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Ms. Sylvie Dupont
Secretary of the Board
Patented Medicines Pricing Review Board
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Standard life Centre
Suite 1400 - 333 Laurier Avenue West
Ottawa Ontario K1P 1C1

Dear Ms. Dupont:

I am writing on behalf of the Pharmaceutical Services Division, British Columbia Ministry of Health Services in response to the draft Revised Guidelines published on August 20, 2008. Thank you for the opportunity to review and respond to the draft document.

We submit the following comments for the Board's consideration. Our submission pertains to two of the issues addressed in Part I of the Guidelines Consultation Package:

I. Issue - Impact of Reporting Benefits

We reiterate our concern that changes to reporting requirements may have the effect of discouraging patentees from providing rebates, compassionate supply or other benefits to customers. We appreciate the Board's stated intention to avoid creating such disincentives for patentees and urge that the Board take every possible step to ensure that this matter is effectively addressed in the revised Guidelines.

We offer specific comments on two points identified in relation to this issue.

CPI-Adjustment Methodology – cap factor

The Consultation Package presents two possible options for changes to the annual prices increase cap under the current CPI-Adjustment Methodology. While it is possible to discern potential advantages and disadvantages of each option from the perspective of different stakeholder groups, it is difficult for us to ascertain fully the relative impacts in the context of the new reporting regime. We also note the Board's decision to defer consideration of the "GAP" scenario pending further analysis once the new reporting requirements are in place.

...2

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Rather than implement a change to the annual price increase cap at this time, we suggest that there may be cause to maintain the status quo until the Board and stakeholders are able to better predict the implications of changes to the CPI-Adjustment methodology and any further exceptions thereto.

Protection of Confidential Information

It is our view that the reporting requirements under the *Patent Act* (the *Act*) should not expose any party to the unnecessary disclosure of sensitive commercial information. Excepting only circumstances relating to a public hearing, the *Act* stipulates that information provided to PMPRB under Section 80, 81 or 82 cannot be disclosed without the authorization of the person who provided it. Particularly in light of the change in reporting requirements, British Columbia is interested to resolve any uncertainty regarding the extent to which pricing information might become available to third parties.

We ask that the Board refrain from releasing any detailed pricing information provided by a patentee, including average transaction prices by market, unless the patentee has provided express consent for disclosure directly to the Board. We submit that consent provided to a third party to access such information from the Board should not be accepted as sufficient for this purpose.

We also ask that the Board provide for the benefit of all interested parties a clear statement of the circumstances and conditions under which confidential information will be disclosed.

II. Issue - Any Market Price Reviews

British Columbia supports the Board's finding that its mandate includes the responsibility to ensure that prices of patented medicines are not excessive in any market in Canada. However, in response to concerns expressed by other parties and referenced at page 7 of Part I of the Consultation Package, we respectfully submit that the mandate to preserve non-excessive pricing across all markets does not extend to enforcement of pricing equity within or between markets. Further, while we support the initiation of any market price reviews on a case-by-case basis under the circumstances outlined in the Consultation Package, these reviews must not have the unanticipated consequence of penalizing patentees for providing benefits in certain markets.

The latter point is material to our consideration of the Board's question regarding the methodology for calculating excess revenues. We are not in a position to provide a definitive comment on that point, absent additional clarity regarding the manner in which the Board intends to apply the CPI-Adjustment methodology in the context of any market review.

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In a typical circumstance, we understand that the MNE price for an existing drug product is based on the national ATP in the benchmark year, as adjusted to reflect inflation. As an inherent attribute of the calculation of any average, we expect it is possible, or even probable, that the prices charged to some classes of customers and/or jurisdictions over the benchmark year would exceed the national ATP. Thus, even if price increases do not exceed the rate of CPI growth in any market in any year, it is possible that the prices charged to some classes of customers and/or jurisdictions will exceed the national MNE price.

From the Consultation Package, we are not able to determine whether the Board would view the above-referenced circumstance as inconsistent with the Guidelines. Accordingly, we are interested to understand whether the Board intends that the ATP for each market will be assessed against:

a) the national MNE (as derived from a national ATP);
b) a CPI-adjusted price based on the ATP for the relevant market in the benchmark year; or
c) some other benchmark price.

I hope the foregoing response is of assistance to the Board. Please contact me should you require any clarification.

Sincerely,

Bob Nakagawa

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Assistant Deputy Minister
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