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

Octavio Gómez-Dantés,a Veronika J Wirtz,a Michael R Reich,b Paulina Terrazas,c & Maki Ortizd

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.1-2 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.3 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.4 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.5

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.6-8 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 2012.9

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.9 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.9

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).10,11

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 de los Trabajadores del Estado] and the Ministry of Health [SSA, for Secretaría de Salud]) to negotiate together as a single entity with individual drug manufacturers for a single procurement

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Submitted: 24 April 2012 – Revised version received: 7 August 2012 – Accepted: 12 August 2012 – Published online: 22 August 2012
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, advisors 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. 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.22

**Annual price negotiation**

During negotiation rounds in 2008, 2009 and 2010, the prices of 135 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 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, 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.

<table>
<thead>
<tr>
<th>Negotiation year</th>
<th>Procurement year</th>
<th>Annual direct savings (million US$)</th>
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<tr>
<td>2008</td>
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<td>121.8</td>
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<tr>
<td>2009</td>
<td>2010</td>
<td>103.6</td>
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<td>2011</td>
<td>2012</td>
<td>77.5</td>
</tr>
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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.

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2. CCS, Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs. Estimated savings 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. Table 1. Estimated savings 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.
Lessons from the field
Negotiating patented medicine prices in Mexico
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Abstract

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.

Acknowledgements:
The authors thank the following persons for their support in conducting the interviews on which this paper is based: Francisco Bañuelos, Mariana Barraza- Llorenz, Eduardo González-Pier, Jorge Medina and Ramiro Tamayo.

Competing interests: This work was commissioned by the Ministry of Health of Mexico. The Ministry had a role in the design, analysis and publication of the results.

Negotiating patented medicine prices in Mexico: lessons for other countries that are seeking to improve their drug procurement processes.

doi:10.2471/BLT.12.106633

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Bull World Health Organ 2012;90:788–792

Keywords

Governmental purchasing; health system; health economics; price negotiations; public health institutions; patented medicines; pharmaceutical costs; procurement; Public Health Reform; Seguro Popular; Chile; Mexico.

Malcolm spectroscopy in biodiesel production: a review

Keywords

Biodiesel; FT-IR; hydrogenation; transesterification; ultrasonic; spectroscopy.
Резюме

Новая организация для ведения переговоров о ценах на государственные закупки патентованных лекарственных средств в Мексике

Проблема. Так как страны расширяют страховое обеспечение по медицинскому страхованию, их расходы на лекарственные средства увеличиваются. Для решения этой проблемы ВОЗ рекомендовала каждой стране составить перечень основных лекарственных средств. Несмотря на то, что большинство лекарственных средств являются непатентованными, во многих странах на патентованные лекарственные средства приходится значительная доля фармацевтических расходов.

Приемущества. Предприятия, занимающиеся лекарственными средствами правительство Мексики в 2008 году создало Координационную комиссию по ведению переговоров о ценах на патентованные лекарственные средства (CCPNM), цель которой, как видно из названия, заключается в ведении переговоров о ценах на патентованные лекарственные средства с их производителями по перечню основных лекарственных средств Мексики.

Местные условия. Государственные расходы Мексики на лекарственные средства значительно увеличились за последние десятилетие в связи с попытками правительства достичь единого страхового покрытия лечения по программе страхования Seguro Popular, внедренной в 2004 году, которая гарантирует доступ к полному пакету услуг в области здравоохранения и лекарственных средств.

Однако Комиссия продолжает решать стоящие перед ней задачи, включающие отсутствие явно выраженных показателей для оценки деятельности CCPNM; недостаток кадровых сотрудников с достаточным техническим опытом; плохую координацию между учреждениями при подготовке исходных материалов для своевременного ежегодного процесса переговоров; недостаточное взаимодействие между комитетами и учреждениями, а также недостаточную государственную поддержку для обеспечения устойчивого развития CCPNM.

Resumen

Nueva entidad para negociar los precios de adquisición pública de los medicamentos patentados en México

Situación. La ampliación de la cobertura del seguro sanitario comporta un aumento del gasto nacional en medicamentos. Con el propósito de abordar este problema, la OMS recomienda que cada país redacte un listado con los medicamentos fundamentales para su territorio. Si bien la mayoría de los medicamentos incluidos en dichos listados son genéricos, en muchos países los medicamentos patentados constituyen una parte considerable del gasto farmacéutico.

Enfoque. Con el fin de ayudar a controlar el gasto en medicamentos patentados, el gobierno mexicano creó en el año 2008 la Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud (CCPNMIS). La misión de dicha entidad consiste, como su propio nombre indica, en negociar con las empresas farmacéuticas los precios de los medicamentos patentados incluidos en el listado de medicamentos fundamentales de México.

Marco regional. El gasto público farmacéutico de México ha aumentado de manera significativa durante la última década, debido al propósito del gobierno mexicano de alcanzar una cobertura sanitaria universal a través del Seguro Popular. Este programa de seguros creado en 2004 garantiza el acceso de los ciudadanos a un amplio abanico de servicios sanitarios y de medicamentos.

Cambios importantes. Desde el año 2008, la CCNPMS ha mejorado las prácticas de adquisición de las instituciones de la sanidad pública de México. Además, ha logrado bajas de precios significativas que han acarreado un ahorro considerable en el gasto público farmacéutico.
Lecciones aprendidas La CCNPMIS ha conseguido cambiar satisfactoriamente el panorama de la negociación de precios de los medicamentos patentados en México. No obstante, la CCNPMIS sigue enfrentándose a nuevos retos, entre los cuales se incluyen: la ausencia de indicadores explícitos para evaluar su rendimiento, las carencias de personal fijo con experiencia técnica suficiente, los problemas de coordinación entre las instituciones a la hora de preparar oportunamente los materiales de base para el proceso anual de negociación, la falta de comunicación entre comités e instituciones y la ausencia de un apoyo político que garantice la sostenibilidad de la CCNPMIS.

References