Policy Analysis

Medicine pricing policies: Lessons from Vietnam

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Abstract

Objectives: The objective of this paper is to provide an analysis of the medicine pricing policies in Vietnam. These policies are reflected in legislation and associated governmental administrative instruments.

Methods: All the legislation and sub-legislation such as laws, ordinances, decrees, and circulars relating to medicine pricing policies in the period of health reform from 1989 to March 2008 and the policy context were examined using a documentary analysis. The analysis was constructed around the three components of the policy cycle: policy formulation, implementation and accountability.

Results: The Vietnamese Government has sought to limit inappropriate increases in medicine prices through legislation designed to ensure public access to essential medicines. The principal legislative mechanism has been one of transparent declaration and publication of medicine prices. The most progressive regulation has been Joint Circular No.11/2007/TTLT-BYT-BTC-BCT, which controls the wholesale mark-ups in the medicine supply chain through the declaration of a reasonable wholesale price to the Ministry of Health. These marked legislative changes have yet to reach their full potential because some administrative prerequisite elements have yet to be implemented.

Conclusions: Analysis of the regulatory reforms demonstrates that Vietnam medicine pricing regulations have become increasingly sophisticated. While appropriate legislation is pivotal to control medicine prices, it is an insufficient mechanism alone to achieve the level of change required. Enforcement of legislation at the administrative level is also of critical importance, as is ongoing monitoring of legislative effects including the socio-economic factors affecting prices. More work is needed to ensure reasonable prices of medicines in Vietnam.

Keywords: Vietnam, medicine pricing policy, access to medicines, policy cycle, policy implementation

Introduction

Almost all developed countries have exercised some form of medicine price control. Those measures include direct price controls (maximum fixed prices, negotiated prices, international price comparisons and price cuts or freezes) and indirect approaches (profit regulation or reference or index pricing). The United States (US) is the only major developed country that does not regulate medicine prices as a matter of policy. However, in the US, Health Maintenance Organizations (HMOs) negotiate the prices of medicines purchased. While often lacking any form of health insurance, developing countries usually have less regulated pharmaceutical markets.

Prior to 1989, the health care system was heavily subsidized in Vietnam. All health care services and medicines were supplied free of charge. A strict medicine price control strategy was in place. Medicines, from central and local sources, were sold only via the public sector with one uniform price set by Government throughout the country. On 5 November 1987, joint Circular 28-TTL of the State Price Committee and the Ministry of Health was issued. This provided a measure of flexibility in medicine pricing by permitting local sources to have a different designated price level within a price bracket set by the Ministry of Health.

In 1989, Vietnam made important health sector reforms. The provision of free medicines dispensed through the public
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health care system was replaced by a system of direct payment by patients. Former restraints on the production and sale of pharmaceuticals were liberalized and private medical and pharmacy practices legalized. With the shift to free market pricing for medicines without government control, medicine prices became unaffordable for most people. Adjusted for Purchasing Power Parity in 2005, the prices to patients in the public sector were 46.58 and 11.41 times the international reference price for innovator brands and lowest-priced generic equivalents, respectively. To remedy this problem, the Vietnamese Government introduced legislation to stabilize medicine prices.

Recognizing the inadequacy of pharmaceutical regulations introduced since 1954, the Vietnam Ministry of Health commenced drafting the first Pharmaceutical Law in 1997 which was finally enacted on 14 June 2005, after almost a decade of consultation, discussion, drafting and development. The new law provided a comprehensive legislative framework for all aspects of the pharmaceutical sector, including specific medicine pricing provisions. Subsequently, additional legislation and regulations on medicine pricing followed. Notwithstanding the significance of these legislative measures, medicine prices in Vietnam kept growing. Prices to patients for some medicines were up to ten times their imported prices, an example being paracetamol intravenous imported by Danang Pharmaceutical and Medical Equipment Joint Stock Company (9.28 times). Low compliance of medicine pricing regulations was also reported when some medicines were sold at prices of up to 300% more than those declared by their registrants at the Vietnam Drug Administration. In other cases, a hedge price of 200% more than the actual imported or selling prices was declared or published. An understanding of how and on what basis the pricing provisions were developed is necessary prior to formulating effective solutions. This paper analyses the strengths and weaknesses of the legislation which determines medicine pricing policy in Vietnam, and its impact on prices. Feasible options are recommended to maintain medicine prices at reasonable levels, including implementation features.

Methodology

A systematic documentary analysis was undertaken in consultation with Vietnam Ministry of Health officials from April to July 2008. Relevant regulatory documents in the Vietnamese language (or English language where available) were obtained and analyzed. All legislation and sub-legislation from January 1989 to March 2008, namely laws, ordinances, decrees, and circulars, regarding medicine prices and policy context were included. Technical reports of implementation of these regulatory documents were also examined. The main sources of these documents were the Drug Price Management Division of the Drug Administration of Vietnam, the Inspectorate of Vietnam Ministry of Health, the website of the Ministry of Justice of Vietnam: http://vbpqpl.moj.gov.vn/law/vn/index_html (later replaced by the current website: http://vbpqpl.moj.gov.vn/Pages/Vbpq.aspx), and a commercial website: http://legal.khaitri.vn.

Web-based searches on Vietnamese language documents as they related to key topics such as giá thuốc (drug price), chính sách giá thuốc (drug pricing policy), quản lý giá thuốc (drug price control) were conducted. The initial list of identified documents was expanded by checking cross-references stated in the legal basis section of each regulatory document. Consultations with officials in the Drug Price Management Division of the Drug Administration of Vietnam were undertaken, in order for them to suggest other documents and reports that were not available on the web prior to finalizing the list of documents for analysis. An analytical framework was developed for the three components of the policy cycle: formulation, implementation and accountability. Policies and legislation related to medicine pricing were analyzed for the extent to which they were appropriately developed and sufficiently implemented to control medicine prices. Also investigated was the degree of government accountability in this process. Based on the policy cycle framework, a structured set of questions adapted from Rist (1994) was developed to facilitate analysis (see Appendix 1).

Individual regulatory documents were analyzed by the first author (ATN) using the questions developed. Technical and inspection reports of implementation of these documents were used to assist in answering these questions. Where documentary data were not available to answer a question, consultations with Vietnam medicine pricing authorities were conducted. Answers attained were compared across different policy documents to assess the regulatory reforms.

Results

Vietnam only accepts legislative and sub-legislative regulatory documents, not case law, as legal manifestation. The former comprises the Vietnam Constitution, Laws or Law Sets, and Resolutions of the National Assembly. The latter includes Ordinances, Resolutions of the Standing Committee of the National Assembly; Decrees of the Government (often issued to elaborate laws/ordinances); and Ministerial Circulars (to guide implementation of Decrees). An extensive discussion of all legal instruments and policies introduced by the Vietnamese Government post 1989 to stabilize unaffordable medicine prices goes beyond the scope of this paper. Instead, the analysis focuses on the most pertinent current medicine pricing provisions regulated by Pharmaceutical Law No 34/2005/QH1l, elaborated in Government Decree 79/2006/ND-CP; and the implementation Joint Circular 11/2007/TTTL-BYT-BTC-BCT. Also investigated were past pricing provisions, outlined in Joint Circular 08/2003/TTTL-BYT-BTC and in Government Decree 120/2004/ND-CP, which formed the basis of current medicine pricing policies.
Context of medicine pricing regulations in Vietnam

In 2003, the Vietnamese Government requested that the Ministry of Health in cooperation with the Ministry of Finance issue a joint Circular guiding price management for essential medicines, to stabilize medicine prices at a reasonable level. Consequently, Joint Circular 08/2003/TTLT-BYT-BTC (Circular 08) was issued and came into force on 21 August 2003, expiring on 16 October 2007. Circular 08 had limited success: medicine prices kept increasing. In response, the Government urged the Ministry of Finance in collaboration with the Ministry of Health to submit a Decree on the management of medicine prices to the Government for approval. Accordingly, Government Decree No 120/2004/ND-CP (Decree 120) on the management of prices of preventive and curative medicines for human use was promulgated. The Decree came into effect from 4 June 2004 to 7 September 2006. This Decree was the first legal instrument issued by the Vietnamese Government specifically designed to manage medicine prices.

Decree 120 was replaced by Decree 79/2006/ND-CP (Decree 79), enacted 9 August 2006. This regulated in detail, implementation of a number of Articles of Pharmaceutical Law No 34/2005/QH11, including elaborating Article 5 of the law on “State management of medicine prices”. A year later, Joint Circular No 11/2007/TTLT-BYT-BTC-BCT (Circular 11), the result of cooperation among the Ministry of Health, the Ministry of Finance, and the Ministry of Industry and Trade, was promulgated to guide implementation of Government Decree 79 on State management of medicine prices. Circular 11 came into force on 16 October 2007 and replaced Circular 08. Circular 11 together with Decree 79, which was effected on 7 September 2006, comprise the current medicine pricing policy in Vietnam.

The mechanism of medicine pricing policies

The regulatory framework for medicine pricing is based on a modified free market pricing structure. Pharmaceutical Law No 34/2005/QH11 states that medicine suppliers and distributors are free to set prices of their products based on market forces, subject to stabilization by the State. Declaration and publication of price information aimed at improving transparency has been one of Vietnam’s main mechanisms for stabilizing pharmaceutical prices.

The reasonableness of declared prices and published prices

Circular 08 did not regulate the reasonableness of the declared prices and published prices. After it came into effect on 21 August 2003, the prices of a number of medicines increased sharply. For example, one box of 10 dissolvable tablets vitamin C 1g had a price of VN Dong* 19,000 to 20,000 in July 2003. It was sold with a price of VN Dong 22,000 to 23,000 in September 2003, while the published price was VN Dong 25,000/box. Pricing instruments other than Circular 08 used one or more tools such as selected international comparisons and imposition of maximum distribution margins to ensure reasonable declared prices.

International comparison system

Decree 120, Decree 79, and Circular 11 all used a comparative pricing system. This system attempted to ensure that the prices of medicines in Vietnam were reasonable in relation to comparable countries. There are, however, differences in the use of the comparative pricing system across pricing instruments, based on the type of prices for comparison, the standard of comparison, and the selection of countries for comparison.

None of the Vietnamese regulations explicitly and clearly defined the type of prices for international comparisons (i.e. ex-factory price or wholesale price or retail price, before or after taxes). By requiring manufacturers not to set a price in Vietnam higher than that of the medicines of the same category sold in comparator countries, Decree 120 implicitly referred to ex-factory price for comparison. It did not indicate if the price was before or after taxes were applied. Decree 79 stated that declared prices could not be higher than corresponding prices for medicines of the same categories sold in comparator countries, implying a range of prices for comparison. Circular 11 used as a benchmark the average cost, insurance, and freight (CIF) price of the medicine that the foreign producer had sold to other comparable regional countries, but did not specify what type of prices declared in Vietnam should be used for comparison.

Decree 120 and Decree 79 used the highest price standard and a category base for international comparisons. They required the price of a medicine sold in Vietnam “not to be higher than” prices of medicines of “the same categories” sold in comparable countries. In contrast, Circular 11 used the average price standard and a medicine-to-medicine comparison base. It stated that the declared price of a medicine imported into Vietnam was not to be higher than the “average CIF price” of “this medicine” sold in comparator countries.

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 (see Article 10(4)): (i) per-capita gross domestic product (GDP) per year; (ii) per-capita GDP at purchasing power parity (PPP) per year; and (iii) networks of providing services for preventive medicine, medical examination and treatment, functional rehabilitation and health improvement, and medicine supply. In 2008, two years after Decree 79 came into force, the Ministry of Health proposed a list of comparator countries: Thailand, Malaysia, Indonesia, The Philippines and Cambodia. This feature, however, has yet to be implemented. Similarly, Circular 11 required the Government to decide and announce the list of comparators annually, but no list of comparator countries has yet been established.
**Table 1. Price declaration provided to the Drug Administration of Vietnam by the registrant Company A for medicine X**

<table>
<thead>
<tr>
<th>No</th>
<th>Brand name</th>
<th>Visa Number</th>
<th>Ingredient</th>
<th>Strength</th>
<th>Dosage form</th>
<th>Packing</th>
<th>Price in India</th>
<th>CIF</th>
<th>Retail price in Vietnam</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>X</td>
<td>…</td>
<td>Y</td>
<td>200 mg</td>
<td>Capsule</td>
<td>Box of 10 Strips x 10 capsules</td>
<td>800,000 (VN Dong)</td>
<td>540,000 (VN Dong)</td>
<td>700,000 (VN Dong)</td>
</tr>
</tbody>
</table>

Source: Drug Administration of Vietnam 2008

**Maximum distribution margins**

Maximum distribution margins to ensure the reasonableness of wholesale and retail prices were only explicitly used in Decree 120. Decree 120 allowed wholesalers and retailers a separate maximum margin for their services. The Ministry of Finance was required to regulate these maximum mark-ups. However, up until Decree 120 expired on 7th September 2006, there was no implementation Circular to guide this provision. As a result, no specific wholesale or retail margin was set or regulated.

As such, a number of preconditions intended to ensure the reasonableness of medicine prices declared in Vietnam have either not been regulated or not administratively enforced. This, together with the shortage of personnel and resources for assessing the reasonableness of declared prices of all medicines marketed in Vietnam, has meant that most of the information on medicine prices declared by pharmaceutical companies has not been analyzed or validated. Not unexpectedly, this situation has been exploited by pharmaceutical companies to an unacceptable degree, as shown by discrepancies in declared and actual medicine prices outlined in the following example.

The CIF price of medicine X in the Vietnam custom declaration for import commodity was US $4.5/box of 100 capsules. However, the registrant (Company A) declared with the Drug Administration of Vietnam a false CIF price of VN Dong 540,000/box (US $ 34.4), 764% higher than the actual CIF price (Table 1). Without validation from the Drug Administration, this inflated, false CIF price enabled the company to declare a reasonable-looking retail price of VN Dong 700,000/box (approximately 30% higher than the false CIF price and still lower than the price in India, which is also unchecked). After being imported from Company A, this medicine went through several rounds of “buying and re-selling” and the final price to hospitals and clinics was VN Dong 650,000/box, still below the declared price of VN Dong 700,000/box but 920% higher than the real CIF price.

**Declaration and publication provisions**

**Relationship between the declared price and published price or selling price**

Circular 08 and Decree 120 did not regulate the relationship between the declared and the published prices, or between the declared and the selling prices, while Decree 79 regulated it insufficiently. In contrast, Circular 11 required medicine producers or importers to declare the final wholesale price of medicines for the entire wholesale chain. Wholesalers were not permitted to sell medicines at prices higher than those declared. Nevertheless, the relationship between the declared and the retail prices was not regulated.

**Responsibility for publishing retail prices on the package of medicines**

Other pricing regulations required retailers to publish retail prices on medicine packages. Circular 08 also required the pharmaceutical manufacturers and importers to do this. However, this provision was opposed by a number of manufacturers and importers when implemented on 1 October 2003. Consequently, the Ministry of Health first delayed the deadline for implementation of this provision to 1 November 2003 (Official dispatch No 9080/YT-QLD of 22 September 2003), then postponed it further to 1 January 2004 (Official dispatch No 9251/YT-QLD of 29 September 2003).

**Re-declaration**

Neither Circular 08 nor Decree 120 regulated how established medicines could receive a re-declared price in future years. In contrast, Decree 79 and Circular 11 required changes to be made to the system of setting declared prices. Producers or importers wanting to sell their medicines at prices higher than those originally declared were required to make a re-declaration with an explanation prior to applying new prices. Table 2 summarizes characteristics of the declaration and publication mechanism used in the pricing regulations of interest.

**Other pricing provisions**

Except for Circular 08, all pricing instruments prescribed additional price controls for two targeted medicine groups. The first group included medicines directly ordered and purchased by the State, not using a tender. 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 budget and health insurance. The prices of these medicines were controlled by a tendering process, first regulated in Joint Circular No 20/2005/TTLT-BYT-BTC of 27 July 2005 and subsequently by Joint Circular No 10/2007/TTLT-BYT-BTC of 10 August 2007. The successful tender prices were not allowed to be higher than the latest maximum price as announced by the Ministry of Health every six months. However, the Ministry of Health has yet to find a way of determining this maximum price. Accordingly, no price-cap or price ceiling has yet been implemented.
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Table 2. Summary of preconditions of declaration and publication mechanism used in Vietnam pricing regulations

<table>
<thead>
<tr>
<th></th>
<th>The reasonableness of declared prices</th>
<th>Declaration and publication provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>International comparison standard</td>
<td>Wholesale/retail mark-ups</td>
</tr>
<tr>
<td>Circular 08 (2003)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Decree 120 (2004)</td>
<td>Highest price</td>
<td>Category base</td>
</tr>
<tr>
<td>Decree 79 (2006)</td>
<td>Highest price</td>
<td>Category base</td>
</tr>
<tr>
<td>Circular 11 (2007)</td>
<td>Average price</td>
<td>Medicine-to-medicine base</td>
</tr>
</tbody>
</table>

Discussion

Vietnam’s legislation and associated instruments were intended to ensure transparency of medicine prices along the supply chain, through the mechanism of price declaration and publication of price information. These initiatives have been less successful than expected because they did not address all the preconditions necessary for the laws to operate effectively in practice. These included the need for reasonableness of declared prices and the relationship between declared, published and selling prices. Additionally, some provisions of the regulations were not monitored or enforced.

The reasonableness of declared prices and published prices

Circular 08 contained a major flaw. It did not require the declared prices and published prices to be reasonable. Thus, pharmaceutical suppliers declared and published medicine prices as high as the market would bear, resulting in a sharp increase in the price of many medicines. In response, the Ministry of Health was forced to proclaim that Circular 08 was not for management of medicine prices, but only for implementation of price declaration and publication. In retrospect, Circular No 08 might be considered of limited benefit in controlling escalating medicine prices.

Although Decree 120, 79 and Circular 11 did require reasonableness of declared prices, the tools for assessing reasonableness were either not complete, or inadequate. Firstly, the type of prices for international comparison was not specified. The final consumer price of a medicine is generally composed of four parts: an ex-factory price paid to the manufacturer; a wholesaler’s margin paid to the wholesaler; a retailer’s margin paid to pharmacies; and whatever taxes are imposed on medicines. The price varies along the supply chain.

A valid comparison is only achieved when prices are compared at similar levels of the supply chain. Without specification of price type, comparisons used in Vietnam became less effective.

Practical consideration was not given to the inclusion of the whole price range for comparison regulated in Decree 79. The comparison with “corresponding price” resulted in a number of comparisons between a range of prices from import price to wholesale price to retail price, or additional taxes. This caused intractable difficulties in the collection of comparative price data as a benchmark for enforcement.

Circular 11 should have clearly indicated that the price at the same level (the CIF price) declared in Vietnam be the comparator. When implemented, the effect was that the system could only ensure the reasonableness of the CIF price, (i.e. the price at ex-manufacturer/importer level). Although medicine prices were controlled at wholesale level through declaration of the final wholesale price for the entire chain, criteria for assessing the reasonableness of the declared price were not clear-cut, causing further compliance difficulties for suppliers.

Secondly, consideration should have been given to the level of the comparison base and standard. The use of category base comparisons posed methodological dilemmas of category definition. Comparisons can be applied to different levels of medicine groups such as those that have identical biochemical ingredients, a group of analogue medicines (i.e. chemically slightly different but related medicines with comparable or identical indications), or a group of all medicines used to treat a particular condition. Using a medicine-to-medicine comparison, specifying the same active ingredients, strength and dosage form, as regulated in Circular 11 avoids this methodological problem.

Using the highest price comparison standard proved problematic. A strict interpretation of the comparison “not
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higher than” implies that the price in Vietnam could be as high as the highest price among the comparator countries. Using this approach, the Vietnamese Government unwittingly created an opportunity for pharmaceutical suppliers to set the highest price for each medicine, resulting in higher average prices in Vietnam than in the comparator countries. Using the average price standard as in Circular 11 overcomes this problem. However, if the comparators include one or more countries with unreasonably high prices, the outliers will result in a higher average price. Choosing a broader list of comparators and taking the average price in the three lowest-priced countries among those referenced, as modeled by Columbia or the Slovak Republic, may be a solution. Alternatively, the median price standard can be used to reduce the influence of outliers.

Finally, because no list of comparators was established in Vietnam, external reference pricing could not be employed. Although the current criteria for selection are specific, it seems difficult to find another country with entire networks of health care and drug supply similar to Vietnam, as regulated in Decree 79. More flexible criteria for medical condition are needed. Selecting countries with some form of price control to ensure prices in the calculation are not unreasonably high, or where reliable medicine price information is available could also be considered.

Declaration and publication provisions

Prior to marketing in Vietnam, a medicine must be registered with the Ministry of Health with a declared price nominated by the registrant company. The Ministry issues an approval license, usually valid for five years after which the product must be re-registered. However, in accepting the declared price, Circular 08 and Decree 120 did not take into account the life-span of the approval license. It 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 to leave room for future cost fluctuations.

Overcoming shortcomings of previous pricing regulations, Decree 79 and Circular 11 required producers or importers to declare increases in prices with an explanation prior to applying new prices. This important clause provided a legal framework for monitoring increases in medicine prices as well as ensuring they remain realistic throughout the license period. The clause also permits suppliers to change their prices after the declaration, thus releasing the pressure of having a fixed price for the entire five-year approval cycle.

This provision however, is only effective if the declared prices are reasonable. The motive remains for suppliers to “hedge” their prices to leave room for future increases. This is problematic because it counters the effect of price declarations. The suppliers can take advantage of this feature to charge customers higher prices based on the hedge price declared to the Government. The authorities also cannot monitor increases in medicine prices if the increased prices are still below the hedge declared prices. Medicine prices can decrease naturally (e.g. when a medicine goes off patent) affording an opportunity which would be lost by reliance on this declaration and publication mechanism. Thus, over-regulation in a functioning market may be counterproductive, keeping prices artificially high.

All pricing regulations have stipulated that drug suppliers cannot sell their products at a price higher than those published. This has enabled the published price to be a ceiling to control actual selling price. The success of this mechanism has depended on the assurance of the reasonableness of the published price. The reasonableness of prices however could not be assessed since the provision of maximum retail margin was not implemented (Decree 120), nor was there any provision of maximum retail margin regulated (Decree 79 and Circular 11). There was also no provision to regulate the relationship between the published and declared retail prices. As a result, pharmacies often published hedge retail prices that were much higher than actual selling prices, sometimes 200% more than the selling prices.

Recommendations

While external price benchmarking is most widely used to limit medicine prices, different countries select different baskets of comparators based on their own goals. As Vietnam aims to control prices, criteria to select comparator countries may include: (1) commercial conditions: per-capita GDP both in real term and at purchasing power parities; (2) medical conditions: coverage of public health insurance; relative importance of domestic medicine production and import; per-capita medicine spending (as a share of total health care spending and as a share of GDP); (3) system for controlling medicine prices and; (4) availability of price information. International cooperation to develop price information linkages would be beneficial. This would enable Vietnam to obtain reliable data to ensure integrity in price reporting.

The Drug Administration of Vietnam should also regularly analyze medicine price trends, including declared prices and those paid by public healthcare facilities. This will assist in future policy development and facilitate monitoring the integrity of reported medicine prices and effectiveness of pricing regulating measures. Nevertheless, a methodology to assess the effect of pricing policy on medicine prices is required, and the development of a drug-pricing bureau with research capacity would be advisable.

Current pricing instruments do not prevent fluctuations below declared prices. Stricter direct limits on price increases are needed. Given Vietnam’s heavy dependence on the international pharmaceutical market, a complete freeze on medicine price increases, although not uncommon in many European countries, is impractical at this stage. Limits on the frequency of price increases in Vietnam may be a policy option. Specific limits on permissible medicine price increases such as limits to...
increases in the Consumer Price Index may provide a better basis for an assessment of reasonable medicine price increases when medicine prices are renewed.

Other provisions of the Pharmaceutical Law such as measures to promote generic medicines and the domestic pharmaceutical industry may also be desirable to complement the medicine pricing policy, entailing in some cases new legislation. However, regulation alone may not guarantee access. Pushing prices too low without taking into consideration socio-economic factors may force pharmaceutical firms to withdraw products from sale to prevent loss, thus reducing the availability of medicines.

Conclusions

Analysis of the regulatory reforms demonstrates that substantial improvements have been made in medicine price control within Vietnam. While appropriate legislation is pivotal to control medicine prices, it is insufficient alone to achieve the required changes. Also critical is the enforcement of legislation and ongoing monitoring, including socio-economic factors affecting prices. More work is still needed to ensure reasonable medicines prices in Vietnam.

This study uses the qualitative method of documentary analysis based on a framework of the key elements of the policy cycle. The study has provided substantial in-depth understanding of the contextual framework of medicine pricing laws and policies in Vietnam, identifying where additional improvements can be made to stabilize medicine prices. Moreover, given the paucity of rigorous quantitative studies evaluating pharmaceutical pricing policies, this study has demonstrated an alternative approach to examining medicine pricing policies. Based on this study, the approach is likely to be more applicable to developing countries which often lack a reliable and systemic data source on medicine prices; a precondition for rigorous quantitative assessment of pricing policies and their impact.

Contributors

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

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References


Appendix 1: Medicine pricing policy in Vietnam: Documentary analysis framework
1. General information:
   1.1. What is the document title and issuer?
   1.2. What is the date of issuance?
   1.3. What is the type of the document?
   1.4. What is the scope and subjects of application of the document?
2. Policy formulation: Addressing this component will assess if past and current pricing policy has been appropriately developed.
   2.1. What is known about the policy problem or condition at hand?
       2.1.1. Are there clear definitions of the problem or conditions for the pricing policy to address?
       2.1.2. What are they?
       2.1.3. How well can they be measured?
   2.2. What is known about previous initiatives in response to controlling medicine prices?
       2.2.1. What regulations have been previously initiated?
       2.2.2. How long did they last?
       2.2.3. Who developed them?
       2.2.4. In what context were they developed?
       2.2.5. How successful were they?
       2.2.6. How receptive were the stakeholders to these regulations?
       2.2.7. How did the stakeholders react to the regulations? Did they request help or resist the regulations?
       2.2.8. What outcomes were resulted because of the regulations, both anticipated and unanticipated?
   2.3. What is known about the previous efforts and their impacts that would help policy makers choose among alternatives?
       2.3.1. What was the time period for measurable outcomes or impacts to appear?
       2.3.2. How did the policy makers in those circumstances hold on to the public support and keep the coalition intact long enough for the results to emerge?
   2.4. What is known about the chosen alternative (the current policy of interest)?
       2.4.1. What are the measures policy makers choose to address the problem or condition?
       2.4.2. What are their strengths and weaknesses?
3. Policy implementation: Addressing this component will determine if the pricing policy of interest was efficiently implemented to control medicine prices.
   3.1. What is known about the implementation process?
       3.1.1. What is the degree to which the policy is reaching the intended audience?
       3.1.2. What are the aspects of the policy that are or are not operational?
       3.1.3. Is there the institutional capacity to respond effectively to the enforcement of the policy?
   3.2. How has the problem changed over time and has the implementation of policy changed with it?
       3.2.1. Has the problem improved, worsened or remained static?
       3.2.2. Do the aims of the policy still match the assumptions and previous understandings of the problem?
       3.2.3. Are there subsequent complementary changes within policies related to the current problem?
   3.3. How and what do institutions or agencies respond to the problem?
       3.3.1. Do the policy makers, policy implementation staff have the same understanding of the problem?
       3.3.2. What has been the transformation of the relevant institutions’ or agencies’ understandings that have taken place when the policy is actually being implemented?
4. Policy accountability: Addressing this component will determine if there has been accountability in relation to the pricing policy of interest.
   4.1. Were the objectives met?
       4.1.1. What were the anticipated and unanticipated outcomes in relation to controlling medicine prices?
       4.1.2. Were changes in the understanding of medicine pricing practice due specifically to the policy?
       4.1.3. What social changes, if any, resulted from the policy?
       4.1.4. What were the strengths and weaknesses of the organizational structure that was used to implement the policy?
   4.2. What changes occurred within the medicine price problem?
       4.2.1. Has the policy changed with the more current circumstances?
   4.3. How accountable was the organization in the implementation of the policy?
       4.3.1. Was the policy appropriately managed or supervised?
       4.3.2. Was data regarding drug pricing practice used in decision making?