Reforming antiretroviral price negotiations and public procurement: the Mexican experience

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Since antiretroviral (ARV) medicines represent one of the most costly components of therapy for HIV in middle-income countries, ensuring their efficient procurement is highly relevant. In 2008, Mexico created a national commission for the negotiation of ARV prices to achieve price reductions for their public HIV treatment programmes. The objective of this study is to assess the immediate impact of the creation of the Mexican Commission for Price Negotiation on ARV prices and expenditures.

A longitudinal retrospective analysis of procurement prices, volumes and type of the most commonly prescribed ARVs procured by the two largest providers of HIV/AIDS care in Mexico between 2004 and 2009 was carried out. These analyses were combined with 26 semi-structured key informant interviews to identify changes in the procurement process.

Prices for ARVs dropped by an average of 38% after the first round of negotiations, indicating that the Commission was successful in price negotiations. However, when compared with other upper-middle-income countries, Mexico continues to pay an average of six times more for ARVs.

The Commission’s negotiations were successful in achieving lower ARV prices. However, price reduction in upper-middle-income countries suggests that the price decrease in Mexico cannot be entirely attributed to the Commission’s first round of negotiations. In addition, key informants identified inefficiencies in the forecasting and procurement processes possibly affecting the efficiency of the negotiation process. A comprehensive approach to improving efficiency in the purchasing and delivery of ARVs is necessary, including a better clarification in the roles and responsibilities of the Commission, improving supply data collection and integration in forecasting and procurement, and the creation of a support system to monitor and provide feedback on patient ARV use.

Keywords Policy implementation, pharmaceutical policy, pharmaceutical price, HIV, essential drugs

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KEY MESSAGES

- Since antiretroviral (ARV) medicines represent one of the most costly components of therapy for HIV in middle-income countries, ensuring their efficient procurement is highly relevant.
- In 2008 Mexico created a national commission for the negotiation of ARV prices to achieve price reductions for their public HIV treatment programmes.
- Although price analysis before and after the commission creation shows ARV price reductions of up to 38%, Mexico continued to pay much higher prices for ARVs than economically comparable countries.
- A comprehensive approach that goes beyond price negotiation and includes better supply chain management data and improved capacity is required to improve efficiency of ARV negotiation.

Introduction

Mexico and HIV/AIDS

Mexico is a middle-income country with a population of 107 million (PAHO 2007). Like most developing countries, Mexico faces the double burden of infectious and chronic diseases that range from recurring epidemics of pneumonia and influenza to diabetes and coronary heart disease. HIV/AIDS is the 16th ranking cause of death in Mexico. In 2007, there were 200,000 known cases of HIV/AIDS, with a population prevalence of 0.3% (CENSIDA/Secretaría de Salud 2010). Although the prevalence is seemingly low, Mexico had the third largest population of People Living with HIV/AIDS (PLWHA) in the Americas in 2007, following Brazil and the United States of America (UNAIDS Global Report 2010).

The Mexican government has made considerable effort to ensure that PLWHA receive care. Between 2001 and 2002, the government declared universal access to antiretroviral (ARV) treatment including providing PLWHA with ARV medicines. As of December 2009, there were an estimated 60,911 people on ARVs, of which 31,641 (52%) received treatment from the Ministry of Health (SSA) and 24,242 (40%) received treatment from the Mexican Social Security Institution (IMSS) (Ortiz 2008a; Secretaría de Salud/CENSIDA 2010). Both of these public institutions operate an independent care programme which includes its own ARV supply chain. ARV procurement in the SSA health system is managed by the National Center for the Prevention and Control of HIV/AIDS (CENSIDA), while IMSS ARV procurement is managed as part of procurement of all other pharmaceuticals. In both health care institutions the body responsible for gathering data on ARV volume needs and price negotiations submits procurement orders on behalf of ARV treatment clinics and hospitals across all 32 states and the federal district. The distribution systems for IMSS and SSA are separate but have some similarities, with each delegation or state receiving its ARV procurement directly from the private distributor or vendor.

ARV cost concerns

Despite the estimated number of PLWHA currently receiving care, there are concerns about the sustainability of the universal access programme that could impact patient access and adherence to treatment. Bautista et al. (2006) analysed the cost of HIV/AIDS treatment in Mexico and concluded that patients could face drug shortages and, as a result, be forced to stop their medication. ARV prices have become a key concern for Mexico’s health systems. In a report published by the SSA Department of Planning and Development in 2008, a comparative analysis of per unit price of ARVs showed that Mexico was paying multiple times the per unit price paid by other developing countries: for example, Mexico paid 46 times the per unit price for lamivudine, a key ARV component for first-line treatment (Pesqueira-Villegas 2008). In addition, a comparative analysis of ARV prices between SSA and IMSS showed a price difference for some ARVs of more than 20%. Finally, both providers of HIV/AIDS care separately negotiated the prices of patented ARVs and relied on procurement volume as a primary strategy for negotiating lower prices.

Spurred by these analyses and the potential consequences for access to ARV medicines, an Inter-Institutional Commission (Commission) was created via a presidential decree in February 2008 with its main objective to increase efficiency of public procurement of patented medicines (Federal Official Daily Declaration 2008). The Commission was made up of representatives of all major public national health care providers, including SSA and IMSS. Three subcommittees were tasked to provide analytical support that informed the negotiation process: (1) technical–clinical, (2) economic evaluation and (3) prices and patents. At its first meeting in February 2008, the Commission developed 11 goals including to: (1) analyse, develop and propose measurements for improving procurement of patented medicines, (2) design and develop strategies for medicines distribution and implementation of evaluation mechanisms for monitoring forecasting and distribution, and (3) ensure government accountability (Federal Official Daily Declaration 2008).

No formal analysis of the Commission’s effect on the process of procurement and the prices of ARVs has been carried out. Lessons learned from Mexico are relevant for other countries that attempt to address increasing expenditure on medicines for chronic diseases like HIV. The objective of this study is to assess the immediate impact of the creation of the Mexican Commission for Price Negotiation on ARV prices and expenditures.

Methods

There is no standard method for evaluating the performance of pharmaceutical procurement. Pharmaceutical procurement as used in this study refers to three key areas of the drug supply
chain process: (1) forecasting or estimating the quantity needed to treat a stated number of patients over a period of time; (2) price negotiation which is considered part of the procurement contracting process, in which drug suppliers/manufacturers and buyers arrive at agreements as to the price and quantity of drugs to be acquired; and (3) procurement which involves the execution of a contract that states a specific quantity, type(s) of drug and unit price (Management Sciences for Health 1997; DELIVER 2006; Simchi-Levi et al. 2008). Several studies have used a wide variety of indicators to measure supply chain performance. For their analysis of ARV prices across countries with similar economic standing, Vasan et al. (2006) compared the price of ARVs quoted by manufacturing companies and the actual price at which the ARVs were procured. Seoane-Vazquez and Rodriguez-Monguio (2007) collected data on negotiated and procurement prices of ARVs through interviews and publicly available sources to assess the impact of price negotiation on procurement price. Awganda et al. (1996) compared forecast volume to procurement volume to assess how procurement meets estimated patient needs. In their publication, Osario-de-Castro et al. (2009) designed and field-tested a framework for monitoring ARV price negotiations in Latin America and the Caribbean whose indicators largely coincide with the outcome indicators used in this study. However, their article was published during the final stages of data collection, making it impossible to include it in the development of this study.

Drawing from the literature, we defined three indicators, reviewed information repositories (databases and websites) containing ARV forecasting, price and procurement from CENSIDA (SSA) and IMSS, and extracted relevant data for analysis as follows.

(1) Percentage change in price variation before and after the creation of the Commission

The average annual procurement price for 13 of the most commonly prescribed ARV dosages was calculated as the average price per unit multiplied by 12 (e.g. tablet, capsule), as the unit was equivalent to a monthly treatment for a 60 kg adult recommended by treatment guidelines of CENSIDA/SSA (2008). The ARVs selected were tenofovir/emtricitabine 300/200 mg (TDF/FTC), zidovudine/lamivudine 300/150 mg (AZT/3TC), efavirenz 150 mg (EFV), lopinavir/ritonavir 200/50 mg (LPV/RTV), atazanavir 150 mg (ATV), ritonavir 100 mg (RTV), saquinavir 500 (SQV), nevirapine 200 mg (NVP), abacavir 300 mg (ABC), tenofovir 300 mg (TDF), emtricitabine 200 mg (FTC), lamivudine 150 mg (3TC) and zidovudine 100 or 250 mg (AZT). At the time of the study the ARV ARVs in Mexico were under patent in Mexico. All ARV prices were converted into US dollars using the conversion rate listed by the Bank of Mexico, and were adjusted for inflation using the average inflation rate for 12 months for each year of recorded prices, using the Consumer Price Index for Prescribed Drugs (as listed by the United States Department of Labor). In the analysis of pre- and post-negotiation prices, the pre-negotiated inflation rate was calculated as the average inflation rate for January to December 2008, while the post-negotiation inflation rate was the average inflation rate for January to December 2009. Since ARV procurement prices for 2009 were only publicly available for SSA and not for IMSS, we assumed that both SSA and IMSS purchased at the same negotiated prices. The percentage change in price between 2004 and 2008 was calculated as well as the annual percentage price change for each of the years before and following the creation of the Commission.

(2) Absolute difference between Mexican ARV prices and international procurement prices and the differences in changes between national and international ARV prices over time

To understand how ARV prices in Mexico compared with global ARV price trends of the same period of time, the average annual price per patient per year for the most commonly used ARV regimens before and after negotiations was compared with median annual price per patient per year of the same ARV for upper-middle-income countries; i.e. countries with a Gross National Income per capita between US$3706 and US$11 455 (for example, Brazil, Bulgaria, Chile, Argentina, Venezuela and the Russian Federation). Data were obtained on median transaction prices of the same type and dose of ARV for upper-middle-income countries from the World Health Organization (WHO) Global Price Reporting Mechanism (GPRM) (WHO 2007; WHO 2008; WHO 2009; WHO 2011), which is a publicly available data source on public procurement transaction prices of ARVs. Between 2004 and 2009, over 25 upper-middle-income countries reported to the GPRM, among them the Russian Federation, Cuba, Jamaica, Botswana and Namibia. The regional office of the World Health Organization, the Pan American Health Organization (PAHO), has information on ARV reference prices for the region; however, this information is not publicly available and is only provided confidentially to the national procurement offices of PAHO-member countries. The prices from the WHO GPRM are reported in US dollars at price per patient per year (PPY) for the defined daily dose of each medicine required to treat an adult patient for one year. GPRM prices were then adjusted for inflation using the Consumer Price Index for Prescribed Drugs provided by the United States Department of Labor. Twelve of the 13 most common ARVs were selected for this comparison [prices for emtricitabine (FTC) for upper-middle-income countries were not reported, so it was excluded]. The average price change for the selected 12 ARVs in Mexico was compared with the median price changes for the same ARVs in upper-middle-income countries.

(3) Comparison of the total expenditure on ARVs with the total expenditure on ARVs if international procurement prices had been applied to Mexico

To understand how prices affect total ARV expenditures, expenditures for 12 ARVs from 2004 to 2009 were calculated and then compared with two hypothetical scenarios: (1) the cost of the same ARV for the same period, assuming the median price for upper-middle-income countries, and (2) the projected cost after 2008 had ARV procurement prices been the same as the year before (i.e. 2007).

Key informant interviews

To explain the plausible causes for price changes, we interviewed 26 stakeholders: five national HIV programme managers...
working in either IMSS or SSA, seven hospital managers, five health policy analysts, four representatives of generic pharmaceutical companies and five research and development pharmaceutical companies. The first and second authors conducted the interviews. Interviews were conducted in English and Spanish depending on the interviewees’ preferences and transcribed by a research assistant and the first author. The transcribed interviews were then compared with notes taken during the interviews to ensure accuracy. Coding was conducted by the first and second authors documenting two key areas: (1) interviewee’s perception/understanding of the Commission and its impact on ARV forecasting, price negotiations and procurement; and (2) interviewee’s perception of previous and current forecasting, price negotiation and procurement procedures. Coding was compared and differences resolved by discussion. Quotes were selected based on the frequency with which the comments were made across interviews and to illustrate in-depth knowledge of the functions of the Commission. However, in cases where diverging views were held by other interviewees, such views were also highlighted.

## Results

### Percentage change in price variation before and after the creation of the Commission

Between 2004 and 2008 there were no substantial changes in prices of the selected ARVs (Table 1). In fact, the average price decrease of 9% appears to be an effect of adjustment for inflation as the nominal prices for 12 of the 13 ARVs remained the same. It is important to note that in 2007, Boehringer Ingelheim, producers of NVP, provided a global price discount, which accounts for the price drop of this ARV (Jack 2007). After the first round of negotiations concluded in September 2008, ARV prices were significantly reduced compared with the prices in previous years. Additionally, looking at the average percentage change from 2004 to 2009, the highest average percentage reduction in prices occurred after the first round of negotiations—a mean of 38% reduction in prices of the selected ARVs. This was then followed by an 8% average reduction in prices after the second round of negotiations.

### Absolute difference between Mexican ARV prices and international procurement prices

As Figure 1 indicates, ARV combination prices pre-Commission were on average eight times higher than ARV combination prices of other upper-middle-income countries. Even though negotiations lowered prices of the most commonly used ARV combinations, there remained large differences between prices of ARV combinations in other upper-middle-income countries and in Mexico (on average 6 times higher). In 2009, as a result of negotiations, Mexico spent an estimated US$169.1 million and in Mexico (on average 6 times higher). In 2009, as a result of negotiations, Mexico spent an estimated US$169.1 million and international procurement prices.

### Stakeholder interviews

When asked if they understood how the Commission would implement negotiations for patented medicines, perceptions and expectations varied across different groups of informants (see Table 2 for a summary of responses). Each category of

## Table 1  Price per patient per year for 13 most commonly used antiretroviral medicines, 2004–2009 (in 2009 US dollars)

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<td>(US$)</td>
<td>(US$)</td>
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<td>(US$)</td>
<td>(%)</td>
<td>(%)</td>
<td>(%)</td>
<td>(%)</td>
</tr>
<tr>
<td>Efavirenz 150 mg</td>
<td>1218</td>
<td>1216</td>
<td>1087</td>
<td>1039</td>
<td>977</td>
<td>440</td>
<td>406</td>
<td>-5</td>
<td>-55</td>
<td>-8</td>
</tr>
<tr>
<td>Tenofovir/emtricitabine 300/200 mg</td>
<td>4194</td>
<td>4009</td>
<td>4380</td>
<td>2215</td>
<td>2043</td>
<td>-4</td>
<td>-49</td>
<td>-8</td>
<td>-8</td>
<td>-8</td>
</tr>
<tr>
<td>Zidovudine/lamivudine 300/150 mg</td>
<td>4432</td>
<td>4018</td>
<td>3592</td>
<td>3455</td>
<td>3227</td>
<td>1971</td>
<td>1818</td>
<td>-8</td>
<td>-39</td>
<td>-8</td>
</tr>
<tr>
<td>Abacavir 300 mg</td>
<td>3871</td>
<td>3699</td>
<td>3307</td>
<td>3161</td>
<td>2970</td>
<td>1361</td>
<td>1255</td>
<td>-6</td>
<td>-54</td>
<td>-8</td>
</tr>
<tr>
<td>Nevirapine 200 mg</td>
<td>3437</td>
<td>3284</td>
<td>2886</td>
<td>520</td>
<td>489</td>
<td>373</td>
<td>344</td>
<td>-33</td>
<td>-24</td>
<td>-8</td>
</tr>
<tr>
<td>Saquinavir 500 mg</td>
<td>2512</td>
<td>2437</td>
<td>2212</td>
<td>2893</td>
<td>3312</td>
<td>2351</td>
<td>2169</td>
<td>6</td>
<td>-29</td>
<td>-8</td>
</tr>
<tr>
<td>Lopinavir/ritonavir 200/50 mg</td>
<td>7264</td>
<td>7332</td>
<td>6555</td>
<td>6265</td>
<td>5888</td>
<td>3596</td>
<td>3317</td>
<td>-5</td>
<td>-39</td>
<td>-8</td>
</tr>
<tr>
<td>Lamivudine 150 mg</td>
<td>3516</td>
<td>3360</td>
<td>3004</td>
<td>2786</td>
<td>2198</td>
<td>959</td>
<td>885</td>
<td>-7</td>
<td>-56</td>
<td>-8</td>
</tr>
<tr>
<td>Tenofovir 300 mg</td>
<td>6240</td>
<td>4365</td>
<td>3675</td>
<td>3366</td>
<td>1918</td>
<td>1769</td>
<td>-23</td>
<td>-43</td>
<td>-8</td>
<td>-8</td>
</tr>
<tr>
<td>Ritonavir 100 mg</td>
<td>3430</td>
<td>3650</td>
<td>3328</td>
<td>3181</td>
<td>2990</td>
<td>2208</td>
<td>1969</td>
<td>-2</td>
<td>-26</td>
<td>-11</td>
</tr>
<tr>
<td>Emtricitabine 200 mg</td>
<td>3362</td>
<td>2240</td>
<td>1838</td>
<td>1256</td>
<td>959</td>
<td>885</td>
<td>-18</td>
<td>-24</td>
<td>-8</td>
<td>-8</td>
</tr>
<tr>
<td>Atazanavir 150 mg</td>
<td>5898</td>
<td>6019</td>
<td>5327</td>
<td>4815</td>
<td>4526</td>
<td>2761</td>
<td>2546</td>
<td>-6</td>
<td>-39</td>
<td>-8</td>
</tr>
<tr>
<td>Zidovudine/lamivudine 300/150 mg</td>
<td>4452</td>
<td>4018</td>
<td>3592</td>
<td>3455</td>
<td>3227</td>
<td>1971</td>
<td>1818</td>
<td>-8</td>
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Sources: CENSIDA/Secretaría de Salud (SSA), Mexican Social Security Institution (IMSS).
informants had a different understanding of the Commission's scope and its processes to achieve its stated goals. Of all the informant groups, hospital managers had the least understanding of the Commission's function. Informants in this group only knew that the Commission negotiated ARV prices and that prices were lower than previous years. Meanwhile, health system managers stated that the Commission was created as an attempt to address price variation and increasing cost of medicines across the major health systems [Mexican Institute for Social Security (IMSS), Ministry of Health (SSA) and Social Security Institute for Government Employees (ISSSTE)]. The majority of health system managers believed that the Commission would combine the expertise from the major health systems to conduct a number of comparative analyses (e.g. therapeutic equivalence analysis, safety and efficacy studies and comparison of drug prices with prices paid by economically similar countries) to be used in developing stronger negotiation strategies.

The majority of policy analysts interviewed were involved in providing technical support to the Commission and its subcommittees, worked closest with the Commission, and as such were able to elaborate on the Commission's functions. This group described how the Commission and its subcommittees conducted multi-level analyses that were assumed to have a crucial role in a successful negotiation process. Representatives from patent-pharmaceutical companies stated that consolidated negotiations and procurement were likely to attain lower ARV prices, while representatives of generic-pharmaceutical companies stated that comparison of procurement prices with economically comparable countries were likely to help lower ARV prices in Mexico.

**Identifying challenges to price negotiation**

The different informant groups were able to identify varying challenges to the Commission's functions. Beyond achieving lower prices, hospital programme managers and health system managers could not say if lower prices would increase ARV procurement, availability or access. For their part, policy analysts described the Commission's functions as still evolving. This resulted in a lack of clarity with respect to the responsibilities of each subcommittee and the Commission. Another example of evolving goals was noted by a senior policy analyst whose comment struck a departure from the general response of other analysts. This informant suggested that the Commission's approach to negotiation might be limited by concerns about the possible impact on the Mexican pharmaceutical market and commercial interests (Interview 8, 2008).

It was not clear how the Commission members planned to balance the differing positions: on one hand, to lower prices and provide more ARVs to the maximum number of patients...
needing treatment, and on the other hand, to place limitations on private sector development and, potentially, economic benefits to the Mexican pharmaceutical industry. This issue was further highlighted when informants stated that the Prices and Patent Subcommittee was not actively involved in providing analysis on the impact of the patent process on the Commission’s goals. On the other side of the negotiation table, representatives of patent-pharmaceutical companies were concerned that the Commission could increase the government’s negotiating power disproportionately. These informants described this power as the ability to make price demands that could threaten the industry’s ability to recoup research and development costs. In addition, they regarded the Commission as a threat to intellectual property rights, fearing the infringement of patents and, hence, financial losses for the Mexican pharmaceutical industry. Representatives of generic-pharmaceutical companies were concerned that the current intellectual property regulations heavily favour patent-holding companies, stifling local competition for drug production necessary for lowering prices.

Another relevant challenge mentioned was the lack of resources in terms of sufficient analytical capacity and time to prepare essential information for negotiation, which was a concern expressed by various interviewees working with the Commission. As a result, the majority of policy analysts stated that they could not conduct an in-depth analysis for every patented ARV ahead of the scheduled negotiations, thereby severely limiting the Commission’s capacity to negotiate with the pharmaceutical industry. A notable example of this limitation was identified as the lack of accurate data on forecast demand for ARV medicines, resulting in uncertainty in ARV volume demand used in negotiations and procurement, and possibly surplus or stock-outs.

Finally, the lack of transparency and accountability was a constant theme in the interviews with policy analysts and some representatives of the generic industry. One interviewee noted the need for a transparent negotiation process to ensure the Commission acted fairly. Another policy analyst mentioned the relevance of accountability in evaluating the achievements of the Commission (Table 2).

Discussion

The establishment of the Inter-Institutional Commission to conduct joint negotiations on behalf of the major health systems has achieved its main goal—substantial reduction in ARV prices through joint negotiations. However, the results of this study indicate that the Commission faces various challenges that are relevant for it to ensure its sustainability and intended impact.

First, a key aspect of the Commission’s development is the lack of specific aims—in particular what the Commission chooses as short-, medium- and long-term goals—regarding the outcome of price reduction and its process and functioning. The lack of a clear set of procedures and performance goals was
Table 2: Summary of informants’ perceptions on the Mexican Commission for Price Negotiation’s potential success and possible challenges

<table>
<thead>
<tr>
<th>Category of informants</th>
<th>Potential successes</th>
<th>Possible challenges</th>
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<tr>
<td>Hospital programme managers</td>
<td>Yes, the Commission negotiated in 2008 and 2009. The prices made a difference for everyone. [But] prices are one thing but there are also infrastructure problems that need to be addressed. (Interview 21, 2010)</td>
<td>We don’t expect [current] forecasting and procurement to change. (Interview 16, 2009)</td>
</tr>
<tr>
<td>National programme managers</td>
<td>They [the Commission] have more people than we do and will be able to do more [analysis]. (Interview 5, 2008) For prices, ISSSTE [doesn’t] negotiate, about 80% of the prices are the same for all the institutions (IMSS, SSA, etc). In 2009, the [institutions as a group] will negotiate for better prices using total ARV volume and the group will try to pay the same price for each medication. (Interview 21, 2010)</td>
<td>They [the Commission] will do the negotiating and we will do the procurement. (Interview 9, 2008)</td>
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<td>Ministry of Health analysts</td>
<td>You want to first add volume, and second improve or institutionalize a more professional process to inform the people who are going to sit down with the industry and negotiate … then adding new elements to the negotiation—economic evaluation, consideration of safety and bio-equivalence and also a more professional way of price comparison with other countries with other equivalence and so on. So you want to pursue these two goals; you have to do it necessarily through an entity that connects the different institutions that operate in the public sector and that is how the idea of the Commission was developed. (Interview 7, 2008)</td>
<td>It is important to understand that the Commission is only a Commission that negotiates. The Commission does not purchase. It is still the responsibility of each institution to conduct their respective purchasing. The Commission will just be involved in negotiation … Also remember, the Commission does not have a separate budget, it cannot tell the institutions [health systems] how to spend their money. (Interview 7, 2008)</td>
</tr>
<tr>
<td>Representatives of patent-pharmaceutical companies</td>
<td>Consolidating procurement results in better prices and better conditions because [they will be] purchasing in bulk through one channel and I think that this will be one way to expand access. (Interview, Patent-holding Pharmaceutical Representative 1, 2008)</td>
<td>The rest of the chain in the process will be supervised by the respective entities. This doesn’t limit the fact that perhaps one or two years, the Minister decides well, the Commission should also go into some other parts of the process. At the moment the scope is very limited, and it’s only the negotiation of prices. (Interview 10, 2008)</td>
</tr>
<tr>
<td>Representatives of generic-pharmaceutical companies</td>
<td>We hope that in the short term, [the Commission] will get a better idea how much Mexico is paying in [medicines] prices in comparison to the United States and other countries in the same economic level. Mexico should be able to sell [medicines] at lower prices. (Interview 3, Generic Pharmaceutical Representative, 2008)</td>
<td>Some of the work was not good, because of time or the methodology. Some of the working groups knew the methodology and some did not. For example, doing lit reviews you follow a particular manner and that is fine, but if you just look at some articles in some places this is not enough. We should have stressed more detail on how to perform the tasks. (Interview 8, 2008)</td>
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ANTIRETROVIRAL PRICE NEGOTIATIONS IN MEXICO

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identified by some interviewees as a problem which makes it very difficult to evaluate the Commission’s achievement. At present, any price reduction achieved by the Commission would be classified as a success. Politically, this has been the case as after each price negotiation the government proudly announced the successful negotiation of a price reduction (Gutierrez 2008; López 2008; Vega 2008; Ortiz 2008b; Toribio 2008). However, this is largely underutilizing the potential of the Commission. Additionally, Mexico is not included in any of the manufacturers’ differential pricing schemes for ARVs and, as such, is required to negotiate with manufacturers directly. Direct negotiation has been identified as a key strategy among many that provides access to high cost medicines (PAHO 2010).

Although there is no agreement on the definition of an adequate benchmark price in this analysis, we used upper-middle-income countries for comparison. The results show that after the creation of the Commission, Mexico continues to pay on average six times more in ARV prices than the average upper-middle-income country. In comparison to prices negotiated by the Commission, the decrease in median upper-middle-income country prices during the same time period suggests that ARV price reduction in Mexico may have been influenced by a global trend and cannot be solely attributed to the Commission’s work. This further suggests that the Commission’s use of global procurement-price comparative analysis may not be as effective a negotiation strategy as stated by informants.

Information about negotiated prices, strategies and goals set out by the Commission in the 2008 and 2009 rounds of negotiations was deemed confidential, making it difficult to evaluate strategy success. Without clearly defined processes, performance targets and transparency of the negotiated prices to compare with actual purchasing prices, the Commission and health systems run the risk of being unable to assess the impact of the negotiations on ARV costs. Other authors have noted similar difficulties when evaluating the procurement efficiencies in other Latin American countries or at the global level (Vasan et al. 2006; Seoane-Vazquez and Rodriguez-Monguio 2007). The issue of transparency highlights a complex challenge in the negotiation process, i.e. what level of transparency is necessary to ensure that cost-reducing goals are met and evaluated, and what level of confidentiality is necessary to address the concerns of patent-pharmaceutical companies, thus ensuring negotiations can be conducted in good faith?

Secondly, the discourse of the interviewees indicates that the Commission relies mainly on volume and Mexico’s economic status as a negotiation strategy. However, it is important to note that an increase in volume did not lead to reduction in prices for the SSA in previous years. Since there does not appear to be a precedent for increased volume as a strategy for reducing ARV prices, it is uncertain how much of an impact pooled procurement will have on ARV price reduction in Mexico, particularly in the long term. Other analysis studying pooled procurement found that using only volume as a cost-saving strategy does not necessarily result in lower prices (Waning et al. 2009).

Thirdly, responses from pharmaceutical representatives raise a key issue that the Commission and its Prices and Patents Subcommittee have yet to address: the complexity of balancing intellectual property rights with the goal of lowering ARV costs. The lack of a functioning Prices and Patents Subcommittee—as mentioned by some interviewees—could be interpreted as a sign of lack of capacity to assess the impact of intellectual property rights information for the negotiation, or as an indicator that the impact of the patent process on ARV price and cost are unknown. The absence of a well-functioning subcommittee will likely impede the Commission’s ability to adequately monitor the impact of the patent process on price negotiations. For example, an analyst working with the Commission stated that during the 2008 price negotiations, Mexico negotiated a price for an ARV that was scheduled to go of patent in 2009, thus unnecessarily locking the government into a higher price. In addition, concerns about the possibility of the government violating intellectual property rights raised by representatives of patent-holding pharmaceuticals are not supported by the data collected in this study. This is borne out by the lack of a functioning Price and Patent Subcommittee and the unwillingness of the Commission to invoke the compulsory licensing clause in multi- and bi-lateral trade agreements as a negotiation strategy. It should be noted that this opposition to government involvement by the pharmaceutical industry appears to follow a pattern first established in South Africa, where pharmaceutical companies sued the South African government over the creation of a law to reduce ARV prices (Sidley 2001). However, contrary to the case in South Africa, the Mexican government’s policy establishing the Commission does not include a law compelling pharmaceutical companies to lower ARV prices. A functioning Prices and Patents Subcommittee would strengthen the Commission by providing information on patent prices and patent life as well as the legal and financial implications of potential negotiation strategies.

Fourthly, to ensure that its policies are implemented, the Commission will need resources or, at the very least, the authority to allocate resources. While not all policies require resource investment, policies aimed at strengthening information infrastructure and capacity building will require some capital and human investment (Management Sciences for Health 1997; DELIVER 2006; Waako et al. 2009). Therefore, the mandate to create policy must be strengthened by a complementary mandate to allocate resources so that cost-saving policy guidelines that require resource investment are not exercises in futility.

Lastly, and most importantly, the negotiation process is only one aspect of addressing ARV expenditure by the government of Mexico. As Seoane-Vazquez and Rodriguez-Monguio (2007), Vasan et al. (2006) and Osario-de-Castro et al. (2009) suggest, without accurate forecasting, negotiators representing the government are unable to assure their counterparts from the pharmaceutical agencies with an accurate demand volume necessary to assess their production capacity or profit margin, and as such, make them less willing to offer lower procurement prices. An integrated approach targeted at improving various steps of the cycle would provide a more effective approach to improving procurement efficiency. Despite a presidential mandate to analyse, develop and propose measurements for improving drug purchasing, it is yet to be seen how and when the Commission intends to develop guidelines for improving forecasting, procurement and distribution efficiency.
to lower the cost of managing the ARV supply chain. While it could be argued that requiring health systems to submit ARV volume forecasts is an important first step towards encouraging use of data in decision making, the lack of a formal and systematized procedure for assessing the quality of data submitted by the health systems fails to address concerns about improving efficiency of the supply chain (Management Sciences for Health 1997; DELIVER 2006). Others have pointed out that a crucial factor contributing to the success of providing access to high cost medicines is a reliable information system which provides information not only on the number of patients on treatment regimes but also on availability of medicines in stock (Homedes and Ugalde 2006; Waako et al. 2009).

**Limitations of the study**

This analysis has certain limitations. Interviews with HIV/AIDS national programme managers, while not substantial in number, were representative of ARV supply chain programme managers who have been key decision-makers in ARV supply for their respective health systems for at least 5 years. Interviews with HIV/AIDS programme managers at the hospital level were conducted with a convenience sample of informants and, thus, may not be fully generalized to their respective health systems. Nevertheless, these informants were heads of HIV/AIDS care at clinics or hospitals serving a broad number of patients (300–5000) with varying needs (i.e. patients on first-line treatment, patients on first-line alternative treatment as a result of toxicity, patients with drug-resistant infections and those on regimens beyond first-line treatment).

Data for 2008 and 2009 annual price and procurement volume were obtained from two possibly related sources. Nevertheless, these data were used in forecasting, price negotiations and procurement decisions by national policy-makers and programme managers, indicating some level of validity of the data. Ideally, the authors would have liked to validate the data from 2008 and 2009 by consulting independent data sources.

Lastly, because data on procurement volume by quantity purchased at a particular time of year were unavailable, this study was unable to calculate the average weighted procurement price. In addition, the authors used the inflation rate per year which may not precisely reflect the actual inflation-adjusted price for ARVs. Similarly, ARV expenditures (actual or estimated) may not be reflective of the precise expenditures; rather they are within the limits of the average inflation per year. However, the inflation rate did not vary more than 1%, which is within acceptable margins. Furthermore, ARV expenditure was calculated as procurement cost and does not include the cost of distribution or storage; thus, the actual costs of ARVs to the system were likely to be higher than this study estimates. Finally, GPRM upper-middle-income median prices per patient per year have an estimated precision of +/-15% given the fact that some reported prices include INCO terms (add-on costs due to shipping, insurance, taxes and other charges) while others do not, but this information is not consistently applied (UNAIDS Report 2010).

**Conclusion**

The Mexican government’s creation of the Inter-Institutional Commission follows a series of policies aimed at streamlining supply chain management to guarantee efficient and sustainable delivery of ARV medicines. It provides relevant lessons for other countries planning to implement similar policies. The Commission’s co-ordination of negotiations on behalf of the major health systems has achieved its main goal—substantial reduction in ARV prices through joint negotiations. As the analysis from this study shows, a country that lacks the necessary policy and infrastructure processes for price negotiation runs the risk of neglecting a broader set of interrelated factors, with implications for overall drug expenditure. Hence, more comprehensive policies regarding performance goals, the Commission’s organizational infrastructure and the role of the Commission vis-à-vis the health systems are required to enhance the capacity of decision makers to adequately negotiate ARV prices. The implementation of these policies will not be a simple undertaking. It presupposes agreement by decision makers within and across health systems on improvements in data infrastructure, as well as providing decision makers with the training and support to accurately manage forecasting, price negotiation and procurement of ARVs.

Additional policies to promote and regulate access to high cost medicines including policies to promote development of medicines at prices affordable to low- and middle-income countries as well as promotion of the use of the trade-related aspects of intellectual property rights (TRIPS) flexibilities and economic evaluations among others will further strengthen the system (PAHO 2010). These policies will also require extensive resource investment and sustained co-operation between the Commission and participating health systems, which may be time-consuming. However, the long-term benefits of decreasing costs and enhancing access to treatment will likely outweigh the initial investment. Furthermore, Mexico’s experience provides a good example for other countries with fragmented health delivery systems interested in lowering costs of ARVs. However, these countries must ensure that in addition to creating a central body to negotiate ARV prices and pool procurement across health systems, they establish supporting policies aimed at improving the quality of supply chain data and ensuring that management systems and personnel have the capacity to identify and address inefficiencies in ARV procurement.

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**Conflict of interest**

None declared.