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

Canada

NEWSletter

Since our last issue...

Volume 17, Issue No. 1, January 2013

Inside...

Board Members

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Our recent key events

October 9:	The Chairperson of the Board approved a VCU submitted by Eisai Limited regarding the price of the patented medicine Banzel (refinamide).
November 1:	Gregory Gillespie participated in the CIHI Database Advisory meeting.
November 5:	Human Drug Advisory Panel (HDAP) quarterly meeting.
November 6–7:	Michelle Boudreau spoke at the 11th Annual Market Access Summit in Toronto.
November 7:	The Chairperson approved a VCU submitted by Pfizer Canada Inc. regarding the price of the patented medicine Lyrica.
November 7–9:	Michelle Boudreau spoke at the 8th Annual Health Insurance Invitational Forum in Cambridge.
November 8–10:	Sylvie Dupont attended the 2012 Canadian Health Policy Assembly in Banff.
November 14–15:	Michelle Boudreau attended the Rx&D Workshop — *Collaboration: Key to better health outcomes, more sustainability* in Toronto.
November 19–21:	Michelle Boudreau spoke at the Market Access Canada 4th Annual EyeforPharma Conference in Toronto.
November 22–23:	The Regulatory Affairs and Outreach Branch presented outreach sessions to Patentees in Montreal and Toronto.
December 5:	The Regulatory Affairs and Outreach Branch hosted a PMPRB 101 session for Patentees in Ottawa.
December 7:	The PMPRB celebrated its 25th anniversary.
December 11:	The Chairperson accepted a Voluntary Compliance Undertaking submitted by Eisai Limited regarding the price of the patented medicine Halaven.
December 11:	The Chairperson approved a VCU submitted by Baxter Corporation regarding the price of three patented medicines: Procylox, Uromitexan and Ifex.

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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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December 12–13:	The Board held its quarterly meeting.
December 13:	Richard Bogoroch was appointed to the PMPRB as a Board Member.

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

Senior Staff

Executive Director:
Michelle Boudreau

Director, Regulatory Affairs and Outreach:
Ginette Tognet

Acting Director, Policy and Economic Analysis:
Tanya Potashnik

Director, Corporate Services:
Marian Eagen

Director, Board Secretariat and Communications:
Sylvie Dupont

General Counsel:
Martine Richard

News from the Chairperson

As the new year begins, I am pleased to welcome Richard Bogoroch to the PMPRB. Mr. Bogoroch was appointed to the Board in December and brings a strong legal expertise with specialized experience in personal injury and medical malpractice law. With his combination of knowledge and experience, Mr. Bogoroch will be a valuable addition to our Board, and we look forward to working with him.

Mary Catherine Lindberg, Chairperson

Last December the PMPRB marked its 25th anniversary, an important milestone for the organization. As we move on, we remain committed to delivering a regulatory regime that is relevant, responsive and appropriate, and to reporting comprehensive information on pharmaceutical trends to assist policy and decision makers.

In response to last year's program evaluation, we will be publishing the Evaluation Report along with our Management Response and Action Plan. The Plan focuses the PMPRB's direction for the upcoming year. We are pursuing our work in the area of regulatory burden reduction, and we continue to attentively monitor the impact of our Guidelines to ensure that they remain relevant and transparent. We look forward to working with our diverse industry and non-industry stakeholder groups and to forging new associations.

As always, I remain committed, as are my colleagues and Staff, to effectively delivering the PMPRB's mandate of serving Canadians and contributing to the health care system. ■

Mary Catherine Lindberg

Comings and Goings

We would like to welcome Monique Krempig, Julie Poirier and Sophie-Catherine Jeaurond to the Corporate Services Branch of the PMPRB. Monique, who recently worked for the Treasury Board of Canada Secretariat, is the Acting Chief of Financial Services, Julie is the new Human Resource Generalist, and Sophie-Catherine, a recent graduate of Ottawa University, has been hired as a Software Developer/Analyst.

We extend our best wishes to Francine Sanche and Marie-Christine Lalonde, who recently left the PMPRB for new career challenges, and to Julia Barss and Jek-Hui Sims, who returned to the Department of Justice and Industry Canada following the end of their secondment. We wish them all the best of luck in their future endeavours. ■

Diamond Jubilee Medal Awarded to Dr. Jean Gray

Dr. Jean Gray, recipient of the Queen Elizabeth II Diamond Jubilee Medal

The Chair of the PMPRB is pleased to announce that Dr. Jean Gray, member of the PMPRB's Human Drug Advisory Panel, is a recipient of the Queen Elizabeth II Diamond Jubilee Medal.

A new commemorative medal was created to mark the 2012 celebrations of the 60th anniversary of Her Majesty Queen Elizabeth II's accession to the Throne as Queen of Canada. The Queen Elizabeth II Diamond Jubilee Medal is a tangible way for Canada to honour Her Majesty for her service to this country. At the same time, it serves to honour significant contributions and achievements by Canadians. In total, 60,000 deserving Canadians have been recognized for their significant contributions and achievements.

"Dr. Gray has made a tremendous contribution in the area of health care in Canada. We at the PMPRB are grateful that she has shared her wealth of knowledge and provided strong leadership on the PMPRB's Human Drug Advisory Panel. My fellow Board Members and Staff of the PMPRB join me in congratulating Dr. Jean Gray on receiving the Diamond Jubilee Medal." Mary Catherine Lindberg, Chair of the PMPRB.

Professor Emeritus of medical education, medicine and pharmacology at Dalhousie University, Dr. Gray has been an exceptional teacher, a gifted leader and a role model. She joined the Faculty of Medicine at Dalhousie and went on as founding Head of the Dalhousie Division of General Medicine, Associate Dean of Postgraduate Medical Education and Associate Dean of Continuing Medical Education. In addition to developing tools to better evaluate residents in training, Dr. Gray championed mentoring programs for women medical students. She also served as President of the Canadian Society of Clinical Pharmacology, the Canadian Society of Clinical Investigation, the American Society for Clinical Pharmacology and Therapeutics, the Canadian Association of Medical Education, the Canadian Institute of Academic medicine and as Chair of the Canadian Cochrane Collaboration Advisory Board and the CIHR Institute of Gender and Health Advisory Board.

Congratulations Dr. Gray! ■

Workplace Charitable Campaign

Thanks to our contributors, this year the PMPRB exceeded its goal for the Government of Canada Workplace Charitable Campaign. The staff organized fund-raising events including the celebrated annual PMPRB breakfast. Thanks go to all of the volunteers for their time, energy and generous contributions. Again, we are especially grateful to Elaine McGillivray for her continued leadership and delicious cooking. ■

PMPRB 101

The junior team of the Regulatory Affairs and Outreach Branch held its very first PMPRB 101 session on December 6, 2012. The session was limited to a small number of participants from pharmaceutical companies who had little experience with working with the PMPRB. Topics addressed during the session included filing requirements; scientific submission and introductory price review; and a review of tests applied on an on-going basis to existing medicines under the jurisdiction of the PMPRB.

The presentations given by Board Staff are available on the PMPRB website under News and Events / Speech Series. ■

Joel Weber explains the introductory price review process.

Patentees Reporting on R&D and Sales

Under the *Patented Medicines Regulations* (Regulations), all patentees are required to file information on revenues and R&D expenditures (Form 3).

Paragraph 5(1)(*c*) of the Regulations specifies that patentees shall indicate total gross revenues from all sales (i.e., of patented and non-patented drugs) in Canada during the year by the patentee. If a patentee has a license or other agreement with a person related to the sale of a drug in Canada, it must also report total revenues received from all licensees/others, including royalties or any other revenues as prescribed by the license/other agreement.

Paragraph 5(1)(*d*) of the Regulations requires that the patentee provide a summary of all expenditures made during the year by the patentee towards the cost of R&D relating to medicines for human or veterinary use carried out in Canada by or on behalf of the patentee. These expenditures are not limited to R&D related to patented drugs under the Board's jurisdiction.

Patentees are reminded that the deadline for filing Form 3 information on revenues and R&D expenditures is March 1, 2013. The *Patent Act* (Act) defines a patentee as the person for the time being entitled to the benefit of a patent and includes both the patent holder and any other person with a license or other agreement that enables the rights under the patent to be exercised.

Form 3, the template created by the PMPRB to help patentees file this information, is available on the website under Legislation, Regulations and Guidelines / Patentee's Guide to Reporting.

Form 3 should be filed at: compliance@pmprb-cepmb.gc.ca

Failure to File

If a patentee fails to file complete information by March 1, 2013, the patentee will be advised in writing that the information required to be filed under the Regulations has not been received by the PMPRB and will be given a further seven (7) days to provide the information. Should the patentee not file within the further period, Board Staff shall request that the Board issue an order pursuant to section 88 of the Act requiring that the patentee file the required information. Orders issued by the Board are reported in the PMPRB's publications and posted on the website. ■

GMEP Update

In June 2011, the PMPRB published the *Monitoring and Evaluation Plan for the Major Changes in the Guidelines* (GMEP) on its website. The purpose of the plan is to assist the Board in assessing the impact and application of the major changes to the Guidelines implemented on January 1, 2010.

Board Staff presented the second annual assessment to the Board in December 2012. This year the GMEP includes information on the application of the DIP Methodology.

The results for two years of the GMEP will be made available and can be found on the PMPRB website under Legislation, Regulations and Guidelines.

The next annual assessment will be presented to the Board in December 2013. ■

Program Evaluation Report and Management Response

In conjunction with the provision of increased resources in 2008/09 and ongoing, the PMPRB committed to an evaluation of its programs to assess the extent to which the increase in resources helped the PMPRB effectively deliver its mandate.

The evaluation was completed, and the Evaluation Report was accepted by the Chairperson in September 2012. On the whole, the evaluation was positive.

In response to the Evaluation Report, a Management Response and Action Plan was developed. The Management Response and Action Plan addresses the four considerations set out in the Evaluation Report. The Action Plan provides details on the initiatives/activities the PMPRB has undertaken, will be undertaking and has completed to address these considerations, as well as the lead Branch for each initiative/activity and target dates for completion.

The Evaluation Report along with the Management Response and Action Plan will be posted on the PMPRB website on February 7, 2013, under Accountability. ■

2012 CPI-Based Price-Adjustment Factors

Preliminary Price-Adjustment Factors (Based on Forecast Inflation Rates)

Table 1 reproduces preliminary price-adjustment factors for 2012 published in the April 2011 *NEWSletter*. These factors were based on forecasted annual CPI-inflation rates of 2.4% and 2.1% for 2011 and 2012, respectively.

Table 1 Preliminary 2012 Price-Adjustment Factors for Patented Drug Products (Based on Forecast CPI-Inflation Rates for 2011 and 2012)

Benchmark Year	(1) 2009	(2) 2010	(3) 2011
Price-Adjustment Factor	1.064	1.046	1.021

These figures imply: (1) a maximum allowable cumulative price increase between 2009 and 2012 of 6.4% for patented drug products with Canadian sales in 2009 (that is, products whose "benchmark year" is 2009); (2) a maximum allowable cumulative price increase between 2010 and 2012 of 4.6% for products whose first Canadian sales occurred in 2010; and (3) a maximum allowable cumulative price increase between 2011 and 2012 of 2.1% for products whose first Canadian sales occurred in 2011.

In addition, the forecast inflation rate of 2.1% for 2012 implies a year-over-year price increase cap (applicable to all drug products, regardless of benchmark year) of 3.2% (= 1.5 x 2.1%) for 2012.

Final Price-Adjustment Factors (Based on Actual Inflation Rates)

The actual rate of CPI inflation for 2011 of 2.9% was published in the January 2012 *NEWSletter*. The actual rate of CPI inflation for 2012 is now available and was 1.5%. These rates (along with the actual 2010 CPI-inflation rate of 1.8%) yield the following final price-adjustment factors.

Table 2 Final 2012 Price-Adjustment Factors for Patented Drug Products (Based on Actual CPI-Inflation Rates for 2011 and 2012)

Benchmark Year	(1) 2009	(2) 2010	(3) 2011
Price-Adjustment Factor	1.063	1.045	1.015

The final year-over-year price increase cap for 2012 is 2.3 % (= 1.5 x 1.5%). ■

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.

Recently, the Chairperson accepted a total of four VCUs. Three VCUs were for the patented medicines Banzel, Lyrica and Halaven. The fourth VCU includes three patented medicines: Procytox, Uromitexan and Ifex.

Banzel (refinamide), Eisai Limited

On October 9, 2012, the Chairperson of the Board approved a VCU submitted by Eisai Limited regarding the price of Banzel (refinamide). Under the terms of the VCU, Eisai Limited agreed, among other things, to offset the cumulative excess revenues received from October 14, 2011, to December 31, 2011, for the 100 mg tablet and August 30, 2011, to December 31, 2011, for the 200 mg tablet, by making a payment of $4,071.55 to the Government of Canada. Eisai Limited is to make another payment to the Government of Canada no later than March 1, 2013, to offset any excess revenues remaining as of December 31, 2012, as a result of selling Banzel 100 mg and 200 mg tablets at a price in excess of the Guidelines.

The price of Banzel is to remain within the Board's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Banzel (rufinamide) 100 mg (DIN 02369613) and 200 mg (DIN 02369621) tablets — prescription medication approved for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children four years and older and adults.

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Lyrica, Pfizer Canada Inc.

On November 7, 2012, the Chairperson of the Board approved a VCU submitted by Pfizer Canada Inc. regarding the price of Lyrica. Under the terms of the VCU, Pfizer Canada Inc. made a payment to the Government of Canada in the amount of $63,981.64 to offset the cumulative excess revenues received from January 1, 2009, to December 31, 2010. In addition, Pfizer Canada Inc. agreed to offset any excess revenues received by Pfizer from January 1, 2012, to the date of acceptance of this VCU by making an additional payment in the amount of the excess revenues, as calculated by Board Staff.

The price of this drug product is to remain within the Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Lyrica (pregabalin) 75 mg/tab — indicated to treat fibromyalgia, diabetic nerve pain and pain after shingles. Lyrica is also indicated to treat partial onset seizures in adults with epilepsy who take one or more drugs for seizures.

Halaven (eribulin mesylate), Eisai Limited

On December 11, 2012, the Chairperson of the Board approved a VCU submitted by Eisai Limited regarding the price of Halaven. Under the terms of the VCU, Eisai Limited agreed, among other things, to offset the cumulative excess revenues received from June 29, 2011, to December 31, 2011, and made a payment of $7,159.67 to the Government of Canada. In addition, to offset any excess revenues remaining as of December 31, 2012, as a result of selling Halaven 0.5 mg/mL at a price in excess of the Guidelines, Eisai will make another payment to of the Government of Canada no later than March 1, 2013, in the amount of excess revenues as calculated by Board Staff.

The price of Halaven is to remain within the Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Halaven (eribulin mesylate) 0.5 mg/mL — a microtubule inhibitor indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease.

Procytox, Uromitexan and Ifex, Baxter Corporation

On December 11, 2012, the Chairperson of the Board approved a VCU submitted by Baxter Corporation regarding the price of three patented medicines: Procytox, Uromitexan and Ifex.

Under the terms of the VCU, Baxter Corporation has made payments to the Government of Canada as follows: $6,520,381.87 for the Procytox DINs, $5,834,001.29 for the Uromitexan DINs and $3,403,234.33 for the Ifex DINs. Also, Baxter Coporation is to notify the PMPRB in the event that other patents pertaining to Procytox, Uromitexan or Ifex are issued in any future period.

Procytox (cyclophosphamide) — indicated for the treatment of frequently responsive myeloproliferative and lymphoproliferative disorders, frequently responsive solid malignancies and malignant neoplasms of the lung.

Uromitexan (mesna) — indicated for the reduction and prevention of urinary tract toxicity (hemorrhagic cystitis) of oxazaphosphorines.

Ifex (ifosfamide) — indicated as first-line single agent therapy or second-line single agent therapy in patients who have failed to respond or who have relapsed on other chemotherapeutic regimens in the treatment of soft tissue sarcoma. Ifex is also indicated as second-line single agent therapy in patients who have failed to respond or who have relapsed on other chemotherapeutic regimens in the treatment of pancreatic carcinoma. Ifex is indicated as well as a single agent or in combination with cisplatin and bleomycin in advanced or recurrent disease in cervical carcinoma.

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 did not issue a Notice of Hearing during this past quarter.

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** **Federal Court Hearing date: February 5, 2013**
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** **Ongoing**

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: August 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 December 12–13, 2012, Board Meeting

At its final meeting of 2012, the Chairperson highlighted the 25th Anniversary of the establishment of the Patented Medicine Prices Review Board. She took the opportunity to thank the Board Members, current and former, for their contribution to the PMPRB as well as the members of the Staff for their commitment and dedication.

The Board approved the Management Response to the Report on the Program Evaluation. The Report and Management Response, along with a detailed Action Plan, will be available on the PMPRB website on February 7 under Accountability.

Board members were briefed on several issues and given progress reports on a number of initiatives including the Guidelines Monitoring and Evaluation Plan, the Alternate Dispute Resolution and the Regulatory Burden Reduction.

Board Members held meetings with representatives of the Board of Directors of Canada's Research-Based Pharmaceutical Companies (Rx&D) and of the Board of Directors of the Canadian Generic Pharmaceutical Association, during which they discussed issues and challenges of mutual interest.

Neil Palmer, President and Principal Consultant of PDCI did an in-depth presentation to the Board on current pricing and reimbursement dynamics in Europe.

The Board's next quarterly meeting is scheduled for March 27–28, 2013.

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

February

February 4:
Human Drug Advisory Panel (HDAP) quarterly meeting

February 6:
Michelle Boudreau to meet with Canadian Generic Pharmaceutical Association representatives, Toronto

February 8:
Michelle Boudreau to meet with representatives of AstraZeneca, Toronto

February 26–27:
Michelle Boudreau to speak at Pharmacare 2020 Symposium, Vancouver

March

March 1:
Deadline for patentees to file Form 3

March 19–22:
Michelle Boudreau to speak at Pharma Pricing & Market Access Outlook Europe 2013, London, UK

March 27–28:
Quarterly Board meeting

April

April 30:
Release of the April 2013 *NEWSletter*

May

May 6:
Human Drug Advisory Panel (HDAP) quarterly meeting

May 8–9:
Quarterly Board meeting

May 31:
2012 Annual Report to the Minister

July

July 30:
Deadline for patentees to file Form 2

July 31:
Release of the July 2013 *NEWSletter*

September

September 12–13:
Quarterly Board meeting

September 16:
Human Drug Advisory Panel (HDAP) quarterly meeting

December

December 12–13:
Quarterly Board meeting

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