

Update on the 2005 Consultations

To gather stakeholder input on proposed regulatory amendments and price increases for patented medicines, we published two Notice and Comment documents in early 2005. Numerous submissions regarding both initiatives, all available on our Web site, were received from both private and public sector stakeholders. Analysis and incorporation of these comments continued.

Proposed Amendments to the *Patented Medicines Regulations, 1994*

Recognizing that timelier price reviews would better serve the needs of Canadians, the PMPRB solicited stakeholder comments regarding proposed amendments to the *Patented Medicines Regulations, 1994*. The proposed amendments were conceived as a way to expedite the price review process by assuring earlier access to the data required to conduct a review. Twenty-one stakeholder submissions were received, providing important input regarding advantages and disadvantages of each proposed amendment. Based on the comments received, the PMPRB has made some modifications to some of the proposed amendments. Subsequent to that first round of consultation, the PMPRB has begun to consult with inter-

ested federal departments and agencies. To date, consultation meetings have been held with Industry Canada, responsible for the *Patent Act*, and Health Canada – as the Minister of Health is responsible to recommend publishing and enactment of regulatory changes. Further consultations are underway with the Department of Justice, the Privy Council Office and Treasury Board. Following these discussions, the next step will be to publish the revised regulatory amendments in the Canada Gazette, Part 1. Publication is targeted for late Fall 2005/early Winter 2006.

Price Increases for Patented Medicines

No additional stakeholder consultations occurred during the summer, as Board Staff continued its review of the nineteen submissions received and formulate potential options for next steps. Analysis of both submissions and possible further analytical work were presented to the Board in September. Additional work is currently underway, both in regard to introductory prices and price increases. Next steps will be communicated in future issues of the NEWSletter. ■