

Quebec Best Available Price (“BAP”) policy, post Bill 28

PRESENTED BY:

Mathieu Gagné LL.M., LL.D.

Leslie Milton

Ingrid VanderElst Ph.D.

Outline

1. Quebec PLAs (bilateral or pCPA)

- i. Bill 28
- ii. Scope of PLAs
- iii. Confidentiality Considerations
- iv. Retroactive Application of PLAs
- v. Obligation to Report

2. Implications of Quebec PLAs for the BAP

- i. The Guaranteed Selling Price (“GSP”)
- ii. The Best Available Price (“BAP”)
- iii. Does the BAP apply to PLAs?
- iv. Conclusion

1. Quebec Best Available Price (“BAP”) policy, post Bill 28

Quebec PLAs (bilateral or pCPA)

i. Bill 28 – Product Listing Agreements

“60.0.1. The Minister may, before entering a medication on the list of medications, make a listing agreement with its manufacturer. The purpose of such an agreement is to provide for the payment of sums by the manufacturer to the Minister in particular by means of a rebate or discount which may vary according to the volume of sales of the medication.”

PLA Timeline



From a strategic standpoint, it may be advisable to proactively initiate a PLA negotiation with the Minister **in parallel** with the evaluation process of your product by INESSS.

ii. Scope of PLAs

- Drugs covered by the RAMQ plan
- Hospital products*

* Regarding hospital products, PLAs will **only** be possible if the products are not subject to the public call for **tenders process**.

PLA Strategy

- In order to keep a competitive edge and thus, to secure the supply of your product in hospitals, it may be advisable that your PLAs include a provision forcing the Minister to allocate a specific budget to the concerned hospitals, covering their expenses resulting from the administration of your product.



A single PLA?

PRO: combining the quantity of products that the RAMQ and hospitals reimburse could **lower the aggregate cost** of medication for the Minister.

CON: Having a different PLA for RAMQ products and hospital products could allow for **more flexibility**, e.g. in view of offering population-specific programs such as optimal drug use programs or patient support programs or in view of terminating only one contract.

iii. Confidentiality Considerations

“60.0.3. [...] Only the following information is to be published in the annual financial report:

- (1) the name of the **drug manufacturer**;*
- (2) the name of the **medication**; and*
- (3) the **annual total sum** received pursuant to listing agreements, but only to the extent that at least three agreements made with different drug manufacturers are in force in the fiscal year.”*

PLA Strategy

- We recommend including bilateral confidentiality provisions in any future PLAs concluded with the Minister in Quebec.



Confidentiality of INESSS recommendations

- For medications that will undergo PLA negotiations, INESSS' recommendations will be not be published according to the current delays (i.e. 30 days after they have been provided to the Minister).
- Rather, these recommendations will be published at a time determined by the Health Minister.

PLA Strategy

- It may be advisable that the Minister undertakes, in a Letter of Intent (“**LOI**”), to effectively **set the time of publication** of the recommendation made by the INESSS to a moment **after the conclusion of the listing agreement**.



Confidentiality of PLAs in Other Provinces

- The LOIs entered into pursuant to the pCPA procedure prior to Quebec's participation should not be applicable to Quebec.
- Even so, it may be advisable to ensure that any pCPA LOI involving your company is subject to a bilateral Non-Disclosure Agreement (“NDA”).

iv. Retroactive Application of PLAs

- Legislation cannot have a retroactive effect unless it is specifically and unambiguously provided for by the legislature.
- Bill 28 does not contain any language that the provisions relating to PLAs should be applied retroactively:
*“The Minister may, **before** entering a medication on the list of medications, make a listing agreement with its manufacturer”.*
- **Therefore, Bill 28 cannot have a retroactive effect on drugs already listed on the List of Medications.**

v. Obligation to Report

- The Minister has an obligation to report on the impact of Bill 28's Health Measures by **October 2017**.
- According to some stakeholders, this will likely **draw** some **attention to the impact of PLAs** which may ultimately persuade the government to reconsider allowing private payers to benefit from PLAs in 2017.

UPDATE

2. Quebec Best Available Price (“BAP”) policy, post Bill 28

Implications of Quebec PLAs for the BAP

i. Guaranteed Selling Price

- *The manufacturer undertakes to submit a **guaranteed selling price** (“**GSP**”) per package size for any drug that he wishes to have entered on the List of medications drawn up under section 60 of the Act respecting prescription drug insurance.*

ii. The Best Available Price (“BAP”)

The GSP shall be established as follows:

- (1) it must be submitted for each package size of the drug;
- (2) it may differ for sales to pharmacists or to wholesalers, but such difference may not exceed 6.50%;
- (3) it must remain in force throughout the period of validity of the List of medications;
- (4) it must not be higher than any selling price granted by the manufacturer for the same drug under other provincial drug insurance programs.**

iii. Does the BAP apply to PLAs?

Can the PLA-negotiated price in Quebec be lower than the listed price?

It may certainly be argued that...

1. The Minister cannot, on the one hand, conclude a PLA with a manufacturer and, on the other hand, claim that same manufacturer is in breach of GSP regulations as a direct result of said PLA.
2. It would be **unreasonable** for the Quebec Government to benefit from all the advantages of the agreements negotiated (and often imposed) by the Provincial Benefit plans without assuming any of the agreed considerations and political commitments.

Does the BAP apply to PLAs?

*Can the PLA-negotiated price **outside of Quebec** be lower than the listed price in Quebec?*

It may certainly be argued that...

1. “The price of the medication indicated on the list does not take into consideration the sums paid pursuant to the listing agreement.” – s. 60.0.1, *Act respecting prescription drug insurance*
2. “The GSP is the price that a **buyer** must pay for a drug... [which] the manufacturer undertakes to respect, in his transactions with **wholesalers** and **pharmacists**”. – ss. 1 & 2, *Manufacturers Commitment*

Does the BAP apply to PLAs?

3. Rebates or discounts provided to a government are not contemplated by the GSP. - *Pfizer v. Canada*
4. Where there is any doubt, the terms and conditions of the GSP should be interpreted in favour of the manufacturer. - *RAMQ v. Altimed Pharma Company*
5. Such agreements, entered into on an ad hoc basis, usually involve considerations other than just Rebates.

iv. Conclusion

- PLAs could include considerations in order to help position your products from a **pharmacoeconomic** perspective, but also from a **therapeutic value** standpoint, (e.g. communication and training plan, patient follow-up program, optimal utilization program, specified clinical studies, etc.)



**FASKEN
MARTINEAU**

