Canadian Life
and Health Insurance
Association Inc.

Association canadienne
des compagnies d'assurances
de personnes inc.

March 3, 2008

Ms. Sylvie Dupont
Secretary of the Board
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, ON
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Dear Ms. Dupont,

The Canadian Life and Health Insurance Association (CLHIA) is pleased to have this opportunity to contribute to the Patented Medicine Prices Review Board's discussion on possible changes to the *Patented Medicines Regulations* and the Excessive Pricing Guidelines.

Established in 1894, CLHIA is a voluntary trade association that represents life and health insurance companies which together account for 99 per cent of the life and health insurance in force in Canada. Our member companies deliver the great majority of Canada's private drug insurance plans which provide drug coverage for close to 17 million Canadians and paid almost $6 billion in drug benefits in 2006. Given this significant role in the delivery of drug benefit programs, the CLHIA is pleased, on behalf of its members, to contribute to this review and consultation on Canada's mechanisms for pricing patented medicines.

A: Proposed Scenarios for Consultation

i) Any Market Price Review

We agree with the proposals outlined in the discussion paper for a price review at: 1) introduction of the medicine in Canada, 2) in future years as the Average Price for Canada appears to exceed the MNE price in any period for any class of customer and each province/territory to determine in which market(s) the price appears to be excessive, 3) if a patentee enters into a Voluntary Compliance Undertaking (VCU), or is subject to a Board order following a public hearing to ensure that the price in any market does not exceed the MNE price, or 4) upon any substantiated complaint of apparent excessive prices in any market.

Our industry would be most supportive of the following measures:

- Average prices, as determined by PMPRB, should be publicly available to ensure a competitive Canadian market for patented medicines.
- The Board should develop transparent policies so that excessive prices in the various market segments/customer classes are identified and no market segment/customer class should pay excessive prices. The development of reporting methodologies so that interested parties can learn of market pricing issues under investigation has also been identified as very useful.

Another suggestion could be for PMPRB to include a maximum variation above the MNE price so that no one market would be overly affected by pricing differences in advance of a complaint.

ii) Re-setting the Maximum Non-Excessive (MNE) Price

When the MNE Price can be Shown to Not Cover the Patentee's Cost of Making and Marketing the Drug (Proposal 1)

We support the review and realistic re-setting of the Maximum Non-Excessive (MNE) price. We recognize that the price could be re-set higher in indications where the price does not cover the cost of manufacturing the drug, or the cost of making and marketing the product does not justify the drug price.

Alternately, we would also expect situations where the price would be re-set lower, if the product has an expanded market for wider use or for further indications and the price then far exceeds the cost of making and marketing the drug following introduction. This may occur when the original analysis considered the approved indication, but subsequently another indication or off label use raised the volume of sales far above the original estimates. To be fair to consumers, as well as to the drug manufacturers, there should be a review in either of these cases.

The cost of "marketing" must also be well defined. For example, if the benefits of free samples are not to be included in the calculation, then those same costs should not be considered as "marketing" costs, otherwise there is a double benefit to the distribution of free samples.

When the Scientific Evidence was Not Sufficient At Introduction of the Medicine (Proposal 2)

Our industry is in agreement that a review should be conducted when the scientific evidence indicates that the original price was inappropriate. Mechanisms should be established to permit re-setting the original MNE price where subsequent scientific evidence or clinical indications show the initial MNE price determination no longer to be valid. It should be noted that this may result in either an increase or decrease in price depending on the outcomes.

Median of the International Price Comparison is the Pivotal Test and the Medicine is Sold in Too Few Countries (Proposal 3)

Concern was expressed that by reducing the number of countries for the median international price comparison from five countries to three, an advantage could be seen to benefit the drug manufacturers at the potential expense of the consumer. If the intent of the PMPRB process is to obtain drugs for Canadians at the median price of the designated seven countries, using only three countries could create a potential incentive for drug manufacturers to manage the introduction of drugs around the world in a manner that maximizes their revenue in Canada. We support the position that Canadians should have access to drugs as quickly as possible, so it would be necessary to establish prices for drugs on an interim basis. However, once the drugs are sold in more countries, the MNE

Price may need to be re-visited to determine whether the price in Canada is appropriate. We would recommend retaining five countries as the benchmark.

Options to Address the Federal Court of Canada (FCC) Decision

We support full disclosure of payments to PMPRB, regardless of customer class, even though negotiations may be confidential. Although free goods should remain reportable to PMPRB, the free goods should not be used to reduce the overall price for the remaining customer classes which may, as a result, be paying among the highest prices in the world.

Discounts allowed to provincial drug programs, or others, should be taken into account when setting the MNE Price. To do otherwise will result in the private payer subsidizing the provincial programs. This already occurs with dispensing fees in the province of Ontario where the government has capped dispensing fees below the "cost of delivery" resulting in fees to the private payer that exceed the cost of delivery. In the drug price model, this would be comparable to a "cost of making" that was not fully paid by the provincial plan payments, resulting in a higher than required cost to the private payer. As a result, Option 2 should not be taken.

Free goods should be considered in the total equation. There may be important reasons to exclude the cost of free goods from the calculation of the Average Price that we are not in a position to comment on. However, if that logic is applied, the same value of goods should not be included as marketing costs. Option 3 could be chosen, but the free goods should then be excluded in all of the analysis.

In accordance with the FCC ruling on the Dovobet matter benefits such as free goods and gifts should be consistently included when determining Average Prices (with the exception of samples and compassionate release). Subsections 4 (4) and 4 (5) of the regulations should make it clear that where concessions are provided to other than the direct purchaser, they must be included in the calculations including concessions to governments in respect of publicly-funded benefit plans, employers (public and private) in respect of employee benefit plans, and administrators of these plans (pharmacy benefit managers, insurance companies and others).

Guidelines Options

These options will depend on the treatment of free goods from the prior sections. If free goods are excluded, then they will not result in a lowering of the price following introduction. However, if they are to be included, then they should be fully taken into account. If the price is fixed at the higher of the current level or the adjusted price target, then the incentive for the drug manufacturers would be to withhold free goods until the price is set, thereby maintaining an artificially high price. Part of the logic used is that if the price wasn't considered excessive before, it should still be considered that way. However, the MNE price is a construct that reflects the benefits included in the calculation. So, if the factors in the calculation change, then the MNE price must change as well.

Voluntary Compliance Undertaking (VCU) or Order to Ensure the Price in Any Market Does Not Exceed the MNE Price

Current legislation requires the patentee to restore the excess and it is allocated to the consolidated revenue fund which historically was a simple and practical solution, given the small roll-backs in proportion to the associated costs of recovery. Early roll-backs and adjustments, which may have been less than the cost of a postage stamp per prescription, negated any further re-distribution formula.

However, in recent years, some roll-backs (Remicade, is an example) have been quite significant. In most cases, this drug was paid for almost entirely by the individual or the individual's private drug plan on his or her behalf. Since the original legislation was introduced, the use of technology for prescription drug payments has become an important part of the transaction and could now enable re-payment to the party that paid for the medicine. Given these significant advancements, our industry would like to see a more equitable formula for re-allocation of excessive pricing that takes into account the actual payer for the medicine.

CPI Methodology

Although we have limited our comments on the possible changes to the CPI-adjustment methodology for determining the MNE price, we would recommend that revisions to the CPI methodology should result in neither large increases in average prices nor prices in any market segment or customer class that exceed MNE prices.

On behalf of our members, the CLHIA would like to thank the PMPRB for inviting the industry's feedback on the discussion paper. We recognize the important role that PMPRB plays to keep drug prices from being excessive for Canadians in order to protect their health and to contribute to Canadian health care.

We appreciate the opportunity to express our support for a transparent system that is fair for all Canadians, regardless of the customer class of the participants. Our industry favours a mechanism that provides a level playing field with clarity, transparency and simplicity that is not overly burdensome for PMPRB or the patentee.

Given the significance of the insurance industry's contribution to the payment of drugs in Canada, our industry also seeks representation on appropriate working groups that are contemplated in this study, and as further work is explored.

We will be pleased to provide any further clarification or feedback that may be helpful as the PMPRB continues to examine possible changes to the Patented Medicine Regulations and Excessive Price Guidelines.

Yours sincerely,

Original Signed

Irene Klatt (Mrs.)
Vice President, Health Insurance