From: Health, HLTH HLTH:EX [HLTH.Health@gov.bc.ca]
Sent: Wednesday, March 05, 2008 5:14 PM
To: Sylvie Dupont
Subject: Ministry of Health Response - 716831

March 5, 2008

Ms. Sylvie Dupont
sdupont@pmprb-cepmb.gc.ca

Dear Ms. Dupont:

Thank you for the opportunity to respond to the Patented Medicines Pricing Review Board discussion paper *Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines*.

In response, the British Columbia Ministry of Health has reviewed the discussion paper, and where applicable, provided comment. Our comments are below:

III. Overall Guidelines Review, A. Proposed Scenarios for Consultation

i) Any Market Price Review

It has been noted that while the Average Prices for some drugs in Canada are considered to be within the Guidelines, the Average Price within some markets (i.e., class of customer or province/territory) exceeded the Maximum Non Excessive price by up to 25 percent. Concern has been expressed that if some provinces/territories and/or classes of customer negotiate price concessions below the Maximum Non Excessive price, the offset may be that other provinces/territories and/or classes of customer will be charged higher prices (above the Maximum Non Excessive price).

We believe that all Canadians should have equal access to safe and effective prescription drugs. One barrier to access is excessive price.

As such, we support the ability of the Patented Medicines Pricing Review Board to conduct price reviews in any market or customer group to ensure prices for each market and customer group do not exceed the Maximum Non Excessive price. The four proposed circumstances that would trigger a price review at the level of any market are wide ranging and should alleviate stakeholder concerns regarding price disparity.

ii) Re-Setting the Maximum Non Excessive Price

The Guidelines currently provide for two cases where the Maximum Non Excessive price for existing drugs may be revisited and a new Maximum Non Excessive price may be set:

- When a drug product sold as an Investigational New Drug or under the Special Access Programme is granted a Notice of Compliance;
- At the end of three years when the pivotal introductory price test for a drug product is the Median of the International Price Comparison Test and the drug is sold in less than 5 countries during the introductory period.

In response to a range of stakeholder positions regarding whether and when to re-set the Maximum Non Excessive price, the Patented Medicines Pricing Review Board is proposing additional circumstances where re-setting the Maximum Non Excessive price may be undertaken.

<u>Proposal 1:</u> When the Maximum Non Excessive price can be shown to not cover the patentee's cost of making and marketing the drug under three proposed circumstances.

We do not support re-setting the Maximum Non Excessive price without detailed definitions of "making" and "marketing" a drug. We view marketing as essentially a business process removed from the elements required to manufacture a drug. Marketing costs can vary widely depending on the product and patentee and may not create any value for consumers such as would warrant an increase in price.

<u>Proposal 2 :</u> When the scientific information/evidence available at the time the medicine was first introduced was not sufficient to determine with confidence its category of therapeutic improvement, or when new post-market evidence suggests the initial categorization was inappropriate.

We base our formulary listing decisions on rigorous scientific evidence. As such, in principle we support initiatives that provide greater scientific evidence and information.

There is general support for re-setting the Maximum Non Excessive price in these scenarios. However, to provide a fully-reasoned position, more information is required as to what constitutes "information/evidence" that would potentially trigger re-setting the Maximum Non Excessive price. Additional information on the parameters of any potential price change is also required.

The cost effectiveness of a drug is pivotal in our assessment for listing the product on the provincial formulary. As such, a resulting price change from introduction of new evidence must take this into account. If new evidence finds the drug to be more or less safe and effective than originally thought, the price should be adjusted accordingly.

<u>Proposal 3:</u> When the Median of the International Price Comparison is the pivotal test and the medicine is sold in too few countries at introduction.

We support option iii) Eliminate a time limit altogether and re-review the interim price of the medicine when it is sold in at least 3 countries, no matter how many years from date of first sale this may be. Reviewing Canada's price for a patented medication against other international comparators when the prices become available is seen as the best option to ensure that prices of patented medicines charged by patentees are never excessive.

IV. Options to Address Issues Arising from the Federal Court of Canada Decision, A. Regulatory Options

We do not support the option of maintaining the current Regulations and respecting the outcome of the Federal Court of Canada decision (Option 1). This option would mean that patentees would be required to include all benefits listed in the Regulations in the calculation of a medicine's Average Price, whether or not they are provided under a compassionate release program, trial prescription program, expenditure limitation agreement or pursuant to any other initiative.

There is strong support for the Patented Medicines Pricing Review Board to exercise its mandate to ensure that Canadians are not subject to excessive pricing for patented medicines. However, there is concern that reporting requirements do not create any obstacle or disincentive for third party payers or patentees to negotiate prices that are lower than the Maximum Non-Excessive Price as determined by the Patented Medicines Pricing Review Board. The requirement to report negotiated arrangements with third party payers could create such a material disincentive for patentees insofar as price concessions negotiated by a provincial drug plan would have the effect of reducing Average Price and impacting the Maximum Non Excessive.

Rather, we support Option 2: Amending the Regulations to exempt patentees from the requirement to report benefits (payments) provided to third party payers (Federal/Provincial/Territorial drug plans and potentially private insurers if similar payments are negotiated in the future). For the reasons set out above, we agree with the rationale presented by the Board.

<u>Option 6</u>: Amending the Regulations to permit the Board to disallow any or all benefits which it determines, pursuant to a public hearing, were implemented by a patentee for the purpose of reducing its liability in regard to excessive pricing in terms of the calculation of excess revenues.

We agree the Board should be vested with the authority, which it may use only in certain limited and specific situations, to disallow the inclusion of any benefit in the calculation of the Average Price under the circumstances proposed. This authority will ensure patentees do not use the regulations to manipulate price in order to reduce liability under the Act.

B. Guideline Options

Possible Changes to Consumer Price Index -adjustment methodology for determining Maximum Non Excessive price:

The Patented Medicines Pricing Review Board presents two possible options to address this issue. Of the two options, the Ministry of Health supports:

<u>Option 2:</u> Amend the methodology in the Guidelines for the establishment of the Maximum Non Excessive price by using the greater of the introductory Maximum Non Excessive price and the Consumer Price Index-adjustment methodology using the highest previous non-excessive Average Price, if the actual Average Price declines due to a new or increased benefit.

We support this option with the provision that there is some formal constraint (ie incremental adjustments) on any single year price increase.

We appreciate the opportunity for feedback on the Patented Medicines Pricing Review Board guidelines review. Please contact me should you require further information.

Sincerely,

Bob Nakagawa, B.Sc. (Pharm.), ACPR, FCSHP
Assistant Deputy Minister
Pharmaceutical Services