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Ontario Public Drug Programs

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15 October 2008

Ms 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 very much for the opportunity to provide feedback on the Patented Medicine Prices Review Board's (PMPRB) "Draft Revised Excessive Price Guidelines" released on August 20, 2008.

Over the past two years Ontario has implemented major reforms of the publicly funded drug system; as a result of these reforms, we have achieved over $260 million of savings for Ontario taxpayers, all of which have been reinvested into the drug system to improve access to new drugs for patients. These savings were achieved most significantly through reduced generic prices, as well as through negotiated pricing and listing agreements with brand name pharmaceutical manufacturers. We believe that the results for Ontario patients and taxpayers have been profound and positive, and are committed to sustained, positive results in the future.

We have done a thorough review of the Draft Guidelines, and noted several concerns related to proposed changes that could potentially inhibit our ability to continue to deliver results for Ontarians; our feedback below is focused primarily on those concerns.

Firstly, we're concerned about the calculation of the Average Transaction Price (ATP) and the implications it may have on the calculated Maximum Non-Excessive Price (MNE) for a drug product. More specifically, we are unclear as to when and how an MNE may be adjusted due to a change within a particular market. The Draft Guidelines state that a review of the ATP may occur at the level of 'any market' on a case-by-case basis – it is unclear whether this review would result in a change to the MNE.

As mentioned above, we have successfully negotiated many agreements with brand name pharmaceutical manufacturers. While the terms of these agreements are strictly confidential, our 'template' agreement is widely available – you'll note that in many cases manufacturers are required to pay a volume discount to the Ontario Government as per the specific terms of the agreement.

Based on numerous prior discussions with PMPRB staff, it has been our consistent understanding that in cases where the ATP may be lower in Ontario within the 'Other' category, as a result of these agreements, the Board would not take action that would either change the MNE or penalize the manufacturer as a result of such an agreement. However, representatives of brand name pharmaceutical manufacturers have shared with us their understanding that the MNE may be 're-set' as a result of a change in the ATP for Ontario due to these agreements. These messages appear conflicting. If, in fact, the agreements change the MNE for a drug product, we would have grave concerns with respect to our ability to negotiate agreements for the benefit of Ontarians. Consequently, we would not support any amendments to the Compendium of Policies, Guidelines, and Procedures (Compendium) that would impose such restrictions.

Furthermore, Section 2.6 of the Compendium infers that the MNE may be adjusted downward as a result of a manufacturer providing a reduced price (or volume discount) as part of an agreement. In particular, the Section states that upon termination of a benefit, the MNE may be set at the previous highest non-excessive ATP instead of the MNE price resulting from the application of the CPI-Adjustment Methodology. The Compendium is not clear as to whether or not this adjustment could occur as a result of the ATP being lower in one particular market – i.e. in Ontario. Again, we would not support a change in the MNE that is prompted directly by a listing agreement negotiated with us. Therefore, we ask that the Guidelines are explicit regarding how PMPRB will use the ATP calculations in 'any market' to assess whether a manufacturer is exceeding the MNE for that product.

Finally, Form 2, as described on page 5 of the Compendium states that the calculation of the average price per package is net of any "...rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature..." that was sold by the patentee or former patentee to each class of customer in each province and territory. While we negotiate rebates and/or discounts as part of listing agreements, it is important to note that the drug products are not sold by manufacturers to the Ministry. Therefore, it is unclear that these agreements would be considered as part of a 'class of customer' as described in the Compendium.

We recognize that there may be situations whereby a product's price may exceed the MNE in a particular market, as a result of different prices provided to different markets. Again, I would like to emphasize that we would not support any situation where the excessive price is deemed so as a result of a negotiated listing agreement in Ontario. We would recommend that those situations are reviewed on a case-by-case basis specific to that market/jurisdiction, and that PMPRB does not link any recovery to an adjusted MNE arising from such an agreement.

We acknowledge the substantial effort undertaken to produce these Draft Guidelines and greatly appreciate the opportunity to provide feedback. We would be pleased to discuss further at your convenience.

Sincerely,

Helen Stevenson

Helen Stevenson
Assistant Deputy Minister and
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c: Ron Sapsford, Deputy Minister of Health
Brent Fraser, Director, Drug Program Services