Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

Canada

NEWSletter

Inside...

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Since our last issue...

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Our recent key events

July 31:	The Chairperson accepted a Voluntary Compliance Undertaking submitted by Biogen Idec Canada Inc. regarding the price of the patented medicine Avonex PS.
September 10–11:	Elena Lungu and Greg McComb attended the Canadian Institute for Health Information (CIHI) Health Data Users Conference in Ottawa.
September 11:	The Board held its quarterly meeting.
September 13:	Michelle Boudreau attended the Canadian Life and Health Insurance Association Roundtable discussion on Prescription Drug Coverage in Edmonton.
September 24:	The Human Drug Advisory Panel (HDAP) held its quarterly meeting.
September 25:	Michelle Boudreau spoke at the 2nd Annual Canadian Association for Healthcare Reimbursement (CAHR) Day in Ottawa.
September 26:	The Board issued a Notice of Hearing in the matter Galderma Canada Inc. and the patented medicine Tactuo.
October 18–19:	Michelle Boudreau participated in the World Health Organization Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies – Pharmaceutical Pricing and Reimbursement Information (PPRI) Network Meeting in Brussels, Belgium.
October 24:	Michelle Boudreau, Ginette Tognet and Gregory Gillespie met with representatives of the Johnson & Johnson Family of Companies.
October 31:	The NPDUIS Steering Committee meeting was held in Ottawa.

PMPRB speeches and presentations are available on the website under News and Events/Speech Series. ■

If you wish to know more about the PMPRB, please contact us at our toll-free number, 1-877-861-2350, or consult our website.

The PMPRB is an independent quasi-judicial body with a dual mandate.
Regulatory: to ensure that prices at which patentees sell their patented medicines in Canada are not excessive; and
Reporting: to report on pharmaceutical trends of all medicines and on R&D spending by patentees.

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News from the Chairperson

December 7, 2012, will mark the 25th anniversary of the Patented Medicine Prices Review Board. The PMPRB was established in 1987 under the amendments to the *Patent Act*, with the objective of protecting consumers by ensuring that prices of patented medicines are not excessive. Twenty-five years later, the PMPRB continues to contribute to the Canadian healthcare system in the same vital consumer-protection role and by reporting on pharmaceutical trends.

Mary Catherine Lindberg, Chairperson

Since its inception, the Board has continually evolved and responded to its environment to meet its regulatory and reporting mandate. It initially set up a series of Guidelines to assist patentees in setting prices that were not excessive, in line with the pricing factors listed in the *Patent Act*. This was done in consultation with stakeholders. The Board also established compliance and enforcement processes to meet the objectives set out by Parliament.

Through the years, the Board continued to consult its stakeholders, reviewing its guidelines and processes to ensure that they remained relevant, appropriate and transparent. The PMPRB went through a number of external reviews, including a full review by a parliamentary committee tasked to examine the pharmaceutical regulatory regime. This was followed by the Board's own comprehensive review of its role and processes, as well as examinations by the Auditor General, the Comptroller General and the Public Service Commission. It established an inclusive consultation policy and created working groups with representatives of diverse stakeholder groups to examine specific issues.

Last year, the PMRPB embarked on a program evaluation to assess the extent to which the increase in resources it obtained in 2008/09 helped to effectively deliver its mandate. The evaluation addressed value for money by including clear and valid conclusions about the relevance and performance of the PMPRB's programs. Both the Regulation and Trends Programs were found to be appropriate for delivery by a federal agency and well-aligned with both government-wide priorities and the PMPRB's Strategic Outcome. The review found the PMPRB to be successful at achieving its expected outcomes. According to the evaluation, the incremental funding that was received was well-used and has achieved the results for which it was approved.

As it moves forward, the PMPRB will continue to improve its programs by monitoring the impact of its Guidelines and clarifying, adjusting and amending them as appropriate. It will also seek opportunities to make its studies and reports available to policy- and decision-makers in the timeliest manner. The Board is currently preparing a Management Response and Action Plan in response to the Evaluation Report. These documents will be available on the website in the New Year.

To meet these objectives, we need the support and contribution of our Staff and Board Members alike. On that note, I want to take this opportunity on behalf of Staff, my colleagues on the Board and past Board members, to thank Tim Armstrong for his valuable contribution to this organization. Tim left the PMPRB this Fall after completing two terms on the Board. We will miss his keen analysis and judicious counsel. We wish Tim the very best in his endeavours.

As Chair of this Board, my goal remains to ensure that the PMPRB framework has a positive impact for consumers and recognizes the value that innovative medicines offer to patients. ■

Mary Catherine Lindberg

Senior Staff

Executive Director:
Michelle Boudreau

Director, Regulatory Affairs and Outreach:
Ginette Tognet

Director, Policy and Economic Analysis:
Gregory Gillepsie

Director, Corporate Services:
Marian Eagen

Director, Board Secretariat and Communications:
Sylvie Dupont

General Counsel:
Martine Richard

Comings and Goings

Congratulations go out to Patricia Hum in her new position as Senior Policy Analyst. Patricia, who has been working in Legal Services, will be joining the Policy and Economic Analysis Branch when she returns from leave in July.

Tom Kloppenburg recently left the PMPRB for a new career challenge. We wish him the best of luck in all of his future endeavours. We also extend our best wishes to Salma Pardhan, who is taking an extended leave of absence to pursue personal interests. ■

Outreach Sessions and the PMPRB 101

Over the next two months, Board Staff will conduct two series of Outreach Sessions, each targeting a different audience.

The first series (part of the Regular Outreach Sessions) is aimed at pharmaceutical representatives who already have experience with the PMPRB processes. Sessions will be held in Montreal on November 22, 2012, and in Toronto on November 23, 2012.

The second series (PMPRB 101) is an introduction to the PMPRB requirements and processes and is designed for pharmaceutical representatives who are just starting to work with the PMPRB. This session will be conducted by the junior team of the Regulatory Affairs and Outreach Branch in Ottawa on December 6, 2012.

An invitation to participate in these sessions was sent to all pharmaceutical companies reporting to the PMPRB in mid-October. ■

Regulatory Filing: Format Changes to Forms 1 and 2

A new Web-based electronic database that is able to receive secure direct entry of data from Form 1 and Form 2 regulatory filings is now in place at the PMPRB. This system will enable the PMPRB to process filings more efficiently and bring direct filing by patentees via the Internet a step closer.

As a result of this new system, some changes have been made to Form 1 and to the Form 2 Cover Sheets. These changes will clarify whether a form is an original filing or an amendment to a previous filing, and if it is an amendment, what section is amended. Corresponding changes have also been made to the instructions in the *Patentee's Guide to Reporting*.

As of November 1, 2012, patentees are required to use the most up-to-date Form 1 and Form 2 – Cover Sheet templates, which are posted on the PMPRB website under Are you a Patentee?/Forms. Note that there are no changes to Form 2 Block 4 and Block 5.

Additional information about these changes will be provided at the next Outreach Sessions. ■

Announcement: Foreign Price Verification Formulas available back to 2002

The formulas used for Foreign Price Verification dating back to 2002 are now available on the PMPRB website under Are you a Patentee? .

Each yearly listing outlines the sources and the methodology used by Board Staff to derive, where applicable, ex-factory prices from national formulary prices. Formulas are provided for each of the seven comparator countries listed in the *Patented Medicines Regulations*. Examples of how to use this information were provided at the Outreach Sessions conducted earlier this year with patentees, and are also available on the PMPRB website. ■

Voluntary Compliance Undertakings

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust its price to conform to the Board's Guidelines. Under the Guidelines, patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price set forth by the patentee for a patented drug product sold in Canada appears to have exceeded the Guidelines. A VCU can also be submitted by a patentee after a Notice of Hearing is issued.

The Chairperson approved one VCU in the last quarter for the patented medicine Avonex PS.

Avonex PS, Biogen Idec Canada Inc.

On July 31, 2012, the Chairperson of the Board approved a VCU submitted by Biogen Idec Canada Inc. on the price of Avonex PS. Under the terms of the VCU, Biogen agreed, among other things, on the National Non-Excessive Average Price (N-NEAP) for the years 2010, 2011 and 2012. Also, in order to offset cumulative excess revenues received from January 1, 2010, to December 31, 2010, Biogen made a payment to the government of Canada in the amount of $76,347.23.

Avonex PS – DIN 02269201 (30 mcg/syringe) is indicated for the treatment of relapsing forms of multiple sclerosis, to slow the progression of the disease, to decrease the frequency of relapses, and to reduce the number and volume of active brain lesions seen on magnetic resonance imaging.

VCUs are available on the PMPRB website under Voluntary Compliance Undertakings. ■

Hearings – Update

The PMPRB's regulatory mandate is to ensure that prices charged by patentees for their patented medicines sold in Canada are not excessive.

In the event that the price of a patented medicine appears to be excessive, the Board can hold a public hearing and, if it finds that the price is excessive, it may issue an order to reduce the price and to offset revenues received as a result of excessive prices. Board decisions are subject to judicial review in the Federal Court of Canada.

The Board issued one Notice of Hearing during this past quarter, into the price of the medicine Tactuo.

Upcoming hearing in the matter of Galderma Canada Inc. and the medicine Tactuo

On September 26, 2012, the Chairperson issued a Notice of Hearing in the matter of Galderma Canada Inc. and the price of the medicine Tactuo.
The purpose of the hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, Galderma is selling or has sold the medicine known as Tactuo in any market in Canada at a price that, in the Board's opinion, is or was excessive and if so, what order, if any, should be made.

The hearing date will be announced on December 13, 2012, or shortly thereafter, following a Case Management Conference.

All requests for information on this matter should be addressed to the Secretary of the Board.

Tactuo is indicated for the treatment of acne.

Status of Board Proceedings

Patented Drug Product	Indication / Use	Patentee	Date of Notice of Hearing	Status
Apo-Salvent CFC-Free	Asthma	Apotex Inc.	July 8, 2008	**Ongoing**
Copaxone – Redetermination	Multiple sclerosis	Teva Canada	New panel struck February 2010	**Order: February 23, 2012** **Application for judicial review: March 20, 2012** ***Hearing date to be announced***
ratio-Salbutamol HFA	Asthma	ratiopharm Inc. (now Teva Canada)	July 18, 2008	**Order: May 27, 2011** **Application for judicial review: June 27, 2011** ***Hearing date to be announced***
Tactuo	Acne	Galderma Canada Inc.		**Notice of Hearing: September 26, 2012**

Patentee	Issue	Date of Notice of Application	Status
Apotex Inc.	Failure to file (jurisdiction)	March 3, 2008	**Ongoing**
ratiopharm Inc. (now Teva Canada)	Failure to file (jurisdiction)	August 28, 2008	**Board Order: June 30, 2011 Amended: October 17, 2011** **Application for judicial review: July 29, 2011** ***Hearing date to be announced***
Sandoz Canada Inc.	Failure to file (jurisdiction)	March 8, 2010	**Board Decision: dated August 1, 2012 – re-issued October 1, 2012** **Application for judicial review: August 31, 2012** ***Hearing date to be announced***

Board decisions and orders are available on the PMPRB website under Hearings and Decisions/Decisions and Orders. ■

Summary of September 11 Board Meeting

At its meeting, the Board welcomed its newest member, Mr. Normand Tremblay, appointed to the Board on May 31, 2012. Also, the Chairperson and Members thanked Tim Armstrong for his commitment and contribution to the PMPRB as he prepared to leave the Board at the end of September. Mr. Armstrong served as a Board Member for 10 years.

The Board received the consultants' final report on the Program Evaluation and discussed the parameters of the Management Response. Members discussed next steps in a number of issues, including the Alternate Dispute Resolution project and the approval of the Board's Rules of Practice and Procedure for Hearings.

The Board's next quarterly meeting is scheduled for December 12 and 13, 2012.

For additional information, please contact the Director, Board Secretariat and Communications, at 1-877-861-2350 or 613-954-8299 or at sylvie.dupont@pmprb-cepmb.gc.ca.

Summaries of Board meetings are available on our website under About the PMPRB. ■

Upcoming Events

November

November 5:
Human Drug Advisory Panel (HDAP) quarterly meeting

November 6–7:
Michelle Boudreau to speak at the 11th Annual Market Access Summit in Toronto

November 7–9:
Michelle Boudreau to speak at the Annual Health Insurance Invitational Forum in Cambridge, Ontario

November 8–10:
Sylvie Dupont to attend the 2012 Canadian Health Policy Assembly in Banff, Alberta

November 21–22:
Michelle Boudreau to speak at the Market Access Canada 4th Annual EyeforPharma Conference in Toronto

November 22:
Outreach Session for patentees in Montreal

November 23:
Outreach Session for patentees in Toronto

December

December 6:
PMPRB 101 Session for patentees in Ottawa

December 12–13:
Quarterly Board meeting

For all Upcoming Events, see the Calendar of Events on our website under News and Events. ■