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March 3, 2008

Ms. Sylvie Dupont,
Secretary,
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
K1P 1C1

Re: PMPRB Discussion Paper – Options for Possible Changes *to the Patented Medicines Regulations, 1994* and the Excessive Price Guidelines

Dear Ms. Dupont,

P&G Pharmaceuticals Canada Inc. (P&G) welcomes this opportunity to comment on the PMPRB's discussion paper released January 31, 2008. As a member of Rx&D, we support the position and comments put forward by our industry association. In addition, P&G is providing the following comments on selected portions of the PMPRB's discussion paper.

1) Regulatory Options – Federal Court Decision re Leo Pharma

It is P&G's position that current regulations already exempt patentees from the requirements to report benefits (payments) provided to third party payers. However if the PMPRB would prefer to amend the regulations to provide greater clarity and to formulize the PMPRB's April 2000 "include or exclude" policy, P&G would be supportive of such an amendment. Any changes to the regulations must not create a disincentive within the industry to offer programs (e.g. special pricing, support services or other means) that provide benefits to Canadians. More importantly, if the price at which the medicine is sold to a pharmacy, hospital, wholesaler, or other is not excessive, then the PMPRB's mandate is achieved, and further reductions in price only further benefit the Canadian public, patients and payers.

Therefore, P&G strongly supports any amendment that would clarify that benefits offered to F/P/T drug plans would be exempted. Doing otherwise would jeopardize the continuation of providing benefits that further reduce costs for F/P/T plans.

2) Changes to the CPI-Adjustment Methodology

While P&G believes that the proposed changes to the CPI-adjustment methodology, and specifically Option 2, are a move in the right direction, the proposed approaches fail to recognize that an increase in the average transaction price following the end of a discount program is not a price increase and may be unavoidable as it could be outside the control of the patentee. The average transaction price is merely returning to its non-excessive level. As such, placing constraints on the amount by which the average transaction price can bounce back following the end of a program or contract forces a company to take some form of corrective action to ensure compliance.

- For example, if a reimbursement bridging program is put in place in Province A to assist patients in obtaining a needed therapy until reimbursement in that particular province came through, the average transaction price of the product would drop although prices in the other provinces remained at the previously non-excessive level. Once reimbursement is achieved in Province A and the bridging program ends, the product's price in Province A would bounce back to the level of the other provinces which already have reimbursement. Under the Discussion Guide's proposed approach, constraints placed on the amount by which the average transaction price can bounce back would result in the average transaction price being considered excessive even though the price in Province A had merely returned to the same non-excessive level as in the other provinces.

In addition, the proposed approaches ignore the fact that a drug product may be sold in two or more very different markets. For example, a product that is sold at its non-excessive list price through regular channels may also be sold at a significantly lower contract price to hospitals, thereby creating two distinct sales streams – regular sales and contract sales. While prices in the latter stream are fixed for the term of the contract, prices in the regular sales' stream may be increasing by CPI in keeping with the PMPRB's Guidelines. Thus, maintaining the MNE price at a fixed level (i.e. the highest previous non-excessive average price) can result in the average transaction price of a medicine being considered in excess of the Guidelines following the end of a contract even though any price increase implemented in the regular sales stream during the contract period has respected the PMPRB's allowable CPI adjustments. Therefore, an appropriate approach would allow MNE prices to increase by CPI during the period in which the product's average transaction price declines.

3) Any Market Price Review

The PMPRB's May 2006 Discussion Guide provided the results of extensive analysis on this issue by the staff of the PMPRB. The analyses examined the prices of all new medicines introduced in 2004 and the prices of all medicines in 2004 in each province and in each class of customer in relation to their corresponding maximum non-excessive prices. The results clearly demonstrated that the prices of the vast majority of the medicines were within ±5% of their MNE price regardless of what market was examined. Given these findings, the PMPRB's proposed change requiring the review of a new medicine's introductory prices in all markets in Canada is, in our opinion, unwarranted. This approach will lead to an increased workload for the staff of the PMPRB, an increased burden on patentees who may be compelled to provide justification for the prices established in each market and cause needless delays in the review of new medicines.

In addition, going back to the reimbursement bridging program example provided in #2 above, an "*any market*" review for new medicines could establish a significantly lower MNE price in the province for which the program applied. Once the average transaction price in that province returned to the level of other provinces following the end of the bridging program, the price in that province could be considered excessive even though the same price was not in excess of the Guidelines for other provinces. In our opinion, the current national approach to establishing MNE prices is the only appropriate approach. The tight investigation criteria already in place for new medicines, including a complaints mechanism, is sufficient to ensure that cases requiring more in depth scrutiny are identified and reviewed.

4) Re-Setting the MNE Price

The PMPRB's proposal to allow the re-setting of a medicine's benchmark price in the future based on new scientific evidence is unworkable and, contrary to the Guidelines' stated goal of providing price certainty, would create a significant level of uncertainty both for consumers and for patentees. In addition, while cases where the review of new literature resulted in the lowering of a medicine's MNE price would result in the implementation of a drop in the medicine's price, it is doubtful that a price could be adjusted upwards in the market even if the medicine's MNE price was increased as a result of the review.

In terms of eliminating the time limit altogether in relation to establishing the final benchmark price based on the median of a medicine's international prices, this approach has the potential to introduce significantly more uncertainty for companies impacted by this proposed change. An interim benchmark must have a definitive end whereby a final benchmark price can be established. In our opinion, the price review process must have a high degree of predictability instilled into it; otherwise companies are forced to operate under a system that could require a price adjustment at any time for reasons beyond their control.

P&G is in favour of maintaining the status quo in terms of number of years and changing the number of countries required to finalize a medicine's median international price from 5 to 3 countries.

P&G has offered comments on many of the proposed changes and options in isolation. However, we must point out that doing so has been extremely difficult in the absence of a full explanation of the impact these changes may have on each other as a result of the strong link between the issues up for discussion. Thus, the comments provided here could not be considered as final. We strongly recommend another consultation process with all the proposed parts clarified before moving forward.

P&G appreciates being offered this opportunity to provide input into the PMPRB's consideration of options for changes to the Regulations and to the Guidelines and hopes that these comments prove helpful in this regard.

Sincerely,

Andy McClenaghan
General Manager
Procter & Gamble Pharmaceuticals Canada Inc.