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Dear Ms. Dupont:

Re: Comments on PMPRB Draft Revised Excessive Price Guidelines

The comments below focus on those areas of the draft guidelines that remain of concern to us, a consumer products company, even though it is evident that the PMPRB has attempted to mitigate the impact of some new initiatives. We commend the PMPRB for acknowledging the value of moderate improvements in medicines by instituting a new therapeutic improvement level.

As in previous correspondence we are of the opinion that patented consumer products should not fall within the review of the PMPRB as they do not enjoy monopolistic protections. The consumer products market is characterized by a wider array of choice and more competition than is seen in the prescription product market. Retailers have far greater control over consumer product prices than is the case in the prescription market. Although patented consumer products are now reviewed on a complaint basis, we feel that the residual review mechanisms are unnecessary and should be eliminated. Consumer product companies should not face sanctions resulting from offering substantial price discounts. The PMPRB price cap mechanisms that may be more appropriate for the prescription market actually hinder price competition within the consumer products market by providing disincentives for reducing prices.

PMPRB Mandate

While we do not take issue with the restatement of the PMPRB mandate to include the interests of consumers and the Canadian health care system, we are concerned that the pricing guidelines will be amended in ways that depart from their historical purpose and evolution. We seek assurance that the PMPRB mandate will remain non-excessive pricing of patented medicines with reference to clearly articulated domestic and international pricing factors, and not branch out to health care policies and reimbursement matters which are outside the intended scope of the underpinning PMPRB legislation.

Publication of Form 2, Block 5 price information

In certain instances publicly available Form 2, Block 5 prices are not available. Patentees sometimes provide non-publicly available information to make up for the information gap. We suggest that in such instances, patentees should be able to specify that certain prices are not publicly available, and those prices should not be published.

"Any Market" Price Reviews

Although the Board has limited "any market" reviews to the medicine's introductory period, the accounting for variations in multiple markets, i.e. trade, geographic, plus trade and geographic combinations, will be complex and present a considerable resource burden for patentees. As consumer goods move about freely within Canada natural arbitrage mechanisms should obviate the need for "any market" reviews.

Criteria for Commencing an Investigation

Schedule 11 states that Board Staff will commence an investigation into the price of a patented drug product when: The National Average Transaction Price or any Market-Specific Average Transaction Price of a new drug product exceeds the Maximum Average Potential Price during the introductory period by more than 5%. Depending on the medicine, a 5% difference in average transaction price, national and particularly "market specific", from the Maximum Average Potential Price can be a very slim variance. The $25,000.00 investigation trigger, a very low threshold that has been in place for many years has been dropped. We would suggest that a more realistic, inflation adjusted trigger should be $50,000.00 on a national basis. We have already questioned the need for specific market investigations on the basis of the free movement of goods and arbitrage mechanisms in Canada.

We continue to believe that patented OTC products should be excluded from PMPRB review due to the nature of consumer products and the consumer market place.

We thank you for this opportunity to comment on the draft guidelines.

Yours sincerely,

Gerry Wright, Ph.D.
Senior Director, Regulatory Affairs