbidden. A major emphasis was put on policies to improve the quality of pharmaceutical products, including Good Manufacturing Practice (GMP) standards⁹ and laboratory quality testing before licensing drugs for use in Vietname.

To improve coordination of drugs policies under a common framework, in 1996, after several years of technical assistance for its development, a National Drug Policy was promulgated.¹⁰ In the same year, the Drug Administration of Vietnam (DAV) was set up under the Ministry of Health with responsibility for state management of pharmaceuticals. (See Exhibit 1 for a list of organizations involved in drug pricing policy).

In 2002, Ordinance No. 40 on prices was issued covering most goods including pharmaceuticals and confirmed the new perspective on pricing – "the State respects the right of organizations and individuals involved in production or trade to set prices and compete based on price". The Ordinance stipulated that the State could implement price stabilization by influencing demand and supply for essential goods or to control inflation including measures such as adjusting demand and supply of domestically produced and imported goods or adjusting demand and supply across regions. Other price stabilization methods included use of national reserves of goods, control over inventories, setting price maximum and minimum, controlling price determination factors, and subsidizing essential goods, if necessary. This set the legal basis that constrained future price policies for all goods, including pharmaceuticals. Transparent posting of prices at point of sale was also an integral part of the Ordinance on prices, ostensibly to help consumers in the market to choose the drugs with the lowest price. In 2002, the Ministry of Health added the requirement that drug prices be listed on the application for approval of both domestic and imported drugs for sale in Vietnam. In 2002, a new Circular on registering a

⁸ A summary of drug price policies is found in Exhibit 2 at the end of this case study.

⁹GMP refers to guidelines specifying principles of the manufacturing process required to ensure quality.

¹⁰ Exhibit 3 contains the full set of World Health Organization recommendations for measures to include in a National Drug Policy.

pharmaceutical establishment required that they post prices and sell according to the posted prices.

Supply measures to ensure stability of drugs included the regulations on drug reserves promulgated in 1998, which could be relied on to increase supply and prevent price rises due to shortages in the market. A strategy was approved by the Prime Minister in 2002 for the development of the pharmaceutical manufacturing and distribution sectors till the year 2010. This included objectives related to ensuring adequate and regular supplies of essential drugs for the people. Increasingly, pharmaceutical state owned enterprises were being reformed and shares sold to the private sector to increase their efficiency.

Pharmaceutical price shock and drug price policies

The relative stability of drug prices with the market reforms was disturbed in 2003. In the first three months of the year, drug prices increased 9% compared to general inflation of less than 2%.¹¹ A meeting was held on 27 March 2003 between two of the Deputy Prime Ministers and the leadership of the Ministry of Health, Ministry of Finance, Ministry of Trade and other related agencies at the Office of the Government to contain the rapid increase in drug prices.¹² The Ministry of Health was assigned to be the agency accountable for investigating and analysing the recent rapid price rises and to lead the process of putting in place measures to prevent any future large increases in drug prices. Within the Ministry of Health, this task was assigned to the Drug Administration of Vietnam and became Mr. Cao Minh Quang's migraine.

In the meeting, the Deputy Prime Minister assigned responsibility to the Ministry of Health and the Ministry of Finance to develop a joint circular on essential drug price management to ensure stability of drug prices by April, and later to develop a Government Decree for a pharmaceutical price stabilization policy.

Analysis of the causes of the rapid price rise initially pointed blame at prices of imported drugs, especially those from Europe and the recent change in import tariffs for pharmaceuticals from 10% to 20%. Some blamed the multiple layers of intermediaries between importers and retailers.

Circular No. 8 on drug prices was eventually passed in July and came into effect in October. The contents of this circular were constrained to following the principles of the 2002 Ordinance on Prices, in which prices were to be set by the manufacturer or importer based on the market. The price (CIF¹³, wholesale, retail) had to be officially declared when the pharmaceutical product was registered for sale in Vietnam. Prices had to be posted at the point of sale and printed on packaging. Pharmacies and other pharmaceutical establishments were not allowed to sell at a price higher than the published price on the packaging.

The Ministry of Finance, collaborating with the Ministry of Health to develop a Government Decree on managing drug prices, responded to criticisms of the weakness of Circular No. 8 by

¹¹ General Statistics Office of Vietnam, Consumer price index by month of the year, http://www.gso.gov.vn/default_en.aspx?tabid=472&idmid=3&ItemID=11811 (accessed January 15, 2012).

¹² Văn phòng Chính phủ, Thông báo số 41/TB-VPCP về ý kiến của Phó Thủ tướng Nguyễn Tấn Dũng tại buổi làm việc về vấn đề tăng giá thuốc, March 28, 2003.

¹³ CIF designates import prices and stands for Cost, Insurance, and Freight.

stating that it was inadequate to manage drug prices and an effective policy to stabilize drug prices would be needed to control price margins.¹⁴ In 2004, Decree No. 120 was passed including ceilings on mark-ups, and requirements that declared prices be compared to international reference prices to determine reasonableness.

A 2005 study discovered another problem with drug prices – not only was there rapid inflation, but drug price levels in Vietnam were found to be extremely high. Mr. Quang co-authored the study and was involved in adapting the World Health Organization (WHO) methodology to the Vietnamese pharmaceutical context. The prices of 42 drugs were compared to international reference prices for the same drugs using data available from Management Sciences for Health (MSH). Results found that in publicly procured drugs, innovator brand drug¹⁵ prices in Vietnam were 8.3 times higher than international reference prices for the same drugs being higher. Not only had prices risen rapidly, but drug price levels in Vietnam were 'considerably' higher than international reference prices.¹⁶

Evidence from this study was used to tighten up the drug price policy, replacing Decree 120 with Decree 79 in 2006 and Circular 11 (2007) to guide its implementation. The revisions dropped ceilings on drug price margins, which had proven difficult to implement, and clarified which kinds of prices should be used for comparison. This policy had remained in effect to date.

Conflicting objectives

While the drug price policy was being formulated and passed, other developments were occurring in the health sector. World Trade Organization (WTO) negotiations were underway and there was strong pressure from developed countries on the Government to put in place strict controls on intellectual property rights in exchange for freeing up export markets for Vietnamese goods.¹⁷ Vietnam agreed to data exclusivity regulations, which could extend patent protection and delay introduction of cheaper generic drugs.¹⁸ Vietnam's market was large in terms of population, but small in terms of purchasing power. Hanging over the head of the Drug Administration of Vietnam was the threat that if policies put too much downward pressure on innovator brand drug prices, the foreign drug companies would simply decide not to supply Vietnam's market.

Decentralization of public finance and granting of autonomy to public hospitals had been taking place in the first decade of the new millennium. There was increased pressure for hospitals to increase their revenues to cover their costs, but also to pay adequate supplementary incomes to

¹⁴ TD, "Nhà nước sẽ quản lý giá thuốc bằng giá trần," *VNExpress*, September 23, 2003, <u>http://vnexpress.net/gl/suc-khoe/2003/09/3b9cbb11/</u> (accessed January 20, 2012).

¹⁵ Innovator brands are the first version of a drug with a given active ingredient to receive FDA approval and benefit from patent protection. Generic drugs are equivalent to innovator brands but are only allowed for sale after the patent protection expires.

¹⁶ Anh Tuan Nguyen, Rosemary Knight, Andrea Mant, Cao Minh Quang, Martin Auton. "Medicine prices, availability, and affordability in Vietnam," *Southern Medical Review*, 2, no. 2 (2009): 2-9.

¹⁷ James Love, "Vietnam cables: Data exclusivity should be automatic, comprehensive, retroactive and without procedures and formalities," *Knowledge Ecology International*, September 15, 2011, <u>http://keionline.org/node/1265</u> (accessed January 12, 2012).

¹⁸ Burcu Kılıç & Peter Maybarduk, "Comparative Analysis of the United States' TPFTA Intellectual Property Proposal and Vietnamese Law," *Public Citizen*, June 2011 (Updated December 2011), <u>http://www.citizen.org/access</u> (accessed January 12, 2012).

retain and motivate their staff. With government user fees as the main official source of revenues, but fees set since 1995, and regulations requiring that pharmaceuticals for hospital inpatients be sold at cost, hospital directors faced a difficult challenge to ensure adequate surplus revenues to pay staff. In 2007, the Ministry of Health and the Ministry of Finance promulgated a joint circular guiding competitive bidding of pharmaceuticals in hospitals in line with the Law on Competitive bidding. In 2008, regulations were put in place to regulate operations of hospital outpatient pharmacies including encouragement of joint ventures with private parties. Competition should have pushed drug prices down to make them more affordable to patients and to the health insurance fund.



Higher priced drug wins the tender Minh Quang, "Đấu thầu thuốc giá 'trên trời'" *Tuổi trẻ Online*. January 10, 2011,http://tuoitre.vn/Chinh-tri-Xa-hoi/419752/Dau-thau-thuoc-gia-%E2%80%9Ctren-troi%E2%80%9D.html (accessed January 15, 2012).

2010 However, а Government inspection found evidence of substantial irregularities bidding in leading to losses of 22 billion VND. In the provinces of Phu Tho, Dong Thap, Bac Lieu and Hanoi, the winning tender price was higher than if the hospital simply went to the retailers to buy drugs. In Nghe An, Thanh Hoa, and Hai Phong, they found the bid invitation prices higher than the actual winning bids from 47% to 357% and the winning tender prices higher prices offered than by competing bidders. А political cartoonist illustrated this cleverly, showing the

two losing bidders from Pharmaceutical Companies A and B with lower prices losing to Drug Company B with higher prices for Drug X (See figure). In Hanoi, Hai Phong and Nghe An, they found the winning bid prices for 75 drug items at 130% to 245% higher than CIF import prices. In the province of Thanh Hoa, they found 161 drug items sold without going through the competitive bidding process.¹⁹ Another article found that prices for the same drug procured through competitive bidding at different facilities varied substantially. They also found evidence of public-private collusion in informal discussions that if a hospital wanted the prices low, competitive bidding would yield low prices, but if the procurement committee of the hospital wanted the prices high, so they could receive 'commissions', then the winning tender would be high. Pharmaceutical companies that wanted to survive had to go along with what the

¹⁹ Minh Quang, "Đấu thầu thuốc giá 'trên trời'," *Tuổi trẻ Online*, January 10, 2011, http://tuoitre.vn/Chinh-tri-Xa-hoi/419752/Dau-thau-thuoc-gia-%E2%80%9Ctren-troi%E2%80%9D.html (accessed January 15, 2012).

procurement committees wanted.²⁰ Hospitals that wanted to survive needed to find additional sources of income to supplement staff salaries.

Another major problem often cited in news articles was that drug representatives paid commissions (called `roses' hefty in Vietnamese) to doctors to prescribe their drugs. As the illustration on the right shows, Doctor X is prescribing medicines and the patient has to bear the burden of a heavy `rose' of commission percentages that would be paid to the doctor.²¹ While there had been explicit regulations forbidding any material or financial rewards to influence prescribing practices of doctors since the 1990s, no effective policies had been put into place to prevent this behaviour. A recent scandal uncovered two doctors in the prestigious HCMC Medical-Pharmaceutical University hospital earning billions of VND in commissions for sales of expensive hepatitis drugs, with commission rates of 30%.²² Pressure for action was mounting, but low official salaries made commissions quite tempting.



Patients bear burden of commissions for doctor prescriptions

Le Thanh Ha, "Giá thuốc tăng cao, **v** sao nên n ỗi?" *Tuổi trẻ online*, May 27, 2008, <u>http://tuoitre.vn/Chinh-tri-Xa-hoi/259727/Gia-thuoc-tang-cao-vi-sao-nen-noi.html</u> (accessed on January 15, 2012).

Social health insurance under Vietnam Social Security, with its huge outlay on drugs each year, was keen to have greater control over drug prices and volume. There was a tendency for doctors to overprescribe for insured patients as the insurance bore the cost. But Vietnam Social Security was severely restricted in what it could do since health insurance policy was determined by the Ministry of Health, while the Health Insurance Agency only implemented the policy. Measures in place to restrict spending on pharmaceuticals such as limiting the value per prescription, or only dispensing low price generic drugs were not popular. Patients and doctors both wanted greater freedom to get the best drugs available, especially if health insurance was paying. Medical facilities got around the regulations by recording more than one visit per patient in order to provide a higher value of pharmaceuticals, or by requiring that patients pay out-of-pocket for alternative, `better quality' drugs on the market.²³ In addition, fraud was prevalent, with a recent

²⁰ Le Thanh Ha, "Lôn xôn đấu thầu thuốc vào bệnh viện công - Kỳ 2: "Chạy" đấu thầu?" *Tuổi trẻ Online*, October 29, 2010, <u>http://tuoitre.vn/Chinh-tri-Xa-hoi/408112/%E2%80%9CChay%E2%80%9D-dau-thau.html</u> (accessed January 12, 2012).

²¹ Le Thanh Ha, "Giá thuốc tăng cao, vì sao nên nỗi?" *Tuoi tre online*, May 27, 2008, <u>http://tuoitre.vn/Chinh-tri-Xa-hoi/259727/Gia-thuoc-tang-cao-vi-sao-nen-noi.html</u> (accessed January 15, 2012).

²² Thien Chuong, "Nghi án hai bác ĩs kê toa thu ốc nhận 'hoa hồng' tiền tỷ," VN Express, March 30, 2010,<u>http://vnexpress.net/gl/doi-song/2010/03/3ba1a415/</u> (accessed January 15, 2012).

²³ Cong Khanh, "TP.HCM: Bệnh viện thiếu thuốc - bệnh nhân 'lãnh đ ủ'," Viet Bao, August 16, 2007, <u>http://vietbao.vn/Suc-khoe/TPHCM-Benh-vien-thieu-thuoc-benh-nhan-lanh-du/75162985/248/</u> (accessed January 12, 2012).

case of a group of doctors making up false patient records to obtain health insurance reimbursements cumulating to over US\$ 200 thousand.²⁴

Many patients and doctors believed that imported drugs were of better quality and more effective than domestically produced generic drugs.²⁵ The doctors, with their greater knowledge of pharmaceuticals compared to the patients, and their hidden incentives to overprescribe expensive drugs, would not always make the best choice in prescribing drugs for the patient. Both when self-medicating and when seeking care at a medical facility, patients considered the price a symbol of better quality so they were willing to pay more money for imported than domestically produced drugs, even though the drugs had the same active ingredients and met good manufacturing practice (GMP) standards.

The local pharmaceutical industry had continued to develop and gradually increased its market share with an explicit policy goal to reach 60% of market share by 2010. Most of its production consisted of low-priced generic drugs, although the Government was providing some assistance for innovation, especially for industrializing production of traditional herbal medicines. All domestic pharmaceutical companies producing modern drugs had to meet WHO good manufacturing practice standards, while herbal medicine producers were striving to achieve appropriate international standards. Government procurement of drugs for reserves and national programs favoured domestic producers.

The Vietnamese Government was very concerned about poverty reduction. Market prices of pharmaceuticals could reduce access to drugs among the poor, especially those living in remote areas where transport costs were high. Several policies had been put in place to continue the market price policy for drugs, while ensuring access for the poor through subsidizing transport of drugs to remote areas, providing free health insurance to the poor and setting up revolving drug funds at commune health station pharmacies. Nevertheless, price continued to be a barrier for the poor to obtain drugs and health insurance co-payments were increasing, especially for chronic illnesses. Sales of drugs turned out to be an important income generation mechanism for commune health stations, and margins allowed on drugs could influence over prescription.

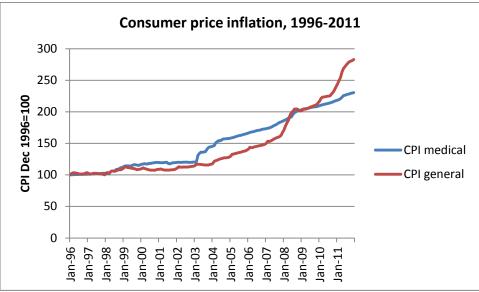
Have drug prices been controlled?

Mr. Quang had reported numerous times to the Minister of Health and in press conferences that his drug price policies had been effective, based on evidence of consumer price inflation (See figure below). According to this indicator, after the major jump in drug prices in 2003, drug price inflation had been kept below general price inflation, especially in the most recent years when electricity and gasoline prices had pushed general inflation to high levels. In October 2011, the new Minister of Health stated that Vietnamese drug prices were only slightly higher than international prices.

²⁴ Cong Quang, "Vụ "rút ruột" BHYT tại Bệnh viện Chợ Rẫy: "Giơ cao đánh khẽ"," Báo Dân Trí. April 27, 2011, <u>http://dantri.com.vn/c170/s170-476528/Vu-rut-ruot-BHYT-tai-Benh-vien-Cho-Ray-Gio-cao-danh-khe.htm</u> (accessed January 12, 2012).

²⁵ Thien Chuong, "Thuốc nội giá rẻ vẫn bị chê," VN Express, May 7, 2011, <u>http://vnexpress.net/gl/doi-song/2011/05/thuoc-noi-gia-re-van-bi-che/</u> (accessed January 12, 2012).

But the Government, Legislature and the people were not satisfied that drug prices were under control. In a meeting with the National Assembly Committee for Social Affairs on 18 October, 2010, the Ministry of Health and other ministries committed themselves to submitting revised drug price management policies, but by October 2011, had still not submitted the revised policy. Many problems remained in the existing policies.



Source: General Statistics Office of Vietnam, Consumer price index by month of the year, http://www.gso.gov.vn/default_en.aspx?tabid=472&idmid=3&ItemID=11811 (accessed January 15, 2012).

Under the current policy, hedging was common, in which pharmaceutical companies declared a very high price when registering their drugs to avoid the paperwork of having to re-declare the price when they wanted to raise retail prices. As long as price rises were below this high declared price they were not punished. But these artificially high prices declared in the licence led to stickiness, and when drugs went off patent, it was hard to reduce the price. It also made it harder to monitor increases in medicine prices when increased prices were below the inflated declared prices.²⁶

A policy to control drug price margins was initially developed in Decree 120 in 2004 but was abandoned because of difficulties in implementing it. New efforts were being piloted to control margins, but mainly for drugs sold through hospital pharmacies with higher margins on less expensive drugs and lower margins on more expensive drugs.

The hospital pharmacy policy had recently been replaced by two new circulars on hospital pharmacy departments and hospital outpatient pharmacies in 2011. These new regulations required that hospital pharmacy prices not exceed the prices in local retail pharmacies, or the competitive bidding prices of pharmaceuticals procured by the hospital inpatient pharmacy department. The policy encouraging private contractors to run hospital pharmacies had now been replaced with a policy banning this practice in central hospitals and discouraging it at other levels. The policy on competitive bidding for pharmaceuticals was still being discussed by the

²⁶ Anh Tuan Nguyen, Rosemary Knight, Andrea Mant, Cao Minh Quang, and Geoffrey Brooks, "Medicine pricing policies: Lessons from Vietnam," *Southern Medical Review* 3, no.2 (2010):12-23.

Government, but the draft policy provided explicit criteria for assessing bids, and more detailed regulations that had the potential to overcome some of the more blatant abuses in bidding for pharmaceuticals.

Managing information about drug prices seemed to be key to effectively managing drug prices themselves. While the Drug Administration of Vietnam had placed winning bid prices and CIF import prices on its website (www.DAV.gov.vn), this information was still inadequate to assess whether the winning bid prices were lower than alternative bids, and the final retail prices could be substantially higher than CIF import prices. In addition, as part of the Government's paperwork reduction policy in 2010, the forms for declaring prices no longer required the applicant to record CIF prices for neighbouring countries, which could be used for assessing reasonableness of prices declared.

High societal spending on pharmaceuticals was not only because of high prices. The types of drugs selected for use (brand name versus generic), and the overuse of drugs that were not necessary also strongly affected total drug spending. These issues were not in the scope of Mr. Quang's work. They fell in the jurisdiction of the Medical Services Administration. Progress in developing standard treatment guidelines and enforcing prescription practices had been very slow. Reforms in the mechanisms to pay providers aimed at reducing incentives for over prescription were also in the pipeline, but under the jurisdiction of the Planning and Finance Department.

Many measures had been put in place, some had failed, others had shown promise at controlling drug prices. While overall pharmaceutical and medical consumer price indexes (CPI) indicated that drug prices were not rising faster than inflation, the picture was much more complex than trends in the CPI. As drugs went off patent, substantial price reductions should be seen, yet seldom did drug companies actually reduce prices. While prices of some drugs did not rise, if the prescribers continued to prescribe different therapies with higher priced drugs, the overall costs for drugs would still continue to rise.

Mr. Quang had been quite successful at achieving improvements in the quality of pharmaceuticals, an issue that lay entirely within his jurisdiction. But drug prices required collaboration with multiple agencies, with competing and often hidden agendas and he himself faced conflicting objectives. Would he be able to meet the challenge?

Exhibit 1: Main government agencies currently involved in drug pricing policy

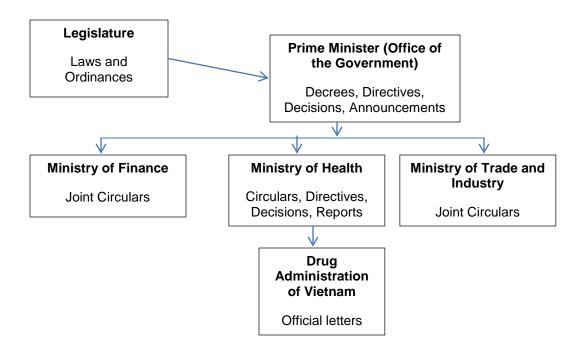


Exhibit 2: Summary of main legislation on drug market price policy in Vietnam

Resolution of the 6th National Party Congress (18 December 1986) – General prices to be set based on production costs and reasonable profit levels.

Circular No. 440 (1989). Drug prices would be set by demand and supply in the market in each locality and for each type of drug. No production subsidies would be provided to cover losses in production.

Ordinance No. 40 (2002). General prices to be set by producers with competition based on price. Government price stabilization by influencing demand and supply for essential goods.

Announcement No. 41 (2003). Deputy Prime Minister call for urgent action to stabilize drug prices.

Circular No. 8 (2003). Drug prices set by producers based on market competition, posted at point of sale, printed on packaging.

Circular No. 120 (2004). Drug prices set by producers, but ceilings on mark-ups, requirement that declared price be compared to international reference prices for reasonableness.

Decree No. 79 (2006) and **Circular No. 11 (2007).** Dropped ceilings on price margins, clarified reference prices. This is the current drug price policy.

Exhibit 3: World Health Organization and Health Action International Recommendations on Component of medicines policy

The following list of actions to influence price, availability and/or affordability is based on the 2008 version of the WHO recommendations on National Drug Policy. An earlier version was available to Vietnamese policymakers at the time of the 2003 drug price shock. Changes between 2003 and 2008 versions are marked in italics.

1. Selection of essential medicines

• Formulation/updating of essential medicines lists and institutional formularies

• Development and use of Standard Treatment Guideline

• Development of quality-assured therapeutic substitution policy

• Requiring the inclusion of medicines on the national Essential Medicines List in health insurance reimbursement lists with minimal co-pay

2. Procurement/purchasing

• Competitive *procurement* (in 2003 tender) with price transparency

• Use of pharmacoeconomics or international price comparisons as guidelines *for fixing prices of originator products*

• Pooled procurement with other national buyers, such as hospitals or health authorities

• Examination of purchasing practices in other sectors to ensure best practice

• For single-source products, pressure for differential prices and exploration of possible parallel importation and the use of TRIPS flexibilities to stimulate generic competition (seek the advice of an intellectual property expert, review the experiences of countries that have implemented TRIPS flexibilities, and/or consult the Guidelines for price discounts of single-source pharmaceuticals (5).

• Assurance of *transparent and quality* price monitoring and public information

• (Create incentives and education for making procurement savings; give margin of preference for local suppliers - dropped after 2003 version)

3. Distribution system

• Analysis of efficiency, *transparency* (in 2003 - probity), competitiveness and intervention to correct, e.g. by contracting to private and not-for-profit logistics and security organizations *with target-setting and performance monitoring*

• Monitoring and regulation/control of mark-ups with fixed fees and regressive margins

4. Generic competition

• Assurance of effective quality assurance capability and promotion of generic substitution at all levels

• Promotion of generic acceptance by professionals, patients and the general community

• Prequalification of generic manufacturers and publication of the quality assurance of such manufacturers

• Fast-tracking of regulatory approval of generic medicines

5. Prescribing and dispensing

• Assurance that consumers, the private sector and NGOs are informed about and involved *with generic and therapeutic substitution, where allowed*

• Building of incentives to prescribe and dispense generic medicines

• Encouragement of separation of prescribing and dispensing, *including banning dispensing doctors*

• Assurance of *unbiased* consumer medicine information

• Assurance that promotion of products by pharmaceutical companies is strictly regulated according to WHO Ethical Criteria and prevention of direct-to-consumer advertising of prescription medicines

• Monitoring of prescribing and dispensing practices, using WHO Drug Use Indicators

6. Financing

• Encouragement of pooled and prepaid financing of medicines, e.g. through employment-based or social insurance schemes

• Support of community-based insurance initiatives focused on improved access to essential medicines

• Assurance of exemptions or differential fee systems to protect access by indigent and disadvantaged groups

• Monitoring of prices and access; for example, routine monitoring of medicine prices and availability

• Assurance that health insurance schemes use limited formularies, based on cost-effective therapeutic guidelines

Source: WHO and Health Action International. 2003 Medicine Prices: A new approach to measurement. Health Action International and WHO. Working draft for field testing and revision.

WHO and Health Action International. 2008. Measuring medicine prices, availability, affordability and price components 2nd edition