POLICY PERSPECTIVES

Evolution of Drug Reimbursement in Canada: The Pan-Canadian Pharmaceutical Alliance for New Drugs

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ABSTRACT

Canada has a unique system of public drug coverage and reimbursement characterized by a centralized review agency that makes funding recommendations along with decentralized authority for delivering health care across 10 provinces and three territories. There has been a significant increase in price negotiation for new pharmaceuticals in the past 10 years, first by individual provinces and now through a collective price negotiation process called the "Pan-Canadian Pharmaceutical Alliance." As of February 2014, the Pan-Canadian Pharmaceutical Alliance has already completed 32 negotiations despite still being in a formative stage; it is anticipated that a formal process will be developed in the coming year. In this article, we describe the evolution of price negotiation in Canada and identify several opportunities for improvement of the current process, including the incorporation of economic considerations into price negotiation.

Keywords: advisory committees/organization & administration Canada, decision making, legislation and jurisprudence, pharmaceutical reimbursement.

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Introduction

Canada has a unique system of public drug coverage and reimbursement characterized by a centralized review agency that makes funding recommendations along with decentralized authority for delivering health care across 10 provinces and three territories. The delivery of health care is guided by principles in national legislation, with no provision for mandatory universal coverage of drugs [1]. This has led to each of Canada’s provinces and territories developing unique systems of public drug insurance within their jurisdictions, with approximately two thirds of the population relying on either employer-funded private drug insurance programs or paying out of pocket [2]. The role of Canada’s federal government in health care delivery is to provide coverage for specific populations, such as Canada’s Military and First Nations and Inuit along with a program of transferring federal funds to provinces for health care. Unlike other countries with decentralized authorities such as Sweden and Germany, any coordination across Canada’s federal, provincial, territorial, and private insurance programs is entirely voluntary.

Despite these challenges, there have been successful attempts to develop shared programs and initiatives across federal, provincial, and territorial jurisdictions. Opportunities to reduce duplication and leverage shared resources through coordination among public insurance programs have led to the development of two intergovernmental health technology assessment (HTA) programs, the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR). Not all public drug insurance programs participate in these initiatives; the pCODR is governed by a collaboration of nine provinces (Quebec has never participated), whereas the CDR additionally involves three territorial and three federal public drug insurance programs. These processes result in nonbinding recommendations based on evidence of clinical effectiveness, cost-effectiveness, and patient input to help individual provinces and, in the case of the CDR, federal programs decide what drugs to list. In addition to gains in efficiency, these programs have been viewed as a means to improve the consistency and quality of the review process, provide equal access to expert advice, and address differences in drug coverage among the publicly funded drug plans [3].

Although decisions based on common recommendations are intended to improve the consistency of listing decisions in theory, participating drug programs have varying capacity to implement recommendations, and may have unique demographics or insurance structures and formulary eligibility that require contextualizing recommendations to unique reimbursement environments. For example, although several drug plans extend public coverage to those less likely to have employer-
based plans (e.g., elderly and social assistance recipients), others have universal public coverage programs [2]. Even provinces with similar drug plans may take unique listing approaches in a given therapeutic area owing to accumulated differences in priorities over time or based on differences in affordability or approaches to the HTA [4]. A recent analysis suggests that the percent agreement between recommendations and decisions after the implementation of the CDR ranged from 60.4% to 96.2% across plans [1].

Although there is a growing body of literature on the processes and effects of drug reviews in Canada [5–11], there is little information about the use and effect of price negotiation for new pharmaceuticals. Despite this, there has been a significant increase in price negotiation for new pharmaceuticals in the past 10 years [12]. In this article, we will outline the evolution of price negotiation, including the development of an interim coordinated process, the Pan-Canadian Pharmaceutical Alliance (PCPA). We will examine the current and potential role of economic evaluation in this process and its fit with other HTA and price regulation activity and outline the challenges and opportunities for formalizing this approach.

**The Role of Price Negotiation in Canada**

Beyond different demographic characteristics and insurance programs, another factor for apparent inconsistencies in listing decisions across Canadian provinces is the varying capacity to locally negotiate prices [13]. Although there is national regulation of the initial price and subsequent price increases for patented medicines that relies to some degree on international price referencing [14], provinces regularly negotiate lower confidential prices, even when provided with a recommendation to “not list” from a national HTA program because of unfavorable cost-effectiveness [5,13].

The first formal price negotiation mechanisms were introduced in the provinces of Ontario and British Columbia, where roughly 50% (Ontario, 38%; British Columbia, 13%) of Canadians reside (another 25% of the Canadians reside in Quebec). In Ontario, legislated authority to negotiate prices in 2006 [15], including changes to generic pricing policies and additional reforms, contributed to a 5% decrease in drug expenditure growth and 2-year savings of more than $600 million by 2009 [16].

A similar program in British Columbia, the Business Management and Supplier Relations Branch, negotiates the price of newly approved drugs as a benefit on their public drug plan formularies [17]. The success of negotiations in Ontario and British Columbia did not go unnoticed by other jurisdictions, which were unable to conduct these negotiations because of legal or resource constraints. Some sought changes to their legal or policy frameworks to allow them to negotiate better prices (for generic as well as brand drugs) [18], whereas some federal programs were able to benefit from policies that pay according to local provincial prices [19].

In the background of these events, the notion of coordinated price negotiation as a means to improve the consistency of decisions and leverage buying power had already existed. In September 2004, Canadian provinces and the federal government established a ministerial task force to develop and implement a National Pharmaceuticals Strategy that included (as one of nine priorities) a commitment to “pursue purchasing strategies to obtain best prices for Canadians for drugs” [20]. A similar initiative, the National Immunization Strategy, had earlier been developed in 2003 and led to the successful implementation of a bulk purchasing program and lower prices for vaccines [21].

**The PCPA**

Official support for a coordinated approach to price negotiation for pharmaceuticals was announced in August 2010 after a meeting of Canada’s provincial premiers. Called the PCPA, the stated aims of this initiative are to “achieve lower drug costs and consistent pricing, increase access to drug treatment options, and improve consistency of coverage criteria across Canada” [22]. Other stated aims included capitalizing on the combined buying power of jurisdictions and reducing the duplication of negotiations to improve the utilization of resources [23]. Currently, all provinces and territories except Nunavut have agreed to participate in the initiative. Federal and private drug insurance plans are not participating. The private insurance industry is excluded but has expressed a willingness to participate in this process [24].

What followed this announcement was a test of the feasibility of a coordinated approach. Within a year of being established, the initiative had successfully negotiated a price for eculizumab (Soliris, Alexion, Cheshire, CT), an orphan drug for a rare blood disorder. By May 2013, the provinces had completed 10 negotiations and 17 negotiations were ongoing [23]. Based on the first nine negotiations, the PCPA had estimated $50 million in avoided expenditure annually [22]. It is unclear whether these savings are over and above what would have been achieved through individual provincial negotiation.

A formal process for negotiation under the PCPA is still under development. Negotiations under the PCPA to date, however, have generally followed these steps [22] (see Fig. 1):

1. Provinces decide whether PCPA negotiations should take place after final recommendations are provided from either the CDR or the pCODR; they may also decide whether it is best to negotiate individually or collectively decide not to negotiate price at all.
2. If interested in PCPA negotiations, a “lead” jurisdiction is assigned to represent provinces wishing to participate in a particular negotiation.
3. Manufacturers are invited to initiate negotiations with the lead on behalf of the participating provinces. Negotiation may include terms and conditions beyond price.
4. If an agreement can be reached, a “letter of intent” (LOI) is signed by the manufacturer and the lead province on behalf of the participating provinces.
5. Manufacturers negotiate product listing agreements (PLAs) with each participating province/territory on the basis of terms in the LOI.

As of February 28, 2014, the PCPA has taken decisions on 61 new drugs, opting to jointly negotiate on 43 drug products (32 negotiations completed on 29 products, 12 negotiations underway, and 2 negotiations closed), not negotiate on 14, and consider individual negotiations on 4 (Table 1) [22]. Most of the successful negotiations have involved oncology products. Although there are no formal timelines, negotiations appear to take between several weeks and more than 6 months to finalize. In July 2013, a working group of Canada’s premiers provided direction to further develop this initiative. The PCPA engaged a management consulting firm to provide advice on a formal model of coordinated negotiation [22]. This advice is based on a review of the current approach, international best practices, and stakeholder experiences. The final report was released October 15th, 2014 and contains several recommendations that are considered next steps toward formalizing this process [22].

**Challenges and Opportunities for a Formal Approach to Collective Price Negotiation**

**Scope of the PCPA and Fit with Other Programs**

Although the prices of patented medicines in Canada are regulated through the Patented Medicine Prices Review Board [14], the
allowable Patented Medicine Prices Review Board price is largely considered a ceiling price from which to begin negotiation, rather than a means to achieve lower prices [25,18].

Recommendations from either the CDR or the pCODR may suggest listing at a lower price (if convinced of additional therapeutic benefit vs. comparators) or to not list at a given price (if convinced of similar therapeutic benefit to comparators) [26]. The CDR does not specify the extent of the price reduction governments should seek; in some instances, a recommendation that the “cost” not exceed that of an identified comparator is given.

Although not their explicit purpose, both CDR and pCODR programs already act as informal mechanisms for price negotiation because manufacturers are able to submit a confidential price and resubmit a lower confidential price after receiving a draft recommendation. In the CDR process, there is a special provision for timely reconsideration if an initial embargoed draft recommendation is to “do not list” for price reasons [27]. This process, however, is limited by allowing only a single opportunity to submit a new price and using only written correspondence. Also, unlike the PCPA, these HTA bodies are able to focus only on price and health care costs/cost-effectiveness, and no other cost offsets and terms that may represent additional value to a province.

In addition to these activities, the use of drug class reviews (literature reviews intended to compare benefits, harms, and costs of all available drugs across a therapeutic area) has become more commonplace as a means to inform listing decisions. This includes a Canadian Agency for Drugs and Technologies in Health (CADTH) “Therapeutic Reviews” program [27] and the Ontario Drug Policy Research Network “Drug Class Reviews” program [28]. CADTH’s reviews are requested by drug plan managers when recommendations regarding new drugs are difficult to make or implement because of perceived inconsistent listing decisions within or across provinces. It is not known how these initiatives will link to formal PCPA
processes and whether price negotiation will extend from new medicines to revisiting previous coverage decisions. The continued and increased use of drug class reviews may have implications for this process.

Table 1 – New drugs subjected to the PCPA process.

<table>
<thead>
<tr>
<th>Therapeutic area</th>
<th>Completed</th>
<th>Underway†</th>
<th>Closed‡</th>
<th>No negotiation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiology/vascular</td>
<td>Effient (prasugrel)</td>
<td>Eliquis (apixaban)</td>
<td>Pradaxa (dabigatran)§</td>
<td>Xarelto (rivaroxaban)§</td>
</tr>
<tr>
<td>Endocrinology</td>
<td>Onglyza (saxagliptan)</td>
<td>Byetta (exenatide)</td>
<td>Victoza (liraglutide)</td>
<td>Genotropin (somatropin)</td>
</tr>
<tr>
<td>Genetic disease</td>
<td>Kuvan (saproterin)§</td>
<td>Kalydeco (ivacaftor)</td>
<td>Soliris (eculizumab)</td>
<td>Soliris (eculizumab)</td>
</tr>
<tr>
<td>Infections and infectious disease</td>
<td>Dificid (fidaxomicin)</td>
<td>Strivid (elvitegravir/ cobicistat/ emtricitabine/ tenofovir)</td>
<td>Nove (efavirenz)</td>
<td>Apprilon (doxycycline)</td>
</tr>
<tr>
<td>Neurology</td>
<td>Gilenya (fingolimod)§</td>
<td>Tecfidera (dimethyl fumarate)</td>
<td>Fycompa (perampanel)</td>
<td>Fampyra (fampridine)</td>
</tr>
<tr>
<td>Oncology</td>
<td>Adcetris (brentuximab)</td>
<td>Erivedge (vismodegib)</td>
<td>Kadcyla (trastuzumab emtansine)</td>
<td>Afinitor (everolimus)</td>
</tr>
<tr>
<td></td>
<td>Afinitor (everolimus)</td>
<td>Alimta (pemetrexed)</td>
<td>Mekinist (trametinib)</td>
<td>Tykerb (lapatinib)</td>
</tr>
<tr>
<td></td>
<td>Brilinta (ticagrelor)§</td>
<td>Halaven (eribulin)</td>
<td>Revlimid (lenalidomide)</td>
<td>Tafinlar (darafenib)</td>
</tr>
<tr>
<td></td>
<td>Inlyta (axitinib)</td>
<td>Mozobil (plerixafor)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td>Oncert (indacaterol)§</td>
<td>Perjeta (pertuzumab)</td>
<td>Xalkor (crizotinib)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Seebri Breezhaler (glycopyrronium bromide)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Jakavi (ruxolitinib)§</td>
<td>Fibrast (ulipristal acetate)</td>
<td>Jetrea (ocipinasmin)</td>
<td>Humira (adalimumab)</td>
</tr>
<tr>
<td></td>
<td>Oralair (grass pollen allergen extract)</td>
<td></td>
<td>Ocrenia (abatacept)</td>
<td>Benlysta (belimumab)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rebif (interferon beta-1a)</td>
<td>Latuda (fusidamate)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sublinox (zolpidem)</td>
</tr>
</tbody>
</table>

Note. Generic names are given in parentheses.
PCPA, Pan-Canadian Pharmaceutical Alliance.
† A completed pan-Canadian negotiation refers to those for which a letter of intent (document that outlines the agreed upon terms and conditions for listing) has been signed between the lead jurisdiction for the negotiation and the manufacturer.
‡ As of February 28, 2014.
§ Agreement not reached.
§ The initial nine products negotiated through the PCPA.

The Use of Economic Evaluation and Value-Based Pricing
There are considerable opportunities to increase the use of economic evaluation and value-based pricing in a formal PCPA
process [17]. In Canada, there is mounting evidence that price rather than the economic consequences of reimbursement has a much more important role in listing recommendations [5,29]. This is also reflected in the current process of collective negotiation in which prices are negotiated without an explicit recognition of social value (i.e., share of the economic benefit that would accrue to consumers and producers) through volume effects.

The degree of price reduction achieved through negotiation remains confidential; however, anecdotal information suggests that it is consistent with 3% to 33% price reductions achieved in Europe and the United States [30,31]. Although focusing on price discounts can lower costs, price negotiation without any consideration of overall value may send distorted signals to innovators and reduce consumer benefits in the long term if the price and discount do not accurately reflect opportunity cost [32]. This situation may additionally create incentives for manufacturers to inflate prices before negotiation (if discount asks are anticipated) and unnecessary delays (if discounts are infeasible).

Assessments of economic impact from the CDR and the pCODR are not aimed at providing decision makers with a “reasonable” price but may do so intentionally or unintentionally through threshold analysis, and acting as a starting point for price negotiation. Like other similar HTA processes, however, these reviews focus on technical rather than allocative efficiency [33]. Because focusing on allocative efficiency (which requires simultaneously addressing many different budgets) is likely to be infeasible in a decentralized environment, a reasonable starting point could be to develop a formal process for PCPA that bases price on a more formal consideration of the social surplus (from price and volume) and how it should be shared [34]. This value-based approach requires an explicit recognition of what constitutes value, and LOIs that extend to considerations of both volume and time frame. This can, in turn, assist manufacturers in making optimal business decisions regarding the future entry of new products in Canada.

Using a “shared social surplus” approach that requires upfront agreement regarding what constitutes societal value as a basis for informing price negotiation is intended to prevent exploitation by monopsony payers and monopoly sellers by clarifying what innovation is valuable and what it might be worth [17,34]. Without some explicit notion of value (that can be characterized through conducting economic evaluation that captures benefits relevant to society), payers can inadvertently reduce societal benefits through demanding arbitrary levels of price discounts (rather than discounts that reflect relevant costs and benefits) or through delaying listing decisions. Manufacturers can also reduce societal benefits through insisting on non-value-based prices (such as prices based on international referencing or individual willingness to pay) or hastening listing through political advocacy. Economic evaluation also provides an explicit framework for valuing resources unrelated to health or the new medicine, such as investments in clinical research, human resources, economic development activities, or other cost offsets proposed by manufacturers. In theory, this approach could bring payers and sellers closer as a starting point for negotiation and hasten patient access to new medicines, while promoting consistency in decisions and incentivizing innovation.

Equity of Pricing and Access

Joint negotiation is intended to ensure that access and approaches to pricing are consistent across Canada. However, a provinces have different formulary populations, revenue bases, demographics, industry policy, and political priorities [4]. The province of Nova Scotia, for example, has much higher rates of chronic obstructive pulmonary disease (COPD) diagnosis than the national average (7% vs. 4.2%). This means, in theory, that a new medicine for COPD that is more cost-effective in patients with severe COPD may be used at higher per capita volumes and could be of better societal value than if listed in a different province. Engaging in collective price negotiation on the basis of product value means that provinces and manufacturers must think about an “average” return on investment for new listing decisions.

Complicating this further, because of a historical divergence of priorities, provinces may have also made variable listing decisions in the past [4,35]. This means that the value proposition of any given product may also vary because of differences in availability of comparators. Similarly, some negotiations will involve drugs for which other drugs in the same class have existing PLAs in some provinces but not in others.

Although the current informal PCPA allows for individual negotiation in situations in which the provinces do not see coordinated negotiation as feasible, inherent variability could, in theory, make negotiations complex and may result in a delay or failure to reach conclusion. The drug ivacaftor (Vertex Pharmaceuticals), for example, was granted a market license in November 2012 and recommended for listing at a “substantially reduced price” by the CDR in March 2013 [36]. Collective negotiation began in July 2013 and led by the province of Alberta. After 8 months of unsettled negotiation, the strain of collective bargaining began to show, with one provincial minister commenting that he would direct his department to leave the pan-Canadian process if a deal was not forthcoming [37]. An LOI was signed with the PCPA in June 2014 [38].

Collective negotiation could also lead to different discounts than some provinces have obtained historically. What this means for future prices is uncertain. On the one hand, manufacturers with Canadian revenue targets for any new medicine may be less prepared to provide the same discounts to provinces other than those that have traditionally been given to provinces with high utilization rates; in a situation in which listing times remain the same, this translates into lost revenues. On the other hand, the increased buying power of a greater number of provinces and the potential for faster listing decisions may provide incentives to provide similar or better discounts afforded to larger provinces.

Any formal process will need to recognize that increased solidarity and equity in access could result in either a potential loss or gain in bargaining position by larger provinces and may depend on individual manufacturers. In addition, the use of confidential price negotiation and variable participation by provinces may increase the complexity of price negotiation, with some manufacturers and provinces unaware or not able to learn of current rebates, creating challenges for budget impact analyses and other analyses used to support negotiation for new market entrants.

A key question for smaller provinces will be the benefits and risks of collective negotiations. If they take part in PCPA negotiations, they may well have access to the same terms negotiated by multiple jurisdictions but may also face significantly more political pressure to list drugs that they would otherwise have not added to their formularies. With smaller budgets, these pressures represent more substantial opportunity costs on other provincial health (and nonhealth) priorities and diminish the ability for a smaller province to tailor its health system to the needs and fiscal situation of its population.

Administrative Efficiency

The PCPA process is intended to improve efficiency because it could reduce duplication of negotiation and bureaucracy by both
governments and manufacturers. From a manufacturer’s standpoint, reducing face-to-face meetings across 10 provinces and five time zones could considerably reduce time and resource commitments for each new product. The current process is yet to resolve this problem because manufacturers are still required to create individual PLAs with each province after collective negotiation. On its face, this means that both manufacturers and governments currently have an additional administrative step. It will be important to consider a process that reduces the burden of future individual negotiations for all parties as a more permanent collective negotiation process is developed.

**Timelines**

The current process targets up to 6 weeks from the time the CDR or the pCODR issues its recommendation for a notice of intent to negotiate to be delivered to a manufacturer [22]. There are no set timelines for the negotiations themselves, which can take anywhere from several weeks to over 6 months, and no timelines for listing a product on provincial formularies once negotiations have been completed [22].

The development of a formal process provides an opportunity to introduce target time frames that consider the needs for timely decisions and incent manufacturers and public drug plan administrators to negotiate efficiently. Similar target time frames have been developed for both CDR and pCODR processes, as well as drug regulators.

**Legal Issues**

In addition to the issues already identified, there are several legal issues that may require consideration as a new process is developed.

**Fairness**

The PCPA is not currently governed by a “legal” structure that gives rise to specific obligations for manufacturers and the provinces. In its current form, it has no governing rules that establish how provincial governments interact with each other or their obligations. A challenge by manufacturer Boehringer Ingelheim against the CDR led to a finding that the CDR is subject to “judicial review” [39].Administrative law principles—such as fairness—do have application to governmental bodies. Accordingly, a formal PCPA process, depending on how it is constituted, could be subject to the principles of administrative law, including a duty of procedural fairness. As a result, manufacturers may be able to seek judicial review of certain actions of the PCPA, for example, where there is a lack of due process.

**Confidentiality**

Confidentiality of information during price negotiation is a central concern for manufacturers. Companies in negotiations expect pricing and rebate information to be confidential. Indeed, the Ontario government faced a challenge from the pharmaceutical industry when the Ministry of Health and Long-Term Care was forced to release certain information relating to the receipt of rebates from manufacturers, sought under a provincial “Freedom of Information” request [40]. Because of international reference pricing, disclosure of an effective discounted price in Canada could have an impact on the price a manufacturer could offer in other countries despite the different factors at play in those jurisdictions [41].

In Canada, executing a nondisclosure agreement with a provincial government in the context of PLA negotiations is possible. Such an agreement may provide that information shared in PCPA negotiations and PLAs be kept confidential. Agreements may also allow information to be shared among all participating provinces. A signed PLA, however, could be potentially disclosed, at least in part, because of provincial legislation permitting access to information. Although some of the information found in these PLAs could be subject to certain exemptions, such as third-party confidential information that could cause the third party prejudice or harm, there are differences in the application of provincial laws and exemptions. Whether such information is accessible will depend on the nature of the information, the scope of the relevant provincial legislation, and how those laws have been interpreted.

**Obligations on Parties during Negotiations**

The current PCPA process is predicated on the parties exercising a measure of good faith. Provinces can sign an LOI on the completion of a PCPA negotiation but are under no legal obligation to list the product on the formulary within any particular time frame. For example, the province of British Columbia ultimately decided not to list the first collectively negotiated drug (ecalizumab) at the discounted price [42].Manufacturers have no redress for delays in listing, or in a circumstance in which a province fails to list a product at all, despite having signed an LOI. This is because there are typically no agreed upon listing deadlines, and the LOI is not, in any event, legally binding. Although provinces acknowledge that an LOI does not guarantee an eventual listing agreement [22], this nonetheless creates significant uncertainty for manufacturers who have to agree on a price point without having any commitment with regard to the volume of sales. It also makes it difficult for manufacturers to accurately forecast sales and revenues. There is also nothing that legally precludes provinces from negotiating different terms from the LOI, which further adds to manufacturers’ uncertainty. Solutions to address or minimize this uncertainty, either through creating legally binding agreements or service performance guarantees, should be explored in the context of developing a formal PCPA process.

**Implications and Lessons Learned for Other Jurisdictions**

The current PCPA process highlights the need for potential change going forward. Such change could include a framework for negotiations with clear priority setting criteria (i.e., what is amenable to negotiation), timelines for negotiations and listing deadlines and incentives for participation, and concluding listing agreements once negotiations have been completed. The process would also benefit from the allocation of adequate resources to avoid unnecessary delay. In addition, there should be clear roles, responsibilities, and obligations for those participating.

Establishing a formal PCPA process should lead to revisiting the roles of existing HTA mechanisms to ensure an efficient process. Most importantly, the formal process should exist within a legal framework and be developed in consultation with all stakeholders affected. Consultations have begun and have included dialogue with manufacturers, patients, and other stakeholders. This ongoing dialogue on the PCPA process, including the appropriate use of economic evaluation in price negotiation, presents an important opportunity to align industry and health system goals in regard to the introduction of new medicines in Canada.

Source of financial support: All authors volunteered their time to conduct this work. Some of its content was based on work previously paid for by the Canadian Foundation for Healthcare Improvement.
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