Ministry of Health
and Long-Term Care

Ontario Public Drug Programs

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Ontario

Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
Standard Life Centre
333 Laurier Avenue West
14th Floor
Ottawa ON K1P 1C1

Dear Ms. Dupont:

Thank you for the opportunity to provide feedback on the Patented Medicine Price Review Board's (PMPRB) Discussion Paper: Options for Possible Changes to the *Patented Medicines Regulations*, 1994 and the Excessive Price Guidelines. This discussion paper includes options for price review and options to address issues arising from the recent Federal Court of Canada (FCC) decision.

In general, the ministry is in agreement with the proposals relating to price review, specifically the reconsideration of the Maximum Non-Excessive (MNE) price in response to the availability of new clinical data. Clearly defined criteria will be required to engage in this process to avoid debates on clinical merit which are beyond the scope of the PMPRB.

There is concern regarding the proposal to reduce the number of countries required for the Median of the International Price Comparison Test for the review of interim prices. If prices that are finalized are based on comparison to only 3 countries, there is a risk that depending on the countries selected, the majority of countries considered in the Test could have unregulated pricing policies leading to an inflated median price.

The ministry also supports considering the costs of manufacturing a patented medicine in determining whether or not its price is excessive. The acceptable costs need to be clearly defined and should only relate to manufacturing. Selling and Administrative expenses, such as Marketing and legal costs should not be considered.

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The ministry has expressed previously the need for price review where the main indication for use of a product changes significantly after market introduction. Often, patented products are launched with very narrow indications for use and there is no opportunity to review the introductory price when new indications are added which tend to expand utilization to a larger or broader population. This consideration has not been included in the current set of options. We strongly encourage you to consider including this.

Since October of 2006, the ministry has implemented the Transparent Drug System for Patients Act (Bill 102), which is part of the government's reform of the provincial drug system to ensure improved patient access to drugs and better value for money. Price and volume negotiation are part of the approved processes in the reforms. The ministry must be able to continue its work consistent with the current environment and would strongly oppose any reporting requirement that would prevent this.

Thus, with respect to the regulatory options arising form the FCC decision, the ministry is supportive of Option 2 which exempts patentees from the requirement to report benefits (payments) provided to third party payers. The focus should be on ex-factory price and not on agreements negotiated by provincial payers.

With respect to options for addressing free goods, the ministry supports the exclusion of goods provided as compassionate supply from the calculation of the Average Price. All other types of goods should be included in the calculation.

In review of the options for possible changes to the CPI-adjustment methodology for determining the MNE price, Option 1 creates the potential for a loss of predictability for government to forecast program growth. If there is large variability, particularly with high utilization categories, then there is more pressure for accurate predictions of growth.

Thank you for the opportunity to comment. If you require clarification on any of the points noted above, please contact Brent Fraser at (416) 327 8315.

Sincerely,

Helen Stevenson

Helen Stevenson
Assistant Deputy Minister and Executive Officer

c: Brent Fraser, Director
Angie Wong, Senior Manager
Mo Hussain, Senior Economist