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

July 2013, Volume 17, Issue 3
ISSN: 1920-3713

PMPRB NEWSletter

Since our last issue...

May 5–7: Elena Lungu and Greg McComb attended the Canadian Agency for Drugs and Technologies in Health (CADTH) Symposium in St. John's, Nfld. Elena presented a poster on the NPDUIS report *The Use of Blood Glucose Test Strips in Select Public Drug Plans, 2008*.

May 6: The Human Drug Advisory Panel (HDAP) held its quarterly meeting.

May 9: The Board held its quarterly meeting.

May 16: A Notice and Comment related to the two initiatives for regulatory burden was posted on the PMPRB website.

May 16: Lama Abi Khaled, John Cook and Kirk Stanley presented a webinar to patentees on the application of the Regular DIP Methodology.

May 24–25: Tanya Potashnik attended the Pharmacare 2013 Conference in Ottawa, Rethinking Drug Coverage: Time for Universal Pharmacare, organized jointly by Carleton University and the Canadian Health Coalition.

May 26–28: Sylvie Dupont attended the Council of Canadian Administrative Tribunals' (CCAT) 6th International Conference in Toronto.

May 28–30: Elena Lungu presented a poster on an upcoming NPDUIS report, *The Drivers of Prescription Drug Expenditures*, and presented *The Use of Blood Glucose Test Strips in Select Public Drug Plans, 2008* report at the Canadian Association for Health Services and Policy Research (CAHSPR) Conference in Vancouver.

May 31: The PMPRB Annual Report for 2012 was submitted to the Minister of Health for tabling in Parliament.

Table of Contents

Upcoming Events

September

- September 12: Quarterly Board meeting
- September 16: Human Drug Advisory Panel (HDAP) quarterly meeting

October

- October 2: Michelle Boudreau to speak at the Canadian Association of Healthcare Reimbursement (CAHR) National Day in Ottawa
- October 7-8: Hearing in the redetermination of the Teva Canada Innovation and Copaxone matter.
- October 30–31: Outreach sessions for patentees to be held by the Regulatory Affairs and Outreach branch in Montreal and Toronto

June 4–5: Michelle Boudreau spoke at the Canadian Institute's 7th Annual Drug Pricing & Reimbursement Canada Forum in Toronto.

June 12: Michelle Boudreau met with representatives of Hoffmann-La Roche in Mississauga, Ont.

June 12: Tanya Potashnik presented a lecture on Pharmaceutical Policies to students at Carleton University's School of Public Policy & Administration in Ottawa.

Throughout the month of June: Michelle Boudreau and Tanya Potashnik launched a Provincial Drug Plan Managers Engagement series. They met with representatives of the Drug Plan and Extended Benefits Branch, Saskatchewan Ministry of Health, in Regina. Ginette Tognet joined them to meet representatives of Manitoba Health, Provincial Drug Programs; Ontario Ministry of Health and Long-Term Care, Ontario Public Drug Programs; Health Canada, Non-Insured Health Benefits Program for First Nations and Inuit; Government of Nova Scotia, Department of Health and Wellness; and Saskatchewan Ministry of Health (by teleconference). The series included meetings with Michael Law, University of British Columbia Centre for Health Services and Policy Research; and Bob Nakagawa and Suzanne Solven, College of Pharmacists of British Columbia in Vancouver, followed by a meeting with representatives of the British Columbia Ministry of Health, Drug Intelligence Branch, Pharmaceutical Services Division, in Victoria.

PMPRB speeches and presentations are available at News and Events/Speech Series.

Comings and Goings

We are pleased to welcome Suzanne Henrion and Kyle Matte to the PMPRB. Suzanne joined the Board Secretariat and Communications Branch as a Web Quality Assurance Officer. Kyle is working with the Regulatory Affairs and Outreach Branch in Research and Data Management.

In addition, we welcome back Patricia Hum and Shirin Paynter, who both recently returned from maternity leave. Shirin will be rejoining the Board Secretariat and Communications Directorate. Patricia moved from her previous position in the Legal Branch to the Policy and Economic Analysis Directorate to take on new challenges as a Senior Policy Analyst. Isabelle Matte-LeBlanc, who was replacing Shirin during her absence, has left to take on new career challenges. We wish her the best of luck in all her future endeavours.

We would like to extend best wishes to Julie Poirier, Anne Tardif and Natalie Lowe, who recently left the PMPRB for other opportunities.

National Public Service Week

With the theme of "Proudly Serving Canadians", National Public Service Week gave the PMPRB the opportunity to recognize our achievements celebrate our contributions to Canadian society.

November

- November 4: Human Drug Advisory Panel (HDAP) quarterly meeting
- November 13–14: Michelle Boudreau to speak at the 12th Annual Market Access Summit in Toronto

December

- December 12–13: Quarterly Board meeting

For all Upcoming Events, see the Calendar of Events at News and Events.

Presentations
Calendar of Events
New Patented Medicines Reported to PMPRB
NPDUIS
Hearings
VCUs
Contact us
Visit our website
Follow Us
Canada

Long-term service awards were celebrated with an afternoon tea, and the week was rounded out with a pizza lunch hosted by the social Committee.

The Board takes this opportunity to thank the employees of the PMPRB for their contribution to the organization.

NPDUIS Update

As part of its ongoing work, the PMPRB recently published a research agenda for NPDUIS as a reflection of the research priorities identified by the NPDUIS Steering Committee. A number of reports are anticipated for completion and publication in 2013/14.

Two new analytical reports are scheduled for release over the next few months: *Analytical Snapshot – International Generic Price Comparison: Early 2011 and The Drivers of Prescription Drug Expenditures, A Methodological Report*. Here is a brief description of each report.

Analytical Snapshot – International Generic Price Comparison: Early 2011
This analysis compares the generic drug prices in Canada with those of other industrialized countries. The report highlights the changes in Canadian generic pricing that occurred between 2008 (the last period reported in previous NPDUIS publications) and the first quarter of 2011.

The Drivers of Prescription Drug Expenditures: A Methodological Report
This methodological report provides the tools required for the analysis of the cost drivers of pharmaceutical drugs by (i) describing the factors that drive prescription drug expenditures; (ii) discussing the data requirements and approaches to the analysis; and (iii) providing the methodology and formulas required to decompose prescription drug expenditures and conduct the analyses.

A complete list of the planned NPDUIS research priorities is provided in the newly released Research Agenda.

Response to Notice and Comment

As announced in the April 2013 NEWSletter, the Board consulted stakeholders on two priority initiatives, to amend the Consumer Price Index (CPI) Adjustment Methodology and the *Patented Medicines Regulations*. In alignment with the Government's Red Tape Reduction Plan and the Economic Action Plan, the PMPRB committed to examine its price review process to identify possible ways to reduce the regulatory burden on patentees and increase efficiency without adversely affecting its mandate to protect consumers.

Board Staff is currently studying the submissions received on the two initiatives. Overall, stakeholders were supportive of both proposed amendments.

A number of stakeholders highlighted the need for further details on how the lagged CPI would be determined and greater clarity on the operational and transitional plan. Options are being developed and will be presented to the Board for discussion later this fall. As noted in the May Notice and Comment, further consultation will be undertaken on the proposed text in the *Compendium of Policies, Guidelines and Procedures*.

The proposed amendments to the Regulations will be subject to formal consultation (Federal Regulatory Development Process) through Cabinet and publication in the *Canada Gazette*. Stakeholders will have an opportunity to comment on that proposal. Comments received on the matter will be taken into account as part of this formal process, prior to final adoption and implementation.

The Board wishes to take this opportunity to thank stakeholders who have participated in this consultation. The submissions are available on the PMPRB website under Consultations. The Board looks forward to its stakeholders' continued engagement.

Outreach Sessions in October 2013

Board Staff will conduct Outreach Sessions in Montreal on October 30, 2013, and in Toronto on October 31, 2013. The sessions will include information on best practices and an update on the proposed policy changes related to the Regulatory Burden Reduction initiative.

An invitation to participate to these sessions will be sent to all pharmaceutical companies reporting to the PMPRB in September 2013.

Human Drug Advisory Panel Process and 2014 Schedule

The Human Drug Advisory Panel (HDAP) provides expertise and advice to Board Staff in conducting the scientific review. The HDAP performs the following functions:

- Reviews and evaluates scientific information;
- Considers advice from other experts (when deemed necessary);
- Recommends the level of therapeutic improvement of the new patented drug product, and identifies drug products for comparison purposes and dosage regimens where possible; and
- Identifies significant uncertainties in the evidence which may affect the analysis on which its recommendations are based.

The HDAP is composed of five members with recognized expertise in drug therapy who have experience in clinical research methodology, statistical analysis and the evaluation of new drug products. The members are: Dr. Fred Aoki, Dr. Jean Gray, Dr. Jacques LeLorier, Dr. Muhammad Mamdani and Dr. Adil Virani.

For further information on the HDAP and the scientific review process, please refer to *Part C, Scientific Review Process, Compendium of Policies, Guidelines and Procedures*.

The HDAP meets four times a year. The dates of the meetings for 2014 are as follows**: February 10**, **May 12**, **September 15** and **November 10**. Patentees will want to consult the 2014 HDAP Schedule for submission deadlines for the HDAP meetings.

The HDAP's last meeting in 2013 will be held on November 4. Patentees who have already filed their product monograph and Form 1 (on or between July 26, 2013) have until August 26 to file their submissions.

In order to provide for fairness to the patentee, assurance that a drug product will in fact be scheduled for discussion at a meeting and to also expedite the process, Board Staff requires that a patentee file a product monograph or information similar to that contained in a product monograph before the scheduled meetings.

A patentee wishing to make a submission with respect to the level of therapeutic improvement, the selection of drug products and dosage regimens to be used for comparison purposes must make its submission no later than ten (10) weeks prior to the particular HDAP meeting. For more information on what should be included in a submission, please refer to the *Schedule 1, Submissions by Patentees on Level of Therapeutic Improvement, Compendium of Policies, Guidelines and Procedures*.

Although the actual submission on level of therapeutic improvement is due no later than ten (10) weeks prior to the particular HDAP meeting, a patentee is requested to indicate whether it intends to make such a submission and indicate the level of therapeutic improvement to be addressed in the submission **at the same time as the product monograph or information similar to that contained in a product monograph is filed**.

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.

Since the April issue of the NEWSletter, the Chairperson has accepted two VCUs, for the patented medicines Airomir and Elocom.

VCUs are available at 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.

During the last quarter, the Board completed one hearing, in the matter of Galderma Canada Inc. and the medicine Tactuo, with the acceptance of a Voluntary Compliance Undertaking. As well, the Board issued one Notice of Hearing for the redetermination of the Copaxone matter, following the April 30, 2013 decision of the Federal Court of Canada on Teva Canada Innovation's judicial review application (2013 FC 448).

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–Redeter-mination	Multiple sclerosis	Teva Canada	New panel struck May 2013 Notice: June 28, 2013	**Hearing to be held October 7-8, 2013**
ratio-Salbutamol HFA	Asthma	ratiopharm Inc. (now Teva Canada)	July 18, 2008	**Board Order: May 27, 2011** **Application for judicial review: June 27, 2011** **Federal Court hearing: November 4–5, 2013**
Tactuo	Acne	Galderma Canada Inc.	Notice September 26, 2012	**Board decision: April 24, 2013**

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** **Federal Court**

			hearing: November 4–5, 2013
Sandoz Canada Inc.	Failure to file (jurisdiction)	March 8, 2010	**Board Decision: August 1, 2012 Re-issued: October 1, 2012** **Application for judicial review: August 31, 2012** ***Federal Court hearing date to be announced***

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

Summary of May 9, 2013, Board Meeting

At its meeting, the Board approved the Annual Report for the year ending December 31, 2012. As in previous years, the Report was submitted to the Minister of Health on May 31.

The Board also approved the Notice and Comment seeking stakeholder submissions on its proposals to amend its Consumer Price Index (CPI) Adjustment Methodology and the *Patented Medicines Regulations*.

The Board's next quarterly meetings are scheduled for September 12 and December 12-13.

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 at About the PMPRB.
