

Product Listing Agreements (PLAs): A New Tool for Reaching Quebec's Pharmaceutical Policy Objectives?

Ententes relatives à l'inscription des produits (EIP) : un nouvel outil pour atteindre les objectifs de la politique du médicament au Québec?



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Abstract

Product listing agreements (PLAs) with pharmaceutical manufacturers are increasingly viewed as an innovative and useful tool in the effort to control drug expenditures. To date, Quebec is the only province that has been reluctant to enter into such agreements, arguing that their confidential nature may lead to a disparity in coverage between individuals covered by the public plan and those covered by private insurance. While PLAs may, in fact, present such a risk, in this paper we will argue that when used correctly, these agreements are actually tools that could help attain all four of the objectives set out in Quebec's policy on medications, namely: (a) improved access to drugs, (b) fair and reasonable drug pricing, (c) optimal drug use and (d) maintaining a dynamic biopharmaceutical industry in Quebec.

Résumé

Les ententes relatives à l'inscription des produits (EIP) avec les fabricants de médicaments sont de plus en plus considérées comme des outils pratiques et novateurs pour le contrôle des dépenses pour les médicaments. À ce jour, le Québec est la seule province qui s'est montrée réticente à prendre part à de telles ententes, sous prétexte que leur caractère confidentiel peut mener à des inégalités entre les personnes qui bénéficient d'un régime public et celles qui ont un régime d'assurance privé. Bien que les EIP puissent effectivement présenter un tel risque, nous soutenons dans cet article que si elles sont employées correctement, ces ententes constituent des outils qui peuvent aider à atteindre les quatre objectifs formulés dans la politique québécoise du médicament, c'est-à-dire (a) l'accessibilité aux médicaments, (b) un prix juste et raisonnable, (c) une utilisation optimale des médicaments et (d) le maintien d'une industrie biopharmaceutique dynamique au Québec.

OVER RECENT DECADES, THE EXPONENTIAL INCREASE IN DRUG SPENDING HAS LED governments to implement traditional cost-saving policies, such as direct and indirect price controls, health technology assessment and reference pricing. However, in the last few years, an increasing number of public payers (Canadian provinces, the United Kingdom, France, Australia, Germany, Sweden, Italy and other jurisdictions) are now also relying on product listing agreements (PLAs, or "risk-sharing agreements") with pharmaceutical manufacturers as a means of limiting the clinical and financial risks linked to drug coverage (Bourassa Forcier and Noël 2012).

Adamski and colleagues (2010) describe PLAs as "agreements concluded by payers and pharmaceutical manufacturers to diminish the impact on the payer's budget of new and existing medicines brought about by either the uncertainty of the value of the medicine and/or the need to work within finite budgets." Usually, in a PLA, the payer agrees to list a new medication on its drug formulary in exchange for a commitment from the pharmaceutical manufacturer. For example, a clinical PLA could involve a commitment, by the manufacturer, to conduct a post-marketing clinical study to further assess the clinical efficiency and effectiveness of the drug. In a financial PLA, the manufacturer could commit to providing a financial discount to the payer (i.e., the insurer) in order to create a positive cost-effectiveness ratio or to limit the impact on its budget of the coverage of the medication. (See Table 1 for a comparison of the advantages and disadvantages of the different types of PLAs and Table 2 for details on PLA policies and practices in other provinces.)

TABLE 1. Types of PLAs

Type of Agreement	Groups	Definition/Use	Advantages [+] / Disadvantages [-]
Financial Agreements	a) Rebate Agreements	Create two different prices for the same medication: a confidential reduced price for the payer and an official public price (higher) for insurees (Ministry of Health and Long-Term Care 2010; widely used in Ontario).	[+] Simple to implement. [+] Generate savings for the payers. [-] High opacity. [-] Create artificial marketed medication prices. [-] Disparity between public and private insurees.
	b) Price-Volume Agreements	The first simple form of a "risk-sharing" agreement. The price of the medication is reduced according to drug utilization.	[+] Improve budget certainty. [+] Greater transparency compared to rebate agreements. [+] Simple to implement. [-] Disparity between public and private insurees.
Clinical Agreements	a) Conditional Coverage Agreements	The coverage of a medication is conditional upon positive post-marketing clinical data. (i) Coverage with evidence development agreements (CED) : Clinical studies required differ from traditional post-marketing studies, their aim being the reduction of the payer's uncertainty about the clinical effectiveness of the medication. (ii) Conditional treatment continuation agreements (CTC) : Coverage is conditional upon evidence of clinical effectiveness for specific patients (clinical targets).	[+] Option for improving healthcare efficiency and effectiveness. [+] Option for obtaining optimal drug therapy and "value for money." [+] Provide improved access to a new, promising drug in a timely manner. [+] Reduce any uncertainty that may remain following the drug's clinical evaluation. [-] Risk that the drug be removed from the list owing to lack of strong clinical evidence. [-] Difficulty in assessing clinical outcomes. [-] Lack of transparency.
	b) Performance-Linked Reimbursement Agreements	Drug coverage is tied to a specific clinical aspect of the drug. (i) Outcome guarantee agreements : "schemes where the manufacturer provides rebates, refunds, or price adjustments if their product fails to meet the agreed upon outcome targets" (Carlson et al. 2010: 184). Two principal components: a data collection process to assess the performance of the medication for each patient treated and a formula that links the reimbursement or the rebate to the data collected. (ii) Process of care agreements : "schemes where the reimbursement level is tied to the impact on clinical decision-making or practice patterns."	[+] Link the price of a medication to its effectiveness for each patient. [-] Clearly defined evidence-based parameters for measuring success of the therapy are often missing. [+] Limit uncertainty concerning the drug's impact on clinical decisions.

TABLE 2. PLAs in other provinces

Province	PLA Policies	Mechanism	Types of Agreements
Ontario	<p>PLAs are negotiated and concluded since the adoption, in 2006, of <i>An Act to Amend the Drug Interchangeability and Dispensing Fee Act and the Ontario Drug Benefit Act</i> (Bill 102) (Government of Ontario 2006).</p> <p>In 2011, the government of Ontario introduced a policy specifically for cancer drugs, allowing the conclusion of CED agreements, called the Evidence Building Program, that aims to “develop and collect real-world data on cancer drugs where evolving evidence demonstrates clinical benefit beyond the current reimbursement criteria” (Cancer Care Ontario 2011).</p>	<p>No official mechanism.</p> <p>Listing recommendations may be conditional based on different commitments from pharmaceutical manufacturers (e.g., commitment to the advertisement of the appropriate use of the medication if concerns exist about “off-label” use or specific evidence to identify clinical or economic uncertainties).</p>	<ul style="list-style-type: none"> • Mostly confidential agreements on prices (98%).
Alberta	<p>Policy that stipulates comprehensive parameters for establishing and executing PLAs through a clear, collaborative, predictable and sustainable process.</p> <p>Four different types of PLAs: (1) price/volume agreements, (2) health research capacity agreements, (3) utilization management agreements and (4) coverage with evidence development agreements (Alberta Health and Wellness 2011).</p>	<p>The Ministry invites manufacturers, via a request for PLA (RFPLA), to submit a PLA proposal. In the RFPLA, the Minister indicates the type of drugs targeted for PLAs and the preferred type of PLA for these drugs. On the basis of the RFPLA response, a pharmaceutical manufacturer can submit a PLA proposal to be evaluated by the Alberta authorities. In their decision on whether or not to recommend the proposed agreement, the authorities take into account the priority status of the pathology, the therapeutic benefits of the medication compared to the comparator, the existence of equivalent drugs, the difficulty of the proposed agreement and the societal benefits that may result from the drug coverage.</p>	<p>PLAs that:</p> <ul style="list-style-type: none"> • Facilitate improved access to innovative drugs in a timely manner. • Ensure the financial sustainability of the drug plan.
Other provinces	<p>No formal PLA policies.</p> <p>Pan-Canadian agreements (in which Quebec has not participated) have been concluded for bulk purchasing, e.g., Soliris (IMS Brogan 2011).</p> <p>Canadian provinces, except Quebec, concluded an agreement on bulk purchasing for six generic drugs after April 1, 2013: Atorvastatin, Ramipril, Venlafaxine, Amlodipine, Omeprazole and Rabeprazole (Lunn 2013).</p>	<p>Willingness of some provinces to implement clear guidelines in order to regulate this process.</p> <p>Atlantic provinces are currently working on a common PLA policy draft that should be similar to the Alberta PLA policy, except that no “health research capacity agreement” will be included in the guidelines. This is due to the fact that the biopharmaceutical industry is not developed in these provinces and thus, is not a priority.</p>	

Interestingly, unlike most Canadian provinces¹ – and although section 52.1 of *An Act Respecting Prescription Drug Insurance*, RSQ (Government of Quebec 1996), c. A-29.01 (“the Act”) allows the Minister of Health (“the Minister”) to enter into PLAs – the government of Quebec has, to date, been reluctant to enter into such agreements (Pelchat 2012). One reason may be that clinically based agreements are difficult to implement (Neumann et al. 2011). Another reason may be that because financial PLAs are confidential, private insurers, and consequently the individuals they insure, do not benefit from the discount granted by the manufacturer to the government. According to Gagnon (2012), this situation contravenes the objective of fairness in Quebec's pharmaceutical policy and therefore, PLAs should be considered illegal.

In this paper, we will argue that not only are PLAs legal in Quebec, but they have the potential to reduce drug expenditures, to improve accessibility to medications and reasonable pricing, to improve drug utilization and to foster innovation. In particular, we will explain why both clinical and financial PLAs are actually a means of reaching all the objectives in Quebec's pharmaceutical policy (“the Policy”).

Objectives of Quebec's Pharmaceutical Policy

The Act defines what is referred to as the “Basic Plan” and sets out all the conditions and guarantees required for both public and private prescription drug insurance in Quebec. The current Basic Plan, which came into effect in 1997, is unique in Canada because it requires all Quebec residents to be covered by a prescription drug insurance plan (mandatory Basic Plan) (Pomey et al. 2007).

Section 51 of the Act requires the Minister to implement a policy on pharmaceuticals. This policy, which was amended for the last time in 2007 (MSSS 2007), sets out four main objectives that the government must strive to achieve: (a) ensure access to prescription drugs, (b) fair and reasonable drug pricing, (c) optimal drug use, and (d) maintain a thriving biopharmaceutical industry in Quebec. For the purpose of this paper, we combined the first two objectives under the title “Fair and reasonable access,” below.

Fair and reasonable access

The objective in the Policy relating to fair and reasonable access is reflected in the Act and the regulations to it. The main elements in the Basic Plan that contribute to reaching these objectives are its mandatory nature; the fact that private insurers are required to cover, at least, the same medications as those covered under the Basic Plan; and the limited financial contribution required of individuals covered by the plan.

The mandatory nature of the Basic Plan was introduced in 1997 in order to guarantee accessibility to prescription drugs in the province. In particular, the plan guarantees all residents coverage of the cost of medications and pharmaceutical services provided in Quebec (the Act, s. 2), regardless of the risk related to the state of health of the patient (the Act, s. 7). In Quebec, a resident who is not covered by private group insurance is automatically covered by

the public plan (the Act, ss. 7, 15–18.1). In 2011–2012, 3.4 million residents, out of a total of 7.7 million (4.3 million being covered by private group insurance), were covered by the public plan (RAMQ 2012: 90).

In order to encourage fair and reasonable access to prescription drugs, both the government and private insurers are required, under the Basic Plan, to provide minimum coverage for medications and pharmaceutical services. The guaranteed minimum coverage involves a defined maximum financial contribution (the Act, s. 10 et seq.) from the individuals covered by the plan and the reimbursement of all drugs listed under section 60 of the Act. Private insurers are required to provide the individuals who are covered by their plans at least the same coverage as that provided by individuals protected by the public plan (the Act, ss. 35 and 60, par. 1).

In Quebec, the Minister is required to first recognize a manufacturer before a drug can be listed. To be recognized, the manufacturer must enter into an agreement by signing the form found in Schedule I of *A Regulation Respecting the Conditions Governing the Accreditation of Manufacturers and Wholesalers of Medications*, c. A-29.01, R.2 (“the Regulation”) (Government of Quebec 2013). One of the more interesting aspects of this agreement is a guaranteed pricing policy that requires the manufacturers to sell their medications at a price no higher than any price granted for the same drug under any other provincial drug insurance program in Canada (the “lowest price” rule) (the Regulation, s. 1(4)). The Policy considers the lowest price rule to be an effective tool in ensuring reasonable drug pricing. Necessarily, the effectiveness of this rule is viewed with scepticism now that other provinces are entering into confidential PLAs in which discounts are actually granted in exchange for drugs being listed (Bourassa Forcier and Noël 2012).

It is feared that confidential PLAs between the government of Quebec and manufacturers could result in disparities between individuals covered by the public plan and those covered by private plans. This risk is related to the confidentiality of the prices agreed to for listed drugs. Private insurers, and therefore individuals who are covered by their plans, would not benefit from the discounted prices. The government of Quebec’s refusal to enter into PLAs for fear of creating disparity is certainly not the solution. Encouraging private insurers to follow the government’s lead would be a better alternative. Actually, it is the private insurers’ lack of interest in this option that would ultimately lead to such disparities.

The fact that PLAs between the government of Quebec and pharmaceutical manufacturers represent the potential to create inequalities between the insured does not mean that such agreements are illegal. Actually, a perusal of the Act and the regulations related to it clearly reveals that the fairness objective is highly relative and is more an ideal to be strived for than a legal requirement. In its application, the Act itself creates certain disparities between the individuals covered by the public plan and those covered by private plans. First, the objective related to “fair and reasonable access” contained in the Policy may be disputed owing to the large disparity between the financial contribution required of residents covered by the public plan as opposed to those paid by individuals covered by private plans. As mentioned above,

the minimum coverage under the Basic Plan requires a financial contribution from those seeking coverage. This participation varies depending on whether a person is covered by a private group insurance plan or by the public insurance plan. The financial contribution paid by an individual covered by the public plan includes a defined annual premium (the Act, s. 28), while no such defined amount exists for those covered by a private plan. Furthermore, the price of pharmaceutical services provided to residents covered by the public plan is negotiated between the Minister and the association representing the owner pharmacists of Quebec (Association québécoise des pharmaciens propriétaires du Québec). In 2012, the negotiated price under the public plan was, on average, \$8.44 per prescription, while its counterpart under private insurance plans was variable and could reach as high as \$50 per prescription (Gazaille 2010).

Finally, Quebec is recognized as the province with the most comprehensive list of covered prescription drugs (Gagnon 2011). Nevertheless, a few years ago, Quebec was criticized for not covering certain cancer drugs (Lacoursière 2011). This criticism was based on a cross-national comparison of access to these drugs (Hughes 2012), which concluded that in 2011, Quebec was not covering certain cancer drugs while other provinces, such as Ontario and Alberta, were (Bourassa Forcier and Noël 2012; Cancer Care Ontario 2011; Hughes 2012). This situation led to a major criticism from the Institut d'excellence en santé et en services sociaux (INESSS) (IHS 2011; INESSS 2011). In response, the province agreed to list these drugs without negotiating PLAs, even though INESSS had recommended they do so (INESSS 2011).

At this point, it can be argued that by not negotiating the price of these drugs, the government failed to fully respect and guarantee the sustainability of the Policy's access and pricing objectives. It is quite probable that in this situation, PLAs would have represented a useful tool for promoting these objectives.

Optimal use of medication

Non-optimal drug therapy, or non-optimal drug utilization, refers to a number of undesirable events, including improper drug selection, inappropriate dosage, adverse drug reactions, drug interactions, therapeutic duplication and patient non-compliance.

In the United States, the costs associated with patient non-compliance are estimated at over US\$290 billion, irrespective of costs related to morbidity and mortality (Hubbard and Daimyo 2010). According to the World Health Organization's report on adherence to long-term therapy, "adherence to long-term therapy for chronic illnesses in developed countries averages 50%" (WHO 2003).

In light of its clinical and financial benefits, optimal drug use is a key objective of the policy of the government of Quebec. In 2002, in order to better meet this objective, the government entered into three financial partnerships with pharmaceutical manufacturers and their association, in which it was agreed to create optimal use programs. These encompass a wide range of programs that can vary in name and by the clauses they contain. Different

optimal use programs are aimed at different targets, ranging from doctors to pharmacists or patients. Such programs may, for instance, include the training of healthcare professionals, patient education, monitoring or some combination of these. Haynes and colleagues (2008) suggest that a patient adherence program may involve counselling services for the patient about the targeted disease, as well as group meetings, follow-ups, simplified dosing, reminders, different medication formulations, increased pharmacy services, mailed communications and appointment and prescription refill reminders.

Unfortunately, all three partnerships failed to reach their objectives because of various shortcomings within the contracts. In our opinion, one of the shortcomings lies precisely in the fact that they did not make the listing of medications conditional upon the manufacturers' investing in optimal use programs and on the collection of new clinical and financial data related to their medications. Clinical PLAs are a new way to create a real incentive for manufacturers to ensure that their medications are properly prescribed and used. Indeed, non-conclusive post-marketing studies may bring about the risk that medications be removed from the formulary or that their listed price are reduced.

However, we wish to emphasize that to date, very few countries have implemented clinical PLAs (Bourassa Forcier and Noël 2012) because of the complexity of their implementation (numerous actors being involved, such as doctors and pharmacists, with the ensuing need of a data register) and the difficulty in quantifying the societal value associated with drug use programs. Indeed, clear guidelines on how to evaluate the health outcomes and economic aspects of such drug use programs would certainly render the economic evaluation process easier and more predictable, both for manufacturers and for the public.

A strong biopharmaceutical industry

Until recently, the policy of the government of Quebec had, as its fourth objective, the development of a strong biopharmaceutical industry in the province. In order to reach this goal, the 2007 policy allowed an annual indexing of drug prices. This new policy brought an end to the "price-freeze" policy that had been in place since 1994 (MSSS 2007: 7). At the same time, in order to limit the negative impact of annual price increases on the sustainability of Quebec's public plan, the government began to enter into confidential compensatory agreements with manufacturers. As of March 31, 2011, 60 compensatory agreements, covering 648 products, were concluded with 59 pharmaceutical manufacturers (RAMQ 2012: 65).

On April 1, 2013, the new government announced a resumption of the price-freeze policy until March 31, 2015.

In addition to the price indexing policy of 2007 and in order to advance research and development (R&D) in Quebec, the government also confirmed, the same year, that it would continue to implement the "15-year rule" (BAP 15). The BAP 15 was an exception to Quebec's "lowest price" policy (the Act, s. 28.2). Under this rule, a brand-name medication was reimbursed at its original price for the first 15 years following its inclusion in the formulary, even if a generic version was available in Quebec (the Act, s. 9). This rule was abolished in January 2013.

The government's reasons for abolishing BAP 15 were the high level of expenditures related to medications resulting from the application of this rule, which reached approximately \$25 million in 2005 (MFQ 2005) and \$193 million in 2011–2012 (Lacoursière 2012), in combination with a growing scepticism regarding its efficiency in encouraging R&D, particularly in view of the closing of several pharmaceutical research laboratories in the province over recent years (Babad 2012).

We believe that it is not too late for the Province of Quebec to find a new and effective alternative to promote innovation and the development of a strong Quebec-based biotechnology industry. Through the negotiation of PLAs, the government could actually provide recognition of the value of a manufacturer's investments in R&D in the province, as is the case in Alberta through its PLA policy (Alberta Health and Wellness 2011; see also Table 2). Through the negotiation of PLAs, the government could also emphasize particularly innovative medications. If PLAs were negotiated to recognize and reward R&D investments made in Quebec and innovation, all residents of Quebec would benefit in the long term.

Conclusion

Undoubtedly, PLAs have considerable advantages. Payers are relying more and more on PLAs to expand drug coverage and to control their drug expenditures. These agreements can also promote the collection of post-marketing clinical and economic data to help support the introduction of new drugs. Finally, through PLAs, the government of Quebec could find a new means of promoting R&D investments and innovation in the province. However, because they may rapidly become an administrative burden for the government, PLAs should be the exception. In particular, these agreements should not supplant traditional pharmaco-economic evaluations, but rather form part of a wide array of tools that can be useful in dealing with clinical or financial uncertainties.

Considering their advantages, the government of Quebec, i.e., the Minister of Health, should consider PLAs when striving to meet each of the four pharmaceutical objectives set out in its policy. However, in doing so, the Minister must not forget the lack of transparency of PLAs and the ensuing risk of creating disparities between individuals covered by the public plan or by private insurance plans. This risk must not be overlooked.

However, in view of the advantages of PLAs, rather than entirely shy away from such partnerships with drug manufacturers, the government should implement a transparent policy that would regulate their use. This policy could, for example, promote transparent agreements where only commercial and financial information would be confidential, all other information being public and accessible online. In implementing such a policy, Quebec would become a pioneer in the field of transparent PLAs and would certainly provide an incentive to other jurisdictions to follow in its footsteps.

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NOTE

1. Alberta and Ontario are the only two provinces with formal PLA policies (see Table 2).

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