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## Negotiating patented medicine prices in Mexico

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### A new entity for the negotiation of public procurement prices for patented medicines in Mexico

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#### Abstract

**Problem** As countries expand health insurance coverage, their expenditures on medicines increase. To address this problem, WHO has recommended that every country draw up a list of essential medicines. Although most medicines on the list are generics, in many countries patented medicines represent a substantial portion of pharmaceutical expenditure.

**Approach** To help control expenditure on patented medicines, in 2008 the Mexican Government created the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (CCPNM), whose role, as the name suggests, is to enter into price negotiations with drug manufacturers for patented drugs on Mexico's list of essential medicines.

**Local setting** Mexico's public expenditure on pharmaceuticals has increased substantially in the past decade owing to government efforts to achieve universal health-care coverage through *Seguro Popular*, an insurance programme introduced in 2004 that guarantees access to a comprehensive package of health services and medicines.

**Relevant changes** Since 2008, the CCPNM has improved procurement practices in Mexico's public health institutions and has achieved significant price reductions resulting in substantial savings in public pharmaceutical expenditure.

**Lessons learnt** The CCPNM has successfully changed the landscape of price negotiation for patented medicines in Mexico. However, it is also facing challenges, including a lack of explicit indicators to assess CCPNM performance; a shortage of

permanent staff with sufficient technical expertise; poor coordination among institutions in preparing background materials for the annual negotiation process in a timely manner; insufficient communication among committees and institutions, and a lack of political support to ensure the sustainability of the CCPNM.

## Background

As low- and middle-income countries seek to expand health insurance coverage, they are faced with an increase in medicine consumption and with the need to mobilize financial resources to pay for rising pharmaceutical expenditure.<sup>1,2</sup> The World Health Organization (WHO) has recommended that each country draw up a national list of essential medicines covered by health insurance to prioritize health interventions and contain costs.<sup>1</sup> Most of the medicines on these lists, patterned after WHO's Model Lists of Essential Medicines, are generic drugs that low- and middle-income countries can usually purchase at affordable public procurement prices.<sup>3</sup> However, high-priced patented medicines can account for a substantial portion of a nation's pharmaceutical expenditure and are seldom affordable to low- and middle-income countries without substantial donor support, as illustrated by the case of antiretrovirals.<sup>4</sup>

In Mexico, public expenditure on pharmaceuticals has increased substantially owing to government efforts to attain universal health-care coverage through *Seguro Popular*, a new insurance programme that guarantees its affiliates access to a comprehensive package of health services and medicines.<sup>5,6</sup> The programme aimed to cover the fraction of the population previously uninsured, which was 50%. According to the government, this target coverage was achieved in 2012.<sup>7</sup>

In Mexico's public sector, all public institutions must tender for pharmaceutical products obtainable from multiple sources, such as generic medicines. For products available only from a single source, including patented medicines, the law allows direct purchase and price negotiation with pharmaceutical firms.<sup>8</sup> However, a recent analysis of the public procurement prices for patented products unveiled price variations as high as 3000% among public institutions, which suggests large inefficiencies and flaws in the public procurement process.<sup>9</sup>

In Mexico, only 4% of all medicines approved for marketing are patented. However, these patented products represent 56% of the total public expenditure on pharmaceuticals (around 1.3 billion United States dollars [US\$] at the mean exchange rate for January 2012, 13.7 Mexican pesos per US dollar).<sup>10,11</sup>

To help control rising public expenditure on pharmaceuticals, in 2008 the Mexican Government reformed the public procurement process for patented medicines by establishing a new entity, the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (CCPNM, for *Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud*). Whereas before 2008 every public institution had negotiated a procurement price for patented medicines individually with each drug manufacturer, the establishment of the CCPNM allowed the primary public health institutions (Mexican Institute for Social Security [IMSS, for *Instituto Mexicano del Seguro Social*], Social Security Institute for Government Employees [ISSSTE, for *Instituto de Seguridad y Servicios Sociales para los Trabajadores del Estado*] and Ministry of Health [SSA, for *Secretaría de Salud*]) to negotiate together as a single entity with individual drug manufacturers a single procurement price applicable nationwide for one year to all public institutions, including those not engaged in the negotiation process.

The present study assesses the operation and performance of the CCPNM to extract lessons for Mexico and other countries that are also attempting to contain pharmaceutical expenditure while expanding health-care coverage. We performed an analysis of the annual reports of the CCPNM provided by the Ministry of Health and conducted 10 formal interviews with key informants, after obtaining their consent, to determine the structure and organization of the CCPNM, its objectives and its performance indicators. The key informants included members of the CCPNM or of its technical advisory committees, advisers to the president of the CCPNM and policy analysts.

## Operation of the CCPNM

The CCPNM was created through a presidential decree signed on 26 February 2008 and is headed by a presidential appointee whose term lasts for two years.<sup>12</sup> Its members are the heads of the finance, economics and health ministries and of Mexico's two main social security institutions (IMSS and ISSSTE), or their official substitutes. Besides its president, who acts as an executive coordinator, the CCPNM has an operating body consisting of a technical secretary and three advisory groups: the clinical, economic and intellectual property advisory committees.

The main functions of the CCPNM are to: (i) annually negotiate public procurement prices for patented medicines; (ii) prepare in advance the technical information necessary to

conduct the negotiation, including the economic documentation; (iii) research the prices of patented medicines as part of the background information for the negotiation; and (iv) implement appropriate negotiation strategies to improve the public procurement of patented medicines.<sup>13</sup>

## Annual price negotiation

During negotiation rounds in 2008, 2009 and 2010, the prices of 155 pharmaceutical products were negotiated. The drugs included agents used in oncology, haematology, infectology, neurology, endocrinology, rheumatology and other clinical specialties. In preparation for the price negotiation, data on the patent status of a large number of medicines were collected by the intellectual property advisory committee and price information for therapeutic equivalents as well as for products marketed outside of Mexico was collected and analysed by the economic advisory committee. The analysis conducted by the clinical advisory committee suggested that some of the medicines being requested by public institutions could have been replaced by cheaper but equally effective substitutes. This resulted in two types of recommendations: some involved changing the clinical indication for the use of various medicines (e.g. restricting the use of bevacizumab, a biopharmaceutical used to treat cancer, to patients with metastatic colon cancer); others involved purchasing generic medicines to replace more expensive products still under patent (e.g. replacing atorvastatin with ezetimib plus simvastatin in combination to reduce high blood cholesterol).

The annual reports of the CCPNM showed that, for most patented medicines, every year the negotiations resulted in large price reductions with reference to the preceding year. According to the reports, the accumulated direct savings (e.g. price reductions resulting from the negotiation) over 2008–2011 reached a total of US\$ 355 million (Table 1).

## Evaluation and lessons learnt

Overall, the actions taken by the Mexican Government to address rising pharmaceutical expenditures in the public sector are marked by some successes but also several challenges (Box 1). One success was the establishment of a new government entity able to promote collaboration among public health institutions in negotiating lower prices for patented medicines despite the prevailing institutional fragmentation of Mexico's health system. Other successes include the mobilization of trained human resources capable of engaging in complex price negotiations and the promotion of inter-institutional learning and cooperation through shared procurement

practices. Another important success is the sharing of information on the patent status of a large number of medicines,<sup>9,14</sup> since such information is often difficult to obtain in Mexico and other low- and middle-income countries.

The new government entity also faces several important challenges that were identified by CCPNM members and technical advisors: (i) the lack of permanent staff with sufficient technical expertise; (ii) poor management of the annual negotiation process, resulting in untimely preparation of background materials and inadequate communication between committees and institutions; (iii) lack of political support for the CCPNM, which threatens its sustainability after the federal administration turnover in December 2012; and (iv) lack of explicit indicators for assessing the CCPNM's performance. For instance, the CCPNM's annual reports say nothing about (i) negotiations that were not concluded on time; (ii) negotiations that resulted in a failure of the parties to agree on the target price and the possible reasons for this; (iii) the operational costs of the CCPNM, or (iv) the accuracy of volume forecasts and the under- or oversupply of patented medicines. The price reductions achieved by the CCPNM may be large, but if these are not matched with accurate forecasts of the drug volumes needed, inefficiency could result and reduce potential savings.

Two other issues should be addressed in the future. First, the CCPNM needs to develop better methods for assessing its impact on prices and the savings produced. This assessment could weigh the costs of establishing and operating the CCPNM against the net benefits achieved through lower prices. Second, the work of the CCPNM needs to be made more transparent, since annual reports are circulated only within the three public health institutions belonging to the CCPNM and the subnational health ministries of the 31 states and federal district. Increased transparency and accountability to other stakeholders (e.g. civil society and academic institutions) could enhance trust and garner support for the work of the CCPNM, since procurement is an area perceived as easily harbouring corruption.<sup>4</sup>

In conclusion, the creation of the CCPNM has changed the landscape of the price negotiation process for patented medicines in Mexico and has improved procurement practices within public health institutions. However, Mexico needs to address several continuing challenges to make the procurement of expensive medicines in the public sector more efficient. Mexico's experiences with its new government entity charged with facilitating the public

procurement of patented essential medicines is a source of important lessons for other countries that are seeking to improve their drug procurement processes.

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### Box 1. Summary of main lessons learnt

- Coordination among public institutions in negotiating the public procurement price of patented drugs can result in large price reductions.
- Well-defined, explicit performance indicators are necessary to rigorously evaluate the impact of Mexico's CCPNM on the procurement price of patented medicines.
- Political support is needed to ensure the timely preparation of the negotiations, the availability of human resources able to conduct complex negotiations and adequate continued functioning of the CCPNM.

CCPNM, Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs.

Table 1. **Estimated savings<sup>a</sup> in public expenditure on patented medicines since the establishment in 2008 of the Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs, Mexico**

<b>Negotiation year</b>	<b>Procurement year</b>	<b>Annual direct savings (million US\$)<sup>b</sup></b>
2008	2009	121.8
2009	2010	103.6
2010	2011	52.1
2011	2012	77.5
<b>2008–2011</b>	<b>2009–2012</b>	<b>355.0</b>

US\$, United States dollars.

<sup>a</sup> With reference to the preceding year.

<sup>b</sup> Adjusted for inflation.