Inside Policy

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Who polices the police?

Guy Giorno calls for consequences when public servants fail to respect Canada's Access to Information law

Photo: Information Commissioner Suzanne Legault

Also in this issue: Stanley Hartt on the national security implications of foreign investment in key sectors • Tom Axworthy examines competing visions of the North • Mary-Jane Bennett on how to end the cross-border airfare discrepancy • Massimo Bergamini on the municipalities' struggle to stay on the federal political agenda • and evaluating the provinces' efforts to save money on brand name drug purchases

Will a pan-Canadian approach to drug purchasing save the provinces money?

In 2010, during a meeting of the Council of the Federation, provincial and territorial premiers announced the Pan-Canadian Pricing Alliance (PCPA), an initiative aimed at facilitating multi-jurisdictional negotiations on prices for brand name drugs. The Premiers believed that combining the purchasing power of the public drug programs would help provinces and territories achieve economies of scale and cost reductions.[1] The authors examine the PCPA from three angles — policy, legal and business — and offer recommendations to help establish a more consistent, predictable and sustainable process.

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Three years have now gone by, and although the Premiers recently confirmed that the Pan-Canadian Pricing Alliance is one of their joint priorities[2] we still know relatively little about the initiative. This is largely due to the fact that the PCPA process, until now, has remained largely undefined. This, however, will likely change, as the provinces and territories are now working with a consultant, IBM Healthcare Solutions (IBM), to recommend options for the development of a permanent model that will facilitate negotiations under the PCPA. IBM is conducting consultations in the fall of 2013 with provincial/territorial governments, the Canadian Agency for Drugs and Technologies in Health, the pan-Canadian Oncology Drug Review, selected manufacturers, industry associations and patient organizations, and is expected to report back to the provinces and territories with its recommendations before the end of December 2013.

It is therefore timely to consider how the PCPA has evolved to date, in terms of objectives, process and implications. In this context, we examine the PCPA from three angles — policy, legal and business

— with the hope that policymakers and stakeholders can be better informed when interacting on specific product negotiations and on the permanent negotiation model to be developed for PCPA.

We end the article by providing recommendations to help establish a more consistent, predictable and sustainable PCPA process.

Background

The PCPA, which is co-lead by the governments of Ontario and Nova Scotia, has the following objectives:

- increase access to drug treatment options;
- improve the consistency of drug listing decisions across the country;
- capitalize on combined buying power of jurisdictions;
- achieve consistent pricing and lower drug costs; and
- reduce duplication of negotiations and improve utilization of resources.[3]

Initially, the provinces and territories agreed to jointly negotiate on selected brand name drugs to determine if the PCPA approach was feasible on a broader scale.[4]

As of September 1, 2013, the provinces and territories had successfully completed negotiations for 16 brand name drugs and were engaged in jointly negotiating 16 additional drugs under the PCPA.[5] Drugs that have gone through the PCPA process include oncology products, drugs for rare disorders and primary care products.

Based on the successes of the PCPA in the initial trial period, the drug plan managers in the provinces and territories have established an informal process to determine the applicability of PCPA to every drug coming out of the national drug review process (i.e., the Common Drug Review and the pan-Canadian Oncology Drug Review).[6]

Although there is no formal negotiation process in place at the present time, some negotiations under the PCPA have followed these steps:

- once a drug has gone through the national drug review processes (i.e., the Common Drug Review or the pan-Canadian Oncology Drug Review), provinces/territories determine whether PCPA negotiations should take place;
- if provinces/territories are interested in PCPA negotiations, they send a request to the manufacturer to initiate negotiations;
- one "lead" province/territory is identified to represent participating provinces/territories in the negotiations with the manufacturer;
- once an agreement has been reached, the terms are reflected in one "Letter of Intent" signed by all participating provinces, which is not a legally binding document; and,
- based on the terms of the Letter of Intent, the manufacturer proceeds to execute a product listing agreement with each participating province/territory in order for the drug to be listed on the individual provincial/territorial public drug plan.

Québec, the federal government and private plan sponsors are not participating in the PCPA.

Considerations

A. Policy Considerations

Equity of pricing and access

When provinces negotiate individually, prices and eligibility criteria for drugs may vary across Canadian jurisdictions. The confidentiality of the rebates in Canada and globally make it difficult for provinces to assess whether they are getting a "good deal" compared to other jurisdictions. By negotiating jointly through the PCPA, provinces/territories are trying to ensure that drug prices and access criteria are consistent across Canada.[7]

One of the potential downsides, however, of striving for consistency in pricing/access is that there may be less flexibility for provinces/territories to address specific health concerns of their beneficiary populations. In addition, there is a risk that PCPA will lead to no access to patients for life-saving medicines that do not make it through a successful PCPA negotiation, highlighting the need for exceptional access policies that allow for case-by-case adjudication, approvals and province-specific listings.

Administrative Efficiency

On the one hand, administrative efficiency could be achieved for both governments and manufacturers by having only one negotiation process in place for Canadian provinces/territories.

On the other hand, however, joint negotiations could end up requiring more time and resources than individual negotiations, given that they involve many parties with varying decision-making processes, policy objectives and political pressures.[8] It remains to be seen whether the permanent negotiation model to be developed for PCPA will be sufficiently streamlined and cost-effective to achieve administrative efficiencies.

Timelines

PCPA negotiations have the potential to further delay the time it takes for a new drug to access the Canadian market given that there are multiple parties involved, no mandated or target timelines around the PCPA process and that drugs must still go through the federal pricing review (Patented Medicine Prices Review Board) and the national and provincial health technology assessment processes. With the development of a permanent negotiation model for PCPA, provinces/territories have the opportunity, however, to put in place a more streamlined, efficient process that leads to timely drug coverage decisions across the country.

Structural Challenges

Provinces/territories face a number of challenges in implementing joint negotiations for pricing. One of the major hurdles is that provinces/territories have different public drug plans, revenue bases, demographics, political priorities and "pressures." These differences mean that the provinces/territories may come to the negotiation table with different and even divergent priorities and goals.[9]

Autonomy of Provinces/Territories

The PCPA process assumes that the provinces/territories be willing to give up some of their autonomy in order to collaborate on joint coverage and pricing decisions. This may prove to be challenging, as the provinces/territories are each responsible for operating their respective public drug programs and remain accountable for pricing decisions that often have important impacts on their budgets and health systems.[10]

Lower Prices

Provinces and territories have estimated that the prices of drugs negotiated under the PCPA will result in savings of approximately $60-70 million annually,[11] although it is not clear if these figures are in addition to the savings that provinces would have achieved if they were negotiating product listing agreements individually.

By leveraging resources from all participating jurisdictions and by achieving savings through PCPA negotiations, governments expect they will be in a position to increase access to, and fund, more drugs, which would be beneficial for all stakeholders.[12] In order to achieve this, however, governments will need to tread carefully and consider the risk of focusing primarily on lowering drug prices.

If PCPA is too focused on obtaining low drug prices and fails to produce acceptable agreements for manufacturers, companies could decide not to introduce, or delay the introduction of, certain products into the Canadian market. If this occurs, there is a risk that it could lead over time to:

- Higher drug prices: fewer products on the market within a given therapeutic class could undermine competition and lead to higher drug prices;[13]
- More restricted access: this would likely have a negative impact on patients' health outcomes, and patients may have to revert to other health interventions such as surgery and hospitalization, thereby increasing spending elsewhere in the health care system;[14] and
- Drug supply problems: the reduced number of suppliers of drugs could lead to lower drug supplies within a therapeutic class.[15]

Finally, it is interesting to note that cost savings achieved through the PCPA may not be shared equally among all provinces/territories. Smaller jurisdictions have the most to gain from joint negotiations, as they have less leverage than larger jurisdictions when they negotiate individually, due to the size of their population and revenue base. They may therefore benefit from greater savings than larger jurisdictions.[16]

Value of New Pharmaceuticals

On a related issue, if the PCPA focuses primarily on reducing costs, it could result in prices that do not reflect the value of medical innovation. Pharmaceuticals allow patients to live longer and healthier lives. They can also allow patients to return to work earlier, reduce absenteeism and improve productivity, which has real economic value and contributes to a stronger Canadian economy. Further, studies have demonstrated that for each dollar spent on prescription drugs, overall health care expenditures have decreased by an amount between $2.06 and $2.65.[17] In PCPA negotiations, the value of new drugs should be considered in the context of long-term health system cost savings from these investments.

B. Legal Considerations

Fairness

There is no "legal" structure that exists within the PCPA that gives rise to specific obligations for manufacturers and the provinces/

territories. There are also no governing rules that establish obligations among provincial/territorial governments and how they interact with each other.

That said, overriding administrative law principles — such as fairness — do have application to governmental bodies. In the case of Boehringer Ingelheim,[18] the Common Drug Review process was found to be subject to "judicial review."

Similarly, the conduct of any formal body dealing with PCPA would presumably be subject to a duty of procedural fairness. Accordingly, manufacturers may be able to seek judicial review of certain actions of the PCPA where they can show there was a lack of due process.

Confidentiality

Confidentiality of information is an issue that manufacturers will have concerns about as they move through the PCPA process. If the agreement reached in the context of PCPA negotiations results in a rebate payable to a province/territory (in the form of a rebate off of the list price) companies will wish to know the extent to which the information will be kept confidential. To disclose what might be cast as "effective" pricing could put at risk the pricing of the product in other Canadian jurisdictions or countries given the degree of price cross-referencing that occurs on a national and international level.

It is possible to execute a non-disclosure agreement with a given provincial/territorial government providing that the manufacturer's information shared in the negotiations and the eventual product listing agreement will be kept confidential. In addition to allowing the manufacturer's information to be shared within the province/territory to which it is provided, a non-disclosure agreement could also allow the information to be shared among all participating provinces/territories.

It should be stressed, however, that even if a non-disclosure agreement has been signed, provincial/territorial access to information legislation would still apply. As such, whether the confidentiality of the information is in fact maintained will depend on the nature of the information, the scope of the provincial/territorial legislation and how it has been interpreted. Access to information legislation generally provides for a right of public access to government-held information, subject to certain exemptions, such as the exemption for third party confidential information, the release of which could cause the third party prejudice or harm.

Legal Obligations on the Parties during Negotiations

There are a number of issues that arise in PCPA negotiations, in part due to the lack of a formal negotiation framework and to the non-legally binding nature of the Letter of Intent.

A manufacturer may not know who is at the negotiation table at a given point in time. As the manufacturer is dealing with only one lead province for the negotiation of a given product, it is not always clear what other jurisdictions that lead province is also representing. There is nothing to legally bind a given province/territory to opt into the PCPA process. Further, it is not prohibited for a province/territory to opt in at the outset but decide to later opt out. More importantly, there is no apparent requirement for provinces/territories to inform manufacturers of which jurisdictions are participating at the outset of the negotiations and of any subsequent "opt-ins" or "opt-outs".

Although there is no doubt good faith on all sides of the negotiation, there is still a risk that a given province/territory could opt in to the PCPA process and sign a Letter of Intent, but be unable to list the product within a reasonable timeframe. There is no redress for a manufacturer if there are delays in listing a product or, worse, if a province/territory fails to list the product at all. This is because the agreement between the pan-Canadian group and the manufacturer is only captured in a Letter of Intent, which has no legal binding effect.

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Similarly, the conduct of any formal body dealing with PCPA would presumably be subject to a duty of procedural fairness. Accordingly, manufacturers may be able to seek judicial review of certain actions of the PCPA where they can show there was a lack of due process.

Finally, there is a risk that a province/territory could sign the Letter of Intent but subsequently decide to negotiate different terms with the manufacturer in the product listing agreement. A province/territory could also conclude a product listing agreement based on the terms of the Letter of Intent, but subsequently decide to amend the terms of the product listing agreement with the consent of the manufacturer but without notifying the other jurisdictions involved in the PCPA negotiations.

C. Business Considerations

Industry Revenues

Decreases in drug prices could result in lower revenues for the pharmaceutical industry, unless PCPA negotiations lead to greater sales volumes that can offset the price reductions. Loss of revenues would affect the ability for manufacturers to conduct research and development into new therapies, and would provide manufacturers with less incentive to do so in Canada.

Further, declining revenues for industry may also affect the ability for manufacturers to continue investing in various programs/services currently in place, including those that support the appropriate use of medication and that contribute to health system efficiency. These programs and services will either be lost or the costs will shift onto other health systems stakeholders and patients.

Business Uncertainty

The PCPA has given rise to a significant degree of business uncertainty, which makes it very challenging for manufacturers to accurately forecast if and how their products can be commercialized in Canada.

As mentioned previously, manufacturers may not know which provinces/territories are participating in the negotiations. This makes it difficult for manufacturers to accurately determine the size of their market and the volume of sales it could generate, so as to be able to decide on an acceptable price point.

As also mentioned previously, there is a risk that a province/territory that signed the Letter of Intent could later decide to change the terms of the deal or even decide not to conclude a product listing agreement to list the product on its formulary.

Finally, in addition to "new drugs," it appears that the PCPA may now be re-visiting drugs that have already been listed on provincial formularies and that may have already been the subject of bilateral negotiations with some of the provinces.

Looking Ahead

Given that the PCPA will have impacts on patient health outcomes and many facets of the health care system, securing the support of stakeholders will be essential to the success and sustainability of the PCPA process.

The consultations undertaken by IBM in fall 2013 offer an opportunity for governments to meaningfully consider the input of all stakeholders (i.e., pharmaceutical industry, citizens, healthcare professionals and patient groups). Providing opportunities for future stakeholder engagement will also be important.

(I)n addition to "new drugs," it appears that the PCPA may now be re-visiting drugs that have already been listed on provincial/territorial formularies and that may have already been the subject of bilateral negotiations with some of the provinces.

Based on our review of the various policy, legal and business considerations, we have formulated a number of recommendations that governments and stakeholders may want to consider in the context of developing a permanent negotiation model for PCPA:

1. Implement a clear and consistent framework to guide negotiations. This framework would include:

- criteria used to determine which drugs would be subject to PCPA negotiations;
- timelines for notice to be delivered to a manufacturer as to whether or not the product will go through the PCPA process;
- requirement to inform manufacturers of which jurisdictions are participating at the outset of a negotiation;
- issues to be negotiated as part of the Letter of Intent (in addition to price and volumes, parties to a Letter of Intent could include other considerations, such as criteria for sub-populations, adherence programs, patient registries or health research commitments, outcomes-based reimbursement criteria);
- guidelines on how provinces/territories can opt in or out of a negotiation, including notification to the manufacturer when this occurs, and rules about using information gained in PCPA negotiations in other contexts;
- policies and increased capacity to address surges in the number of products subject to PCPA negotiations at a given time;

- timelines for both parties to respond to an offer or counter-offer; and;
- timelines for product listings following the conclusion of a Letter of Intent.

2. Provide an opportunity to negotiate a Letter of Intent that includes incentives for parties to meet their commitments (e.g., include milestones for implementation such as better prices as more provinces reimburse the product according to a time schedule).

3. Ensure that the new PCPA structure is adequately resourced in order to promote timely decisions.

4. Ensure there is a clear and consistent process in place for approving negotiation mandates and Letter of Intent to promote timely completion of negotiations.

5. Revisit the roles of existing processes such as the Common Drug Review, the pan-Canadian Oncology Drug Review, the Patented Medicine Prices Review Board and the provincial health technology assessment committees and processes, to ensure they serve complementary and not duplicative roles in the context of PCPA negotiations.

6. Ensure that negotiation positions take into account the value of new drugs for the health care system.

7. Unless there is a compelling reason to do so, avoid applying the PCPA process to products that have already been listed, as this creates significant business uncertainty for manufacturers and could lead to inequitable treatment for older products.

8. Ensure the process allows sufficient flexibility for provinces/territories to address specific health concerns of their beneficiary populations.

9. Include periodic evaluations of the process that incorporate the input of stakeholders.

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Endnotes

1. Council of the Federation news release, August 6, 2010: http://www.conseildelafederation.ca/en/latest-news/17-2010/153-premiers-protecting-canada-s-health-care-systems.
2. At the last meeting of the Council of the Federation in August 2013, the Premiers confirmed that the PCPA is one of their joint key health priorities. See Council of the Federation news release, July 26, 2013: http://www.councilofthefederation.ca/phocadownload/newsroom-2013/health_care_july26-final.pdf.
3. Presentation by Diane McArthur, Assistant Deputy Minister and Executive Officer, Ontario Public Drug Programs, May 5, 2013:http://www.ihe.ca/documents/Diane%20McArthur_Current%20drug%20funding%20paradigm%20%20May%205%202013%20FINAL.pdf.
4. Ibid.
5. Communication from Ontario Public Drug Programs with the author (W. Dempster), September 19, 2013.
6. Supra note 3.
7. Supra note 3.
8. See Morgan S. et al., Inter-jurisdictional cooperation on pharmaceutical product listing agreements: views from Canadian provinces, BMC Health Services Research, 2013: http://www.biomedcentral.com/1472-6963/13/34, p.3.
9. Supra note 3.
10. See Dempster B., Provincial Purchasing Alliances — Drivers, Challenges and Implications, Provincial Reimbursement Advisor, February 2011, p. 15 and Morgan S. et al., supra note 8.
11. Council of the Federation news release, July 26, 2013: http://www.councilofthefederation.ca/phocadownload/newsroom-2013/health_care_july26-final.pdf. These savings were based on the 27 drugs that had been negotiated or that were in the process of being negotiated at the time of the Council of the Federation news release.
12. Increasing access to drug treatment options is one of the publicly stated goals of the PCPA. See presentation by Diane McArthur, supra note 3.
13. This risk has been mentioned in the context of tendering systems, which undermine the competitive market over time. See Hollis A. et al., "Tendering generic drugs: what are the risks?," Paper commissioned by the Canadian Generic Pharmaceutical Association, October 2012 cited in Labrie Y., Wrong Prescription — The Unintended Consequences of Pharmaceutical Cost Containment Policies, Montreal Economic Institute, June 2013: http://www.iedm.org/files/cahier0613_en.pdf, pp. 26-27.
14. For an overview of how restrictions on pharmaceutical availability in New Zealand have had a negative impact on health outcomes and have also shifted costs to other, more invasive, costlier treatments, see Lybecker K.M., "The Bulk Purchase of Pharmaceuticals: The Experiences of the United States, Europe, and New Zealand, Studies in Health Care Policy, Fraser Institute," May 2013: http://www.fraserinstitute.org/uploadedFiles/fraser-ca/Content/research-news/research/publications/bulk-purchase-of-pharmaceuticals.pdf, pp. 43-44.
15. In New Zealand, the purchasing and tendering policies have been accompanied by numerous instances of drug shortages. See MacKay P., Is PHARMAC's sole-supply tendering policy harming the health of New-Zealanders?, New Zealand Medical Journal, Vol. 118, 2005, No. 1214: http://journal.nzma.org.nz/journal/118-1214/1433/ cited in Lybecker K.M., supra note 14, p. 41 and in Labrie Y., supra note 13, p. 27.
16. Supra note 8.
17. These figures are based on American studies. It was also found that spending on more recent patented drugs have resulted in even more significant savings elsewhere in the health care system.
Economists have found that this is also true in Canada. See Lichtenberg F.R., "Do (more and better) drugs keep people out of hospitals?," American Economic Review, Vol. 86 (1996), No. 2, pp. 384-388; Shang B. et al., "Prescription drug coverage and elderly Medicare spending, National Bureau of Economic Research, Working Paper No. 13358," September 2007; Lichtenberg F.R., "Benefits and costs of newer drugs: an update, Managerial and Decision Economics, Vol. 28" (2007), pp. 485-490; Civan A. et al., "The effects of newer drugs on health spending: Do they really increase the costs?, Health Economics," Vol. 19 (2010), pp. 581-595; Crémieux P.-Y. et al., "Do drugs reduce utilization of other healthcare resources?, Pharmacoeconomics, Vol. 25" (2007), No. 3., pp. 209-221; all sources cited in Labrie Y., supra note 13, p. 16.
18. Boehringer Ingelheim (Canada) Ltd. v. Canadian Agency for Drugs and Technologies in Health (2008), 243 O.A.C. 200 (Ont Div Ct).