Ronnie Miller
President and C.E.O.

October 6, 2008

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

Subject: PMPRB Notice and Comment: Draft Revised Excessive Price Guidelines

Dear Ms. Dupont,

This letter is in response to the Notice & Comment issued by the PMPRB on August 20, 2008 in regard to the draft revised Excessive Price Guidelines being proposed by the PMPRB. As a member of Canada's Research-Based Pharmaceutical Companies, Hoffmann-La Roche Limited (Roche) fully supports the positions put forward by Rx&D on behalf of member companies in its response to the PMPRB's draft revised Excessive Price Guidelines. In addition to those comments, Roche wishes to highlight some specific areas of concern with the proposed new guidelines and with the PMPRB's August 18, 2008 Communiqué.

Roche is compelled to comment on the PMPRB's August 18, 2005 Communiqué in relation to the reporting of all benefits "connected to sales transactions". In particular, the Communiqué makes specific note in regard to rebates as "including rebates/payments to third parties". The fact that these rebates are described by the PMPRB as having been made to a "third" party indicates that they are not involved in sales transactions between the supplier and the customer. On this basis, Roche objects to the requirement that these payments should be included in its reporting of price and sales related to a patented medicine. Doing otherwise compromises the viability and intent of these programmes. Furthermore, these programmes are enacted through discussions with the provinces culminating in private and confidential agreements between the parties. Regardless of the confidentiality provisions in the Patent Act, Roche is highly concerned about the intended or potential use and release of this information by the PMPRB.

Roche has significant concerns about the unnecessarily complicated nature of the revised Guidelines that, in practice, will impose a substantial burden on the industry to ensure that actions taken in the normal course of business do not have the potential to impact on current compliance status and future allowable pricing. In our opinion, the Guidelines should create an environment that fosters the implementation of programmes that benefit patients rather than impose limitations and applying methodologies that threaten to jeopardise their viability. These Guidelines should be transparent, and easy to apply so that companies can ensure compliance in the first instance. The new limitations placed on individual markets have the potential to impact on Roche's ability to offer special programmes during the introductory period and in some instances after introduction because of restrictions on the applicability of alternate reviews in these cases.

Hoffmann-La Roche Limited 2455 Meadowpine Boulevard Mississauga, Ontario L5N 6L7 www.rochecanada.com President & CEO Tel. 905-542-5522 Fax 905-542-5507

Roche has several concerns relating to the proposed de-linking methodology and its failure to address circumstances that are inherent in the sale and distribution of pharmaceuticals, or any other product for that matter. During the PMPRB staff's recent briefing session on the proposed guidelines, companies identified numerous situations that left the staff suggesting that the methodology might not be ideal and indicated that a case-by-case approach would likely be required to determine the compliance status of many patented medicines. In our opinion the need for case-by-case review as a rule rather than an exception provides a clear indication that the methodology and its proposed application are inadequate to deal with the "standard" situations it was intended to address.

The day-to-day marketing of pharmaceuticals involves sales of the products but also the provision of free goods, contract pricing, returns, discounting and special programs. Each of these has the potential to cause fluctuations in a product's average selling price from year to year. Because the PMPRB reviews medicines on the basis of average selling price rather than list price, its guidelines for determining the presence of excessive pricing must contain general provisions to handle these variations as standard practice. In this regard we offer the following observations:

- The important issue of hospital contracting and other circumstances where a shift in sales between markets can have a significant impact on a product's compliance status during the period under review and a lasting impact on its maximum non-excessive price in future periods must be addressed. The unnecessary limitations placed on the application of the de-linking methodology are such that the normal fluctuations in a product's average selling price are not addressed and result in the need for continued undue effort on the part of patentees to provide proof that the average selling price was affected by normal market conditions rather than as a result of any excessive pricing. Without standard provisions involving easily applied methodology to properly address these issues, the requirement that patentees report all benefits, as opposed to the previous consistent inclusion or exclusion approach, will only compound the problem.

- Intuitively, a price that is below a non-excessive level established by the PMPRB cannot be deemed excessive. Nevertheless, the revised Guidelines for existing medicines and their proposed application have the ability to create just such a situation. Each example of excessive pricing presented by the staff during its briefing sessions involved cases where the new "any market" review and the de-linking methodology would consider such a price excessive and in each case this involved the lowest priced market in Canada (either a province or a class of customer). Surely the intent of the *Patent Act*'s "any market" provision did not contemplate the lowest price in Canada being considered excessive and neither should the Guidelines governing the PMPRB staff's price review.

Roche also has concerns regarding the removal of important provisions relating to the price review for some new medicines. In particular, we note the absence of secondary price testing methodology when circumstances indicate that the primary price test is not appropriate, an important aspect of the current guidelines. According to the draft revised guidelines, unless the company makes a submission claiming therapeutic improvement, the standard price test methodology will apply even if that methodology renders unusual or less than meaningful results. Given that the proposed guidelines require HDAP involvement in the review of all new medicines for which a submission of therapeutic improvement has been filed, that panel's workload can be expected to increase significantly.

Moreover, there is an added burden on patentees to justify alternate testing methods in the case of more routine situations that are addressed in the existing Guidelines. The requirement to provide a submission on therapeutic improvement for line extensions representing new modified release formulations, different indications, different dosing schedules is unnecessary and creates an environment of uncertainty in an area that has, in the past, been transparent.

Although there has been no prior hint of potential revisions to the existing price tests applicable to new medicines, no recommendation from the Working Group in that regard and no mention of such a change in the Notice & Comment discussion document, the revised Guidelines include an important change to the Reasonable Relationship methodology's different strength test. Under the new version of this test, a subsequent entry will be limited to the price per mg of the existing DIN when it is the only one available for comparison. This new approach to the different strength test runs contrary to typical pricing models for multiple DINs within the industry and has a heavy impact on the allowable price of a subsequently introduced lower strength. Under the current test, the lower strength tablet can be priced up to the higher strength's price per tablet, an approach that recognises that an equal per mg price across strengths is not the norm.

We believe our comments, in addition to those supplied by Rx&D; provide important information that must be considered in the Board's deliberations on its proposed new guidelines. We will be pleased to discuss them with you.

Yours sincerely,

Hoffmann-La Roche Limited

Ronnie Miller
President & CEO