Schering-Plough
16750, route Transcanadienne
Kirkland, Qc H9H 4M7
T +1 514 426 7300
F +1 514 428 8832
www.schering-plough.ca

Carlos G. Dourado
Président et directeur général
President and General Manager

Kirkland, April 27, 2009

BY EMAIL AND BY MAIL

Dr. Brien G. Benoit
Chairperson
Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1

Dear Dr. Benoit:

On behalf of Schering-Plough Canada, I am writing in response to the Patented Medicines Price Review Board request for comment on the Draft Revised Excessive Price Guidelines document released on March 25, 2009.

I welcome your willingness to have met with RX&D over the past several months, and your participation in a working group to address the concerns of our industry as it relates to this issue.

However, we believe the revised draft does not alleviate many of the concerns Schering-Plough and others have had with the PMPRB excessive pricing regime, including clarity and consistency in determining what constitutes excessive pricing. In addition, by responding to the interests of other stakeholders – namely provincial governments – we suggest the PMPRB is going beyond the original mandate for which the Board was established in 1987.

On many fronts, the PMPRB has successfully achieved the public policy objectives set out by Health Canada to ensure Canadians fair access to pharmaceutical products at prices better or equal to those of other comparable nations. Over the past 20 years, Canada's research-based pharmaceutical industry has reinvested 10% of revenues directly back into Canada, and prices are 9% lower than our global comparators.

I recognize that some moderate changes have been made in this revised version - in part as a result of consultations with Rx&D and industry members – yet there remains far too many cumbersome pricing requirements that do not alleviate the regulatory burden placed on companies. By not providing clarity, stability or pricing options that would nurture competition and investment to develop a thriving pharmaceutical industry, these guidelines do little to improve the overall regulatory environment, and impose a logistical management burden on those companies who sell multiple products into multiple markets.

The vast majority of investment in Canada's research-based industry comes directly from major global pharmaceutical companies. Canada has benefited greatly from this investment, both through bettering the health of Canadians, and by providing stimulus to Canada's economy. By ensuring a stable and competitive regulatory and business climate, Canada has been an attractive place in which to invest. This investment in turn has helped nurture smaller, domestic biopharmaceutical firms.

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However, other countries are also now looking at policies and best practices to encourage investment in their respective knowledge-based sectors, including the pharmaceutical industry. Incremental changes in regulatory policy domestically can and will impact bottom line results, and will be a consideration as future investment decisions are made.

The continued intervention of the PMPRB beyond regulating excessive prices will become an obstacle to attract research and development in Canada, and is inconsistent with broader public policy objectives to nurture and develop key knowledge-based sectors.

In revising these guidelines, the PMPRB has an opportunity to show leadership and implement a regulatory framework that reflects this changing global dynamic. To ensure Canada remains competitive, the PMPRB needs to reflect changes in regulatory policy that includes clear pricing policies to stimulate competition; the ability to negotiate discounts and pricing benefits without penalty; and policies that encourage the introduction of new medicines.

In my letter of response to the initial draft guidelines of October 6, 2008, I suggested that the revisions represented an unprecedented intervention into the pharmaceutical market, and would be an obstacle to attracting research and development dollars. In reviewing this new draft, I continue to stand by this belief.

I believe an opportunity has been missed to put forward progressive policies that meet both the interests of Canadians, and Canada's health care industry, while ensuring Canada's leadership role in the global pharmaceutical sector.

In a time of serious economic uncertainty, it is even more important to weigh the full consequences of proposed regulatory changes. The implementation of these draft guidelines will have a serious and deleterious effect on the pharmaceutical industry in Canada without positively impacting those in need of health care.

Sincerely,

Carlos G. Dourado
President and General Manager
CGD/lv

Cc: Hon. Leona Aglukkaq, Minister of Health, PC, MP
Hon. Tony Clement, Minister of Industry, PC, MP