BREVE 14
MEXICO’S COORDINATING COMMISSION FOR NEGOTIATING THE PRICE OF MEDICINES AND OTHER HEALTH INPUTS

Based on a presentation by Dr. Francisco Bañuelos, July 2016.

A series on policies and methods based on presentations for experts. Prepared by CRITERIA, a knowledge network on prioritization and health benefit plans from the Inter-American Development Bank.
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ACRONYMS

CCNPNM Coordinating Commission for Negotiating the Price of Medicines and Other Health Inputs

IMSS Mexican Social Security Institute

ISSSTE Government Workers’ Social Security and Services Institute
INTRODUCTION

This Breve is based on a webinar presented by Dr. Francisco Bañuelos, who was a member of Mexico’s Coordinating Commission for Negotiating the Price of Medicines and Other Health Inputs (hereafter referred to as the CCPNM or the Commission) for three years.

The presentation was delivered on July 13, 2016, to the members of CRITERIA, the Inter-American Development Bank’s knowledge network on priority setting and health benefit plans.

Rising pharmaceutical expenditures constitute a burden for health systems around the globe. In low- and middle-income countries, where universal health coverage has been the goal for the last several years, drug purchases have increased considerably. In this context, in 2008, the Mexican government decided to centralize the negotiation process for single-source or patented medicines, to set a single, nationwide price, which applies to all public institutions for one year. The CCPNM was established mainly as a reaction to the country’s fragmented public procurement system for pharmaceuticals, which resulted in a lack of bargaining power, as well as heterogeneous pricing, purchasing processes and payment conditions.

First, this Breve gives an overview of the characteristics of the pharmaceutical sector in Mexico and the main factors resulting in the decision to establish the CCPNM. It briefly discusses the legal framework of the Commission. Then, it looks at the CCPNM’s objective and operations, before describing the negotiation process. The results of the CCPNM in economic and organizational terms, as well as other positive impacts, are analyzed in the subsequent section. Finally, the Breve concludes by presenting some of the challenges emerging from the Mexican experience with its price negotiation scheme.

1 Francisco Bañuelos is a surgeon who graduated from the National Autonomous University of Mexico (UNAM) and completed a degree in Hospital Management from the University of Rennes, France. He has held several positions in the health sector, including that of president of the Mexican Hospital Association from 2010 to 2012. He currently teaches at La Salle University in Mexico City.

2 The audio, PowerPoint slides, and transcript of this presentation in Spanish can be accessed on the CRITERIA website at http://www.redcriterias.org/webinars
CONTEXT OF THE MEXICAN PHARMACEUTICAL SECTOR AND DRIVERS FOR THE ESTABLISHMENT OF A DRUG PRICE NEGOTIATION COMMISSION

In addition to the steadily rising cost of pharmaceutical inputs, Mexico faces challenging health care needs and structural difficulties: important segments of the population are poor; the health care system is fragmented and consists of several, largely disconnected sub-systems; and considerable inequalities exist in access to services. Furthermore, the rising prevalence of chronic diseases results in high costs for the health care system, including increased spending on prescription medicines (OECD, 2016).

In Mexico, drug expenditures have also increased substantially as a consequence of the country’s commitment to universal health care coverage. Seguro Popular, a public insurance program introduced in 2003 to cover those without formal health insurance, guarantees its enrollees access to a comprehensive package of health services and medicines (Gómez-Dantés et al., 2012).

Some of the main challenges of the pharmaceutical sector in Mexico are outlined below. They have been addressed by the Mexican government in recent years through a series of measures, which will be discussed in the next section.

Main challenges of the pharmaceutical sector in Mexico

- **Fragmented public procurement:** Before 2008, each public institution individually negotiated a procurement price for medicines with drug manufacturers; therefore, institutions had little bargaining power, resulting in heterogeneous pricing, purchasing processes and payment conditions. Huge price differences were an indication of the inefficiencies and weaknesses in the public procurement system (Gómez-Dantés et al., 2012).

- **Vulnerability to corruption:** Contracts for the procurement of patented medicines were vulnerable to corruption. In the absence of competition, there was the potential for officials to accept higher prices in exchange for bribes (OECD, 2013a).

- **Constant increase in prices:** The prices of medicines sold at private pharmacies rose constantly and far beyond the rate of inflation. This development caught the attention of policy makers and raised the need to curb this trend.
• Maximum retail price mostly applied in poor rural areas: Although the packaging of most medications displayed the maximum retail price (and still does), it was primarily small pharmacies in poor, rural areas that charged those prices. Larger pharmacies in urban areas offered prescription drugs at prices much lower than those indicated on the package. As a result, this labeling proved to be more misleading than informative (FUNSALUD, 2011, p. 147-150).

• Limited generic market: The market for generic drugs was growing very slowly. The Mexican population distrusted generic products and a lot of work had to be done to inform the public about the actions that had been taken to ensure the quality of generics. It was especially important to explain the studies related to their interchangeability and bioequivalence (Ibid., p. 135-138).

• Illegal drug market: The falsification and smuggling of drugs, as well as stolen drugs, also constituted a challenge. Private pharmacies, for example, were selling prescription drug samples to the public. In other cases, institutions inadvertently purchased medicines that had been stolen from other public institutions (e.g., from warehouses, hospitals or health clinics), but since they were all labeled the same (“health sector”), buyers never grew suspicious of their origins (Ibid., p. 86-88).

• Growth in the number of unnecessary and inappropriate prescriptions: The information received by doctors about prescription drugs was either inadequate or insufficient (Ibid., p. 109-111).

• Adverse events due to inappropriate drug administration: A monitoring system introduced at some hospitals to measure adverse events based on quality standards showed an increase in these events over the years. At the same time, a high number of inaccurate or incorrectly interpreted prescriptions at private pharmacies were reported (Ibid., p. 102-103).

Main drivers of the establishment of the CCPNM

It was in this context that the CCPNM was established in 2008, mainly as a response to the fragmentation of the public procurement of medicines, which mirrored the fragmented structure of the Mexican health system as a whole. Fragmentation was the main driver, since it led to a lack of bargaining power and heterogeneous pricing, purchasing processes and payment conditions. The decentralization of the health system, a crucial part of the health reforms made around 2000, led to the creation of 32 different purchasing entities (one for each state) with different needs, characteristics and regulations. In addition, about 50 different public institutions (e.g., IMSS, ISSSTE, Pemex, the Mexican Army and Navy, and state social security
schemes) were purchasing medicines separately. According to a study carried out by the Ministry of Health’s unit for economic analysis (Subsecretary for Innovation and Quality, 2007), the prices of purchased drugs varied from 2% to 300%, with the largest variations seen among single-source or patented drugs.

Prior to the establishment of the CCPNM in 2008, several developments were already under way to address some of the challenges faced by Mexico’s pharmaceutical sector and to lay the path for the establishment of the centralized price negotiation scheme. In 2002, the Mexican government established the foundations of a comprehensive pharmaceutical policy (Ministry of Health, 2005). Five years later, in 2007, inter-institutional working groups were created to address the following topics (Bañuelos, 2016):

1) price regulation and competition in the private sector, 2) measures to improve price regulation, 3) best practices for drug prescription and drug administration, and 4) financing mechanisms and public drug procurement.

As a further step, that same year, pharmacies, distributors, academics, physicians, and representatives from the pharmaceutical sector, state government, and the legislative and executive branches of the federal government signed an agreement to guarantee the adequacy, availability and fair prices of medicines. In addition, the decision was made to form an inter-institutional group to manage national drug policy. Several parts of the existing legal framework justified and enabled the creation of a coordinating commission. For example, the Mexican Constitution states that the drug procurement process should be efficient, cost-saving, transparent and honest. Other legislation, such as the General Health Law or laws applying to the Mexican Social Security Institute (IMSS) and Government Workers’ Social Security and Services Institute (ISSST), states that patients must be guaranteed access to medicines.

The synergy of these developments and measures, along with the support of the existing legal framework, laid the basis for the creation of the CCPNM through a presidential decree signed into law on February 26, 2008. It presents the reasons for creating the CCPNM, its mission, objectives, role, scope and tasks, as well as its composition, structure and functioning. The CCPNM’s operational guidelines are laid out in a separate document.

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3 Detailed content of the topics addressed by the working groups, as well as the composition of these groups, is described in Castro Albarrán, J.M. (2008). Medicamentos en México: Hacia una política nacional”, CIES – Centro de Investigación y educación para la salud

4 For more details, consult Breve No. 3 on Mexican pharmaceutical policy. Política farmacéutica y priorización en salud: el caso de México. Based on a webinar presentation by Mariana Barraza, October, 2012. Available at http://www.redcriteria.org/biblioteca/

5 The agreement is available at Presidencia de la República, México: http://calderon.presidencia.gob.mx/2007/02/el-presidente-calderon-en-la-firma-del-compromiso-para-garantizar-la-suficiencia-disponibilidad-y-precio-justo-de-los-medicamentos/

6 See Article 134 of the Constitution of Mexico.

7 All related documents are available at http://www.sidss.salud.gob.mx/contenidos/OrganosColegiados/ComisionCNPMIS.html
OBJECTIVE AND FUNCTIONING OF THE COMMISSION

One of the key characteristics and advantages of the CCPNM is that the IMSS and the ISSTE—Mexico’s most important public health institutions—together with the Ministry of Finance and Public Credit, the Ministry of Economy, and the Ministry of Health, negotiate the prices for patented or single-source medicines as a single entity with the drug manufacturers. These negotiations are conducted on a yearly basis.

To be considered for negotiation, a drug must fall into one of the following categories:

- A medicine under patent
- A single-source medicine (can only be purchased from one provider)
- A medicine for which there are no available substitutes

In addition, it must be listed on the National Medicines Formulary (CBCI), which establishes the list of medications the public health institutions can choose from to finance and prescribe (Bañuelos, 2016). In the case of non-patented (generic) or multiple-source medicines, public institutions have to put out a request for tender.

The universe of drugs potentially subject to the centralized negotiation process is substantial when taking into account that patented medicines represent more than half of Mexico’s total public expenditure on pharmaceuticals.

The CCPNM has three main tasks:

1. To determine which drugs and health inputs are to be included in the negotiations.

2. To prepare the technical and economic elements to be taken into consideration during the negotiation process, including estimated demand, evidence from economic evaluations, the evidence-based evaluations of health interventions, information regarding the terms of sale in international markets, prices and terms of payment, the validity of patents and licenses, and the validity of import licenses.

3. To negotiate drug prices with the pharmaceutical industry for the entire public sector.

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8 The IMSS is Mexico’s largest public health institution.

9 In addition, two institutions (the Ministry of Public Administration and the Federal Economic Competition Commission) participate as permanent advisors to the CCPNM.

10 According to a study carried out in 2008 by the General Health Council, therapeutic substitutes exist for about 74% of all patented drugs on the Mexican pharmaceutical market (FUNSALUD, 2007, p. 176).

11 The CBCI consists of a list of medications that public health institutions are authorized to prescribe. It is updated annually and can be consulted online at http://www.csg.gob.mx/contenidos/CB2013/cuadro_basico.html

12 According to Gómez-Dantés et al. (2012), patented drugs represented 56% of total public expenditure on pharmaceuticals in 2012.
The Commission is headed by a president, who is appointed to a two-year term by the president of Mexico. It is supported by a technical secretariat, which coordinates the operational tasks of three related committees: 1) a clinical–technical committee, 2) a price and patent committee, and 3) an economic evaluation committee (see Figure 1).

The committees respond to requests for information from the Technical Secretariat or leaders of the negotiation team. The committees coordinate their research efforts, with each committee compiling the necessary information within its area of expertise. The committees receive advice from independent technical experts as well as public institutions, and they exchange information to ensure synergies. In addition, they communicate and coordinate with providers and other pharmaceutical institutions. The information they collect is then provided to the negotiation team. They also collaborate on the development of an annual work plan.

**Figure 1. Structure of the CCPNM**

Source: Health Sector Integration and Development Division
A maximum of two representatives from each institution (IMSS, ISSSTE, Ministry of Finance, Ministry of the Economy, and Ministry of Health) form part of each committee. The Technical Secretariat and the president recommend a coordinator for each committee. Committee members work without remuneration. Figure 2 shows the specific tasks of each committee.

**Figure 2. Committee tasks**

<table>
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<tr>
<th>Clinical–Technical Committee</th>
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<tbody>
<tr>
<td>• Analyzes the safety and efficacy of drugs based on evidence and clinical practice.</td>
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<td>• Decides whether a drug represents a good treatment option.</td>
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<tr>
<th>Price and Patent Committee</th>
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<tr>
<td>• Collects and analyzes data on volume, terms of payment, distribution, international price comparisons, etc.</td>
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<tr>
<td>• Coordinates the needs of those public institutions that are not members of the committee but are interested in joining the negotiation process.</td>
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<tr>
<th>Economic Evaluation Committee</th>
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<tr>
<td>• Collects and analyzes information from the economic evaluation, with a special focus on comparing a drug’s cost-effectiveness with that of relevant therapeutic alternatives.</td>
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</tbody>
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Source: Bañuelos (2016)

**NEGOTIATION PROCESS**

**Negotiation teams**

Each year, the Technical Secretariat selects a negotiation team, headed by a lead negotiator, for each medicine; the team of negotiators proposed by the Technical Secretariat must be approved by the CCPNM.

Teams are composed of officials with experience in either the planning or implementation stages of the pharmaceutical procurement process. The number of negotiators selected per institution depends on the relative importance of each institution in terms of its annual purchasing volume for a specific medicine. Due to the fragmentation of the Mexican health system, several institutions with differing needs are involved in the bargaining process; therefore, the Commission determines, on a case-by-case basis, which public institution has the greatest need for a particular medicine. That institution will then play a more important role in the negotiation process.
Schedule and agreements

Each year, the Technical Secretariat establishes a schedule for negotiations, usually organized by pharmaceutical specialty, with the drug companies. The schedule includes the following information: estimated purchasing volume, scheduled date of purchase, a delivery schedule based on the needs of each institution, and the names of the representatives of each institution. Once negotiations have concluded, an agreement—valid for one year—is established. Each committee delivers a report to the Technical Secretariat on the results achieved, and together they establish a plan of action to follow up on the agreements that were reached. Purchasing is then organized separately by each buyer in a decentralized way.

Framework contract

Negotiations result in a framework contract that applies to all public sector institutions, even if they did not directly participate in the negotiations. This arrangement has several advantages:

- The pricing and purchasing conditions for patented medicines are homogeneous.

- It facilitates the purchasing process.

- It leads to savings due to better terms of trade.

- It lowers transaction costs.

The contract also establishes the authorized distributors from which buyers must purchase medicines to ensure that all parties comply with the conditions set forth in the framework contract. An example of a framework contract signed in 2012 can be found on the website of the Mexican Ministry of Public Administration.13

IMPACT AND ACHIEVEMENTS

Financial impact

Reforms introduced by the Mexican government over the last few years in the area of pharmaceutical procurement—including the establishment of the CCPNM—have led to significant savings, mainly due to the consolidated purchasing of medicines. On average, the government has seen savings of 7% to 15% per year (Bañuelos, 2016); however, the discount varies considerably depending on the product. In some instances, it has only been 1% or 2%, while in other cases, savings of 50% or even 60% were achieved. For example, the manufacturers of a drug that is about to go off patent do not have much bargaining power; therefore, a higher discount can be obtained. In contrast, negotiations in cases for which a manufacturer has a monopoly on a particular medicine might not yield much in the way of results. Table 1 shows the total savings achieved since the CCPM was established in 2008.

The CCPNM was initially established on a temporary basis, with the idea that it would be in place for a few years, until negotiations no longer yielded further price reductions; however, the Commission has now been functioning for nine years, and price reductions are still being achieved. Although the savings appear to decrease over the years, this decline is actually due to the fact that price cuts—achieved through negotiations in previous years—are not applied to figures for subsequent years.

One of the main achievements of the Commission is that the constant, significant increase in drug prices has been slowed.\textsuperscript{14}

### Additional achievements

In addition to financial gains, the introduction of the CCPNM has also made other positive impacts. The main achievements (Bañuelos, 2016; Gómez-Dantés et al., 2012) of the CCPNM include the following:

Better organized public procurement of approximately 145 patented and single-source medicines, leading to more homogeneous prices and treatment schemes (The CCPNM’s clinical–technical committee analyzed clinical practice guidelines and used them to make recommendations to institutions as to whether they should increase or reduce the purchasing volume of certain drugs).

Increased certainty for purchasers and suppliers with regard to the prices and quantities of medicines purchased, as well as improved communication between the two.

Improved understanding of the market and the therapeutic schemes used by public health institutions (The volume calculation is now based on consumption figures, whereas before it was often estimated or adjusted to the available budget).

Smoother, more efficient purchasing processes and transactions.

Enhanced market stability and availability of medicines.

Encouragement of inter-institutional learning and cooperation in a fragmented health system through shared procurement practices.

Enhanced sharing of information on the patent status of a vast number of drugs, which is generally difficult to obtain in low- and middle-income countries.

There are other areas where possible synergies and potential for further improvements have been explored (Bañuelos, 2016). For example, greater cooperation among different institutions has also had a positive impact on the procurement of medicines purchased through tendering. Several of the coordinated planning and procurement mechanisms applied in this area have led to better and more uniform price conditions. Institutions have learned from CCPNM processes and can use this knowledge during the tender process for generic, multiple-source drugs.

Another initiative undertaken since the establishment of the CCPNM focuses on supporting the development of new drugs through the introduction of risk-sharing models—with risk borne by the industry and the public sector—for pharmaceuticals with development potential. In an effort to foster further successful development of a particular drug, the negotiating team does not insist on the same degree of price cuts at the negotiations, an approach that particularly applies to treatments for cancer or cardiovascular disease.

The regulation of prescriptions has also been addressed. The consolidated planning and purchasing process described above has led to increased access to and sharing of information between institutions. Consequently, they have been able to analyze the prescribing and use of
medicines, resulting in savings and the improved use of pharmaceutical products.

Furthermore, the Commission has been supporting measures to promote generic markets and to foster the development of substitutes for patented drugs without waiting until they go off patent. As a consequence, the Mexican regulatory agency COFEPRIS\textsuperscript{15} has implemented a mechanism whereby drugs set to go off patent are analyzed to facilitate competition once patents have expired.

In addition, in cases in which the Commission was unable to negotiate a price reduction because it was confronted with a monopoly, it has published reports proposing to open the Mexican market to new pharmaceutical products and to improve research on alternative treatments in order to counter monopolies.

From the pharmaceutical industry’s perspective, this centralized price negotiation mechanism also affords certain advantages. Legally, industry members are not obliged to participate, yet they benefit from a better organized and more unified process, the exchange of information, and greater certainty regarding sales volume, which in turn facilitates planning.

CHALLENGES
Notwithstanding the considerable savings and positive impacts made by the CCPNM, Mexico’s public health sector still faces some challenges in terms of dealing with the pharmaceutical industry. These challenges are presented below.

Insufficient cooperation and coordination
Despite improved coordination across various institutions, there are still flaws to be addressed, for example, with regard to the timely preparation of background materials required for negotiations. Furthermore, in spite of current efforts, there is still a need for improved communication between committees and institutions.

There have also been challenges in terms of cooperation within negotiation teams. The level of dedication and commitment of team members varies, and sometimes a sense of distrust exists among members, which has, in some cases, had a negative impact on the results of a negotiation.

Technical skills
Another challenge is the inadequate number of permanent CCPNM members with sufficient technical expertise (OECD, 2013b; Gómez-Dantés et al., 2012). Critics have also suggested that members of the Commission should receive further training on negotiation techniques and pharmaceutical procurement schemes (Bañuelos, 2016).

\textsuperscript{15} Federal Commission for the Protection against Sanitary Risk
Lack of performance indicators

Another aspect highlighted by a World Health Organization (WHO) study is the lack of explicit performance indicators to assess the work of the Commission. For example, WHO points out those annual reports fail to include information on negotiations that were not concluded on time or that did not result in an agreement, nor do they discuss possible reasons for these outcomes. The CCPNM’s operational costs are also not stated, even though calculations on the savings achieved should take them into account (Gómez-Dantés et al., 2012).

Access to information

The varying amount of information gathered for each negotiation is also a challenge. The committees find it difficult to obtain extensive information on some pharmaceutical products. In these cases, their negotiation power is limited, resulting in less dramatic price reductions as compared to those obtained for drugs for which they are able to successfully compile a large amount of information (Bañuelos, 2016); therefore, it is crucial to enhance the exchange of information on both a national and international level. The exchange of information also helps to critically analyze the stated benefits of a pharmaceutical product, which in turn allows the negotiating team to question the high prices of certain drugs.

A good practice in this context is an initiative by the Mercosur countries that involves the sharing of information on high-cost drugs, as well as collaboration to jointly purchase high-cost medicines.

Monopolies

In some situations, it has been difficult or impossible for the CCPNM to achieve price reductions, especially in cases of national or international monopolies.

Control mechanisms

In some cases, there has been a disparity in the documented quantity of pharmaceutical products purchased by public institutions versus the quantity of products sold by the manufacturer, with health sector quantities being greater (Ibid.). Normally, the negotiation team compares its numbers to the drug company’s numbers to establish a control mechanism of shared responsibilities; however, this mismatch suggests that the control measures in place are inadequate in terms of verifying the quantities purchased and avoiding the misuse of funds or corruption.

Transparency and accountability

Procurement in the pharmaceutical sector offers many opportunities for corruption. As Roberts et al. state, “Particularly at the procurement stage, government decision makers are distributing contracts that create significant profit opportunities for private parties” (Roberts and Reich, 2011). In this context, it is important to
ensure that information regarding negotiations is distributed not only among CCPNM institutions—as is currently the case—but also to civil society, academics and other interested stakeholders (Gómez-Dantés et al., 2012).

During the initial years of the CCPNM, a five-year moratorium was imposed on the release of information related to price negotiations. Furthermore, given the CCPNM’s rotating presidency and the fact that it does not fall under any specific institution, this information is scattered across different entities. Currently, even though negotiation results and agreements are still not published, they can be requested directly from the institution that holds the presidency. Nevertheless, this procedure may be rather complicated, especially for someone unfamiliar with the process.

It should also be noted that the Ministry of Public Administration, which monitors the functioning of Mexico’s public sector, is present throughout the negotiation process, from the preparation phase to the final phase. It recommends switching negotiation teams after a maximum of three negotiations to mitigate the risk of corruption.

**External pressure**

Some external stakeholders have put pressure on the Commission. First, some pharmaceutical companies have tried to influence the composition of the CCPNM and its decisions. There has also been pressure from specific interest groups worried about the impact that negotiations might have on their access to medicines. Lastly, the media, at one point, discredited the work of the CCPNM; however, these criticisms stopped after publication of the first report detailing the results achieved.

**CONCLUSIONS**

- Like many other countries around the globe, Mexico is facing increasing pressure on health care spending and is looking for ways to improve efficiency to mitigate the impact of this development.

- In this context, Mexico introduced a centralized drug price negotiation process, which takes advantage of the combined bargaining power of various public sector entities to achieve lower prices for patented single-source drugs.

- This mechanism has generated significant savings, as well as other positive externalities, including enhanced inter-institutional cooperation, learning and sharing of information, increased certainty for purchasers and suppliers about prices and the therapeutic effect of drugs, more efficient purchasing processes, a greater understanding of the market, and increased market stability.

- This policy still faces important challenges, such as the need for permanent members of the Commission with sufficient technical expertise, the absence of performance indicators and control mechanisms, limited transparency and accountability, and the
existence of monopolies and external pressures. The centralized negotiation mechanism is a policy still under development and, therefore, requires continuous adjustments and improvements based on lessons learned.

- Despite the aforementioned challenges, this case serves as an interesting example of a tool that can be implemented by other countries to control drug expenditures.

REFERENCES


