

Research Synthesis: Institutions

v1.0 researched and written by Elise Erickson, edited by Suerie Moon, last updated June 2018

Introduction

The literature regarding pricing institutions is thin.* Most of the literature looks at a specific aspect or function of an institution, rather than discussing the developments, achievements, organization or characterization of the institution as a whole and its impact on prices.

Search terms

National pricing commission; specific institutions e.g. PBAC, CDR, NICE and pricing

Synthesis of the literature

Specialized institutions to manage medicines pricing have been established in some countries and regions, and several papers analyze these. For example, Adesina, Wirtz, and Dratler (2013) examined the impact of the creation of Mexico's commission for price negotiation on antiretroviral (ARV) prices, and found ARV prices dropped by 38% on average after the first round of negotiations, but noted that this reduction cannot be credited fully to the commission. Also, Mexico continued to pay an average of six times more than similar countries for ARVs despite the commission. The authors suggest that forecasting and procurement process inefficiencies might have negatively impacted the negotiation process for the commission.

Gómez-Dantés et al. (2012) described Mexico's Coordinating Commission for Negotiating the Price of Medicines and other Health Inputs (CCPNM), an agency created in 2008 for price negotiations for patented drugs on Mexico's essential medicines list. The authors note the agency's success in price negotiations, but also highlight major limitations such as: absence of appropriate indicators to mark the commission's performance, coordination with other institutions, and sustainability concerns (political will, insufficient staff).

Australia's Pharmaceutical Benefits Advisory Committee (PBAC) has been widely studied. Recently, Vitry and Shute (2018) described the funding and pricing policies for high-cost medicines listed by Australia's Pharmaceutical Benefits Scheme (PBS). Turkstra et al. (2017) found that a medicine's expected financial impact to the government is negatively associated with a PBAC recommendation. Others point more explicitly to PBAC's limitations. For instance, Carter, Vogan, and Afzali (2016) highlighted PBAC's use of ICER (incremental cost-effectiveness ratio) thresholds for decision-making, and the absence of community values considered in cost-effectiveness evaluations as two major limitations. Langley (2017) examined version 5.0 of the Guidelines for Preparing Submissions to PBAC, arguing that the guidelines do not meet scientific standards and discussing how the guidelines could be altered to reflect standard scientific practice. Lu et al. (2008) examined the balance between limited resources and

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community needs with regards to high-cost medicines in Australia, illustrating their concerns with rheumatoid arthritis.

Pricing institutions do not exist in a vacuum; rather, they can be impacted by other sectors such as trade. For instance, Harvey et al. (2004) discussed how the Australian-United States Free Trade Agreement (AUSFTA) had the potential to undermine Australia's Pharmaceutical Benefits Scheme (PBS), thereby increasing the cost of medicines for Australian consumers, or delaying the entry of generics.

Research gaps

- Research on pricing institutions in low and middle-income countries
- Further research on the effectiveness of a pricing/procurement agency, such as impact on price or availability (similar to Adesina, Wirtz, and Dratler (2013) and Gómez-Dantés et al. (2012)), with particular emphasis on lessons learned

Cited papers with abstracts

Adesina, Adebisi, Veronika J. Wirtz, and Sandra Dratler. 2013. "Reforming Antiretroviral Price Negotiations and Public Procurement: The Mexican Experience." *Health Policy and Planning* 28 (1): 1–10. <https://doi.org/10.1093/heapol/czs015>.

Abstract: 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.

Link: <https://academic.oup.com/heapol/article/28/1/1/643825>

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Carter, Drew, Arlene Vogan, and Hossein Haji Ali Afzali. 2016. "Governments Need Better Guidance to Maximise Value for Money: The Case of Australia's Pharmaceutical Benefits Advisory Committee." *Applied Health Economics and Health Policy* 14 (4): 401–7. <https://doi.org/10.1007/s40258-015-0220-3>.

Abstract: In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to the Minister for Health on which pharmaceuticals should be subsidised. Given the implications of PBAC recommendations for government finances and population health, PBAC is required to provide advice primarily on the basis of value for money. The aim of this article is twofold: to describe some major limitations of the current PBAC decision-making process in relation to its implicit aim of maximising value for money; and to suggest what might be done toward overcoming these limitations. This should also offer lessons for the many decision-making bodies around the world that are similar to PBAC. The current PBAC decision-making process is limited in two important respects. First, it features the use of an implicit incremental cost- effectiveness ratio (ICER) threshold that may not reflect the opportunity cost of funding a new technology, with unknown and possibly negative consequences for population health. Second, the process does not feature a means of systematically assessing how a technology may be of greater or lesser value in light of factors that are not captured by standard measures of cost effectiveness, but which are nonetheless important, particularly to the Australian community. Overcoming these limitations would mean that PBAC could be more confident of maximising value for money when making funding decisions.

Link: <https://link.springer.com/article/10.1007%2Fs40258-015-0220-3>

Gómez-Dantés, Octavio, Veronika J Wirtz, Michael R Reich, Paulina Terrazas, and Maki Ortiz. 2012. "A New Entity for the Negotiation of Public Procurement Prices for Patented Medicines in Mexico." *Bulletin of the World Health Organization* 90 (10): 788–92. <https://doi.org/10.2471/BLT.12.106633>.

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.

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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.

Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3471060/>

Harvey, Ken J., Thomas A. Faunce, Buddhima Lokuge, and Peter Drahos. 2004. "Will the Australia-United States Free Trade Agreement Undermine the Pharmaceutical Benefits Scheme?" *The Medical Journal of Australia* 181 (5): 256–59.

Abstract: The Australia-United States Free Trade Agreement (AUSFTA) contains major concessions to the US pharmaceutical industry that may undermine the egalitarian principles and operation of the Pharmaceutical Benefits Scheme (PBS) and substantially increase the costs of medicinal drugs to Australian consumers. AUSFTA's approach to the PBS excessively emphasises the need to reward manufacturers of "innovative" new pharmaceuticals, instead of emphasising consumers' need for equitable and affordable access to necessary medicines (the first principle of our National Medicines Policy). Several features of AUSFTA may bring pressure to bear on the Pharmaceutical Benefits Advisory Committee (PBAC) to list "innovative" drugs that the committee initially rejected because the evidence for cost-effectiveness was not compelling. Intellectual property provisions of AUSFTA are likely to delay the entry of PBS cost-reducing generic products when pharmaceutical patents expire. We support the many concerned health and consumer organisations who have asked the Senate either not to pass the enabling legislation, or to delay its passage until a fairer deal in terms of public health can be obtained.

Link: <https://www.ncbi.nlm.nih.gov/pubmed/15347273>

Langley, Paul C. 2017. "Dreamtime: Version 5.0 of the Australian Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee (PBAC)." *INNOVATIONS in Pharmacy* 8 (1). <https://doi.org/10.24926/21550417.1346>.

Abstract: In September 2016 the Australian Department of Health published Version 5.0 of the Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee (PBAC). These guidelines, which were first published for comment in 1990, set out how to prepare a submission to list a new medicine or medicinal product on the Pharmaceutical Benefits Schedule (PBS). The guidelines give instructions on the information required by the PBAC and the Economic Sub-Committee (ESC), the most appropriate form for presenting clinical evidence and the standards for an economic evaluation. The purpose of this commentary is to consider whether or not the evidence standards proposed and the consequent modeled claims for economic effectiveness meet the standards of normal science: are the claims

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presented to support PBS listing credible, evaluable and replicable. The review concludes that the PBAC guidelines do not meet the standards expected in normal science. The absence of empirically evaluable claims means there is no way of judging whether they are right or even if they are wrong. If the Guidelines were never intended to support experimentation and systematic observation to generate feedback to health system decision makers, then this should be made clear by the PBAC. If not, then consideration should be given to redrafting the guidelines to ensure they conform to these standards. Hopefully, future versions of the guidelines will address this issue and focus on a rigorous research program of claims assessment and feedback.

Link: <https://pubs.lib.umn.edu/index.php/innovations/article/view/485>

Lu, Christine Y, Paul Macneill, Ken Williams, and Ric Day. 2008. "Access to High Cost Medicines in Australia: Ethical Perspectives." *Australia and New Zealand Health Policy* 5 (May): 4. <https://doi.org/10.1186/1743-8462-5-4>.

Abstract: Access to "high cost medicines" through Australia's Pharmaceutical Benefits Scheme (PBS) is tightly regulated. It is inherently difficult to apply any criteria-based system of control in a way that provides a fair balance between efficient use of limited resources for community needs and equitable individual access to care. We suggest, in relation to very high cost medicines, that the present arrangements be re-considered in order to overcome potential inequities. The biological agents for the treatment of rheumatoid arthritis are used as an example by which to discuss the ethical issues associated with the current scheme. Consideration of ethical aspects of the PBS and similar programs is important in order to achieve the fairest outcomes for individual patients, as well as for the community.

Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2412887/>

Turkstra, Erika, Emilie Bettington, Maria L. Donohue, and Merehau C. Mervin. 2017. "PHARMACEUTICAL BENEFITS ADVISORY COMMITTEE RECOMMENDATIONS IN AUSTRALIA." *International Journal of Technology Assessment in Health Care* 33 (4): 521–28. <https://doi.org/10.1017/S0266462317000617>.

Abstract: Objectives: The aim of this study was to examine submissions made to the Pharmaceutical Benefits Advisory Committee (PBAC) and assess whether the predicted financial impact was associated with a recommendation. The second objective was to assess whether the financial and utilization estimates for listing the proposed medicine were reliable.

Methods: Data were extracted from public summary documents of major submissions considered by the PBAC from 2012 to 2014. Information collected included whether submissions were accepted, rejected, or deferred; estimated use; and financial impact. For those submissions that were recommended in 2012 and listed on the Pharmaceutical Benefits Scheme (PBS) by January 2014, a comparison was made between predicted and actual use and cost in 2014, based on PBS utilization.

Results: In 2012 to 2014, the PBAC considered 142 unique major submissions; of those, 65 were recommended for listing. A higher financial cost to the government was a statistically significant

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factor in predicting rejection ($p = .004$ for cost > AUD 30 million Australian dollars [20.7 million Euros] compared with cost-saving). Of the submissions that were recommended in 2012 and listed by 2014, the actual use was higher than predicted for 5/19 medications. The estimated cost was outside the predicted bracket of cost for 10/19 medications, with 8/19 medications having threefold underestimated expenditure, and 2/19 items having lower than predicted expenditure.

Conclusions: This study highlights that the predicted financial impact of a medication to the PBS budget is associated with a PBAC recommendation and also highlights that predicted use may not reflect actual prescribing practices.

Link: <https://www.cambridge.org/core/journals/international-journal-of-technology-assessment-in-health-care/article/pharmaceutical-benefits-advisory-committee-recommendations-in-australia/846950622484B6C71B793EF1AB028D01>

Vitry, Agnes Isabelle, and Russell Shute. 2018. "Chapter 11 - Access to High-Cost Medicines in Australia." In *Equitable Access to High-Cost Pharmaceuticals*, edited by Zaheer-Ud-Din Babar, 165–81. Academic Press. <https://doi.org/10.1016/B978-0-12-811945-7.00011-7>.

Abstract: This chapter presents an overview of access pathways to high-cost medicines in Australia, including funding and pricing processes for medicines subsidised by the national pharmaceutical insurance system, the Pharmaceutical Benefits Scheme (PBS) as well as other avenues for accessing non-PBS-funded medicines. It describes current and emerging policies for facilitating access to high-cost medicines by providing better information of the public and improving engagement in decision-making.

Link: <https://www.sciencedirect.com/science/article/pii/B9780128119457000117>

** For the purposes of this review, we have established three categories to describe the state of the literature: thin, considerable, and rich.*

- *Thin: There are relatively few papers and/or there are not many recent papers and/or there are clear gaps*
- *Considerable: There are several papers and/or there are a handful of recent papers and/or there are some clear gaps*
- *Rich: There is a wealth of papers on the topic and/or papers continue to be published that address this issue area and/or there are less obvious gaps*

Scope: While many of these issues can touch a variety of sectors, this review focuses on medicines. The term medicines is used to cover the category of health technologies, including drugs, biologics (including vaccines), and diagnostic devices.

Disclaimer: The research syntheses aim to provide a concise, comprehensive overview of the current state of research on a specific topic. They seek to cover the main studies in the academic and grey literature, but are not systematic reviews capturing all published studies on a topic. As with any research synthesis, they also reflect the judgments of the researchers. The length and detail vary by topic. Each synthesis will undergo open peer review, and be updated periodically

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based on feedback received on important missing studies and/or new research. Selected topics focus on national and international-level policies, while recognizing that other determinants of access operate at sub-national level. Work is ongoing on additional topics. We welcome suggestions on the current syntheses and/or on new topics to cover.

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