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Roche

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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: Notice and Comment – Draft Revised Excessive Price Guidelines (March 2009)

Dear Ms. Dupont,

This letter is in response to the Notice & Comment issued by the Patented Medicine Prices Review Board (PMPRB) on March 26, 2009 in regard to its proposed draft revised Excessive Price Guidelines. As a member of Canada's Research-Based Pharmaceutical Companies (Rx&D), Hoffmann-La Roche Limited (Roche) fully supports Rx&D's response to the PMPRB on this matter. In addition, Roche is taking this opportunity to focus on some of the specific areas within the proposed new Guidelines.

Roche recognizes the Board's efforts at addressing the issues raised by stakeholders following release of the previous version of the draft revised Guidelines. Many improvements have been made since that previous version. However, we continue to have significant misgivings about the complexity associated with the latest revised version and its potential to alter established business practices. Guidelines are meant to provide clarity to allow a regulated party to effectively meet its regulatory obligations while at the same time allowing the conduct of day-to-day activities without unnecessary regulatory burden. In our opinion the proposed new Guidelines impose a significant additional burden on patentees. Their application is not easily adapted to the realities of marketing pharmaceuticals. In particular, areas relating to "any market" reviews and the "dip" methodology will require significant effort and constant in-depth monitoring to ensure that normal business activities do not inadvertently put a product's compliance status in jeopardy. These provisions encourage the establishment of level pricing across all customer classes at introduction and throughout a product's patent life to the detriment of special programs, discounts and other benefits.

We have serious reservations about the International Therapeutic Class Comparison (ITCC) Test as currently described. While we recognize that the PMPRB has modified its stance on generic products suitable for inclusion in this test, the inclusion of any generics in the analysis will negatively skew the results. In our opinion, there is no justification to support the inclusion of generic products in the price review of a branded product, either within Canada or in other countries. Further, we believe the language outlining the "straight class" and "ratio" approaches for the ITCC requires clarification. As currently worded, it is not clear if the "straight class" approach envisages use of the overall median price among all prices identified or among the median for each country. If the former, then there is a serious weighting issue created by the approach since some comparator products may not be available in some countries, thereby skewing the results in favour of pricing in countries where a greater number of comparators are available. In either case, we question the use of the median since the PMPRB's TCC methodology considers the top of the therapeutic class as the appropriate price limitation. A more representative approach is to select the highest priced comparator in each country, as per the Canadian TCC, and then consider the median of those prices. The ratio approach, as described, is also problematic since it considers the overall median of the ratios of all comparators – again a serious weighting issue.

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We take issue with the approach being contemplated for products deemed to provide slight or no improvement as it relates to the identification of "superior" projects. The PMPRB's Guidelines fail to specify precisely how it will define drugs that are considered "superior". This approach lacks transparency since companies will not be able to predict with any degree of certainty which drugs will be considered "superior". It will also needlessly increase the workload of the Human Drug Advisory Panel and the PMPRB staff since it increases the likelihood of disagreements regarding particular products' comparability. In our opinion, existing medicines are either comparable to the new medicine under review or they are not. If they are not comparable then the median international price should be used for price review purposes.

While the PMPRB has taken steps to simplify the DIP methodology, the proposed approach still includes unnecessary complexities. In addition, it continues to lack the ability to reflect market realities since there remains the potential for a price in one market to be considered excessive while a higher price in another market is considered not excessive – a counterintuitive notion that should not result from the Guidelines' application. We are also concerned about instances where the prices in a market that is offered a benefit must be frozen at the pre-benefit level over the period of the benefit rather than be allowed to "bounce back" to current non-excessive prices in other markets. This approach discourages the implementation of special programs.

With regards to the proposed change to the management of excess revenues whereby levels below the criteria for investigation will require repayment if they persist for three years, this requirement is unnecessary. The $50,000 limit on cumulative excess revenues was put in place to ensure that the PMPRB's workload is concentrated on the most important cases and to allow companies a small degree of latitude in their efforts to maintain average selling prices below the maximum limits established by the Guidelines. The approach recognizes that managing and predicting year-end average selling prices is not an exact science and thus there will be instances where those prices may creep over the maximum levels by small amounts from time to time. Indeed, even a price that is less than $0.01 above the limit will generate excess revenues. In our opinion, expending PMPRB staff time on such cases is not a good use of available resources.

Although we support the change in certain terminology to improve the clarity of the PMPRB review, such as "Maximum Average Potential Price", we are deeply concerned about the proposed use of the term "appears excessive" in reports published by the PMPRB. Roche fails to see the rationale for including such provocative language in the context of products with prices and/or excess revenues that have not reached a level that triggers an investigation. In our opinion this terminology is more damaging than the "Under investigation" label proposed for products that have met the investigation criteria. As such we urge the PMPRB to consider other terminology more in keeping with the price status of these products.

Finally, proposed timing of the implementation of these guidelines is problematic. As with prior changes to the guidelines, a mid year implementation date will lead to inconsistencies and unnecessary confusion for Roche and Board staff. In addition, the outstanding resolution of the judicial review in the summer of 2009 could have further implications for these guidelines. To this end, we request a postponement of the implementation to January 2010.

Roche appreciates the opportunity to comment on the draft Guidelines. We trust that our comments, coupled with those of Rx&D, will provide important feedback that will help improve the Guidelines in the best interests of consumers, the industry and the PMPRB.

Sincerely yours,

Ronnie Miller
President and CEO
Hoffmann-La Roche, Ltd.