CANADIAN PHARMACISTS ASSOCIATION
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Ms. Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
P.O. Box L40
Standard Life Centre
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by email: sdupont@pmprb-cepmb.gc.ca

Dear Ms. Dupont

On January 31, 2008, the Patented Medicine Prices Review Board (PMPRB) made a request for consultations on the Discussion Paper *Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines*. The purpose of this consultation was to discuss scenarios or triggers to indicate when the Board should review prices for any relevant market and not just on a Canada-wide basis and to identify circumstances when it may be appropriate to deviate from the current CPI methodology and consider re-setting the MNE price for an existing medicine.

The Canadian Pharmacists Association (CPhA) is the national organization of pharmacists, committed to advancing the profession of pharmacy so as to contribute to the health of Canadians. CPhA wishes to outline its position on specific issues from the Discussion Paper.

Issue 1: Scenarios or triggers to indicate when the Board should review prices for any relevant market and not just on a Canada-wide basis.

CPhA supports the four proposed circumstances when a price review at the level of any market would be conducted.

PMPRB's current mandate allows for the comparison of medicines sold in any market in Canada. The current reality in Canada is that there is not one standardized price for any medicine; jurisdictions and customers are free to negotiate individually with manufacturers to secure the best price in their marketplace. The National Pharmaceutical Strategy is working towards a national formulary; in this case, it would make sense to work towards standardizing prices in all Canadian markets. If there are wide variations in the prices of medicines across markets in Canada, PMPRB should be able to review the prices and enforce adjustments where necessary.

As mentioned in the Discussion Paper, the process for initiating a price review by PMPRB should remain open and transparent. CPhA supports a mandate for PMPRB that ensures drug prices across Canada not excessive and are consistent in all markets.

Issue 2: Circumstances when it may be appropriate to deviate from the current CPI methodology and consider re-setting the MNE price for an existing medicine.

CPhA supports the proposed circumstances when it would be appropriate to consider re-setting the MNE price on a case-by-case basis. The proposed scenario where the existing timeframe of three years is maintained but it is aligned with the timeframes adopted under Health Canada's Progressive Licensing initiative is supported by CPhA.

Other issues under Guidelines review.

CPhA backs the continuing work of PMPRB on the issues raised during the course of the Guidelines review. CPhA is encouraged the work of the Board's Working Group on Therapeutic Improvement and is in favour of changing the current categories of medicines. Defining the categories and setting evidence requirements will help to clarify the review process. We would like to see a system of four categories, separating "moderate improvement" from "little/no improvement," which would allow for incremental innovation by the pharmaceutical industry.

Work of PMPRB is important to ensure affordable medications for all Canadians. The international therapeutic class and price comparison tests seem to be reasonable as comparisons to ensure Canadian prices are not excessive. CPhA looks forward to the final reports from the Working Groups on international therapeutic class and price comparison tests.

Options to address issues arising from the FCC decision.

The options proposed to mitigate concerns arising from the Federal Court of Canada (FCC) decision are necessary to clarify the guidelines and regulations the PMPRB uses to fulfill its mandate.

CPhA believes that transparency and equity should be the ultimate goal with respect to PMPRB's mandate to ensure fair and non-excessive drug prices. The Discussion Paper identifies the current inequalities present in drug prices across Canada. Currently, there is no single price for any medicine; pharmacies, wholesalers, hospitals, jurisdictions and third-party payers are free to negotiate a best price with the manufacturer. CPhA would like to see a detailed assessment of the impact of transparency on drug pricing in Canada. This assessment should study the economic impact if transparency was applied to drug pricing agreements.

The impact of benefits (in the form of payments, free goods [samples], free services and gifts) on the price of pharmaceuticals in Canada is an important issue for PMPRB to address. In principle, CPhA believes that there should be no leeway in the regulations—either all benefits must be included or all benefits must be excluded in the calculation of Average Price. In addition, CPhA would prefer a system in which all benefits are reported all of the time for Average Price calculations. Under this system, transparency would be applied to the calculation of Average Price.

The Discussion Paper proposes six regulatory options address the issues arising from the FCC decision. The options presented suggest excluding or exempting particular benefits from the calculation of Average Price under certain conditions. Some consideration should be given to the impact of including various benefits in the calculation. The options presented may require more investigation. CPhA questions Option 4 and why services subsided by patentee should be included in the calculation of Average Price. In our opinion, patient support services, (such as a website) should be considered as marketing support not part of what makes up the price of the drug.

CPhA does not support amending the regulations to exempt patentees from the requirement to report payments to third party payers. As noted in the Discussion Paper, we have significant concerns that if one payer benefits from a preferred pricing agreement, then another payer may pay higher prices to offset lost revenue. Of particular importance are uninsured patients who will not benefit from preferred pricing arrangements and the effect on the cost of health care.

Thank you again for the opportunity to provide comments on the Discussion Paper. We look forward to the outcomes of the working groups and to future consultations on specific issues that effect drug pricing in Canada.

Yours sincerely

Jeff Poston, PhD., MRPharmS.
Executive Director