June 14, 2013

Sylvie Dupont
Director, Board Secretariat
Patented Medicines Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Address Locator 0701D
Ottawa, Ontario K1P 1C1

Dear Ms. Dupont:

Rx&D Response to PMPRB Notice and Comment on Regulatory Burden Reduction Initiative

Canada's Research-Based Pharmaceutical Companies (Rx&D) is pleased to provide the following comments in response to the PMPRBôs Notice and Comment associated with the Regulatory Burden Reduction Initiative.

We commend the PMPRB for undertaking this important initiative and fully support the proposed amendments to the Guidelines as is reduction in regulatory burden for patentees will have an immediate, positive impact upon implementation.

We address each proposal below as they appear in the consultation document.

Consumer Price Index (CPI) Adjustment Methodology

> *PMPRB Proposal for Consideration:* ñMaintain current CPI Adjustment Methodology for existing drug products, except replace the use of the forecast CPI with actual CPI in calculating the CPI Adjustment Factor for the forecast period.ò

Rx&D supports this measure because the predictability of a fixed CPI will streamline work for both patentees and Board staff. We would encourage the Board to provide clear guidance to patentees on the implementation of this new approach and provide a suitable transition period from the current method to the proposed one.

Reduction of Filing Requirements – Yearly Reporting

> *PMPRB Proposal for Existing Patented Drugs:* ñFor existing drug products, to replace the semi-annual regulatory filing of Form 2- Information on the identity and prices of the medicine by an annual filing.ò

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Rx&D fully supports this proposal and notes that patentees will continue to bear the responsibility of monitoring their own compliance throughout the year. It should be noted that the current midyear reporting does not aid patentees in monitoring their compliance status, as the PMPRB makes no judgement or assessment of the submitted data.

In order to create the greatest value in the proposed annual compliance report, the PMPRB should consider providing an anticipated non-excessive average price (NEAP) for the upcoming year for all DINs monitored.

In addition, it will be important for the PMPRB to confirm that they continue to follow the established 6 months reporting requirement to allow the setting of an Introductory Benchmark Price (IBP). Rx&D member companies support the 6 month reporting requirements for new product introductions as it provides clarity and predictability at a very important phase of a products life cycle.

Reduction of Filing Requirements – Form Changes

> *PMPRB Proposal for New Patented Drugs:* ñTo eliminate the requirement to submit Form 2 information for the first day of sales of a patented drug product in Canada and to add a section in the Form 1-Medicine Identification Sheet to report the publicly available ex-factory price in Canada on the date of first sale.ò

Rx&D supports migrating key Form 2 requirements onto the Form 1 in an order to reduce duplication in paperwork and information submitted to the PMPRB. However, we would request additional information from the PMPRB as to the expected timing of submission of this new form and what specific information will be required.

Conclusion

Rx&D commends the PMPRB for its commitment to a regulatory framework that is relevant, responsive and appropriate. We anticipate further productive dialogue in order to fine tune these proposed changes and to develop an implementation plan that will facilitate a smooth transition for patentees and Board staff maximizing the intended benefits of these changes in a timely manner. We thank the PMPRB for this opportunity to comment on its specific regulatory reduction efforts and look forward to working with Board staff to further explore opportunities to alleviate regulatory burden on an ongoing basis.

Sincerely,

Jared Rhines
Rx&D Scientific & Strategic Affairs