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

Canada

www.pmprb-cepmb.gc.ca

NEWSletter

Inside...

Board Members

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Since our last issue...

Volume 16, Issue No. 2, April 2012

Our recent key events

February 6:	The HDAP held its quarterly meeting.
February 8:	Michelle Boudreau, Sylvie Dupont and Ginette Tognet met with the Johnson & Johnson Family of Companies in Canada.
February 14:	Michelle Boudreau met with Helen Stevenson, Reformulary Group Inc.
February 16:	The Board held it quarterly meeting.
February 23:	The Board issued its Decision and Order in the redetermination of the Copaxone matter.
February 28–29:	The Regulatory Affairs and Outreach Branch held information sessions for patentees in Montreal and Toronto.
March 2:	Michelle Boudreau, Gregory Gillespie and Robert Squires met with the Canadian Generic and Pharmaceutical Association (CGPA).
	The PMPRB launched its new Twitter account.
March 6:	The Chairperson accepted a Voluntary Compliance Undertaking (VCU) submitted by Hospira Healthcare Corporation (Canada) regarding the price of the patented medicine Precedex.
March 13:	Michelle Boudreau, Tanya Potashnik and Carol McKinley met with Don Wildfong, Canadian Nurses Association.
March 19:	Michelle Boudreau and Ginette Tognet met with representatives of UK Health in London, UK.
	The PMPRB published an updated version of the Patentee's Guide to Reporting.
March 21:	Michelle Boudreau gave a presentation at the Sixth Annual Pharmaceutical Pricing, Reimbursement and Market Access Summit in London, UK.
April 16:	The Board issued a Notice and Comment seeking comments on proposed changes to the *Compendium of Policies, Guidelines and Procedures*.

PMPRB speeches and presentations are available on our 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

My first year at the helm of this organization has been both interesting and challenging in terms of fulfilling the Board's mandate.

In overseeing the activities of this organization, I have had the pleasure of working with dedicated and knowledgeable colleagues on the Board. As Anne Warner La Forest's five-year term ended in March, I would like to take this opportunity to thank her for her tremendous contribution to the Board and to wish her success in her endeavours.

The PMPRB's role is an important one as it contributes to the government-wide goal of healthy Canadians. In this last quarter, we have continued our work to enhance transparency and uphold fairness in our regulatory responsibilities. In keeping with our commitment to adjust and amend our Guidelines as required, we are currently consulting stakeholders on proposed changes to certain sections within the Guidelines through our Notice and Comment process. Details of these consultations are available in this issue of the *NEWSletter*. In addition, the Board will be releasing the results of the evaluation of its pilot project initiated a year ago to address challenges in applying the DIP methodology.

Mary Catherine Lindberg, Chairperson

We are pursuing our efforts to enhance compliance by ensuring that our Guidelines are responsive to changes in the environment we regulate, examining alternate dispute resolution models, exploring ways of decreasing the patentees' regulatory burden and making the most effective use of our resources.

We remain committed to ensuring that the PMPRB meets its challenges effectively.

For the coming year, our priorities are to enhance compliance through examining alternate dispute resolution models, decreasing the regulatory burden and moving to a more effective use of our resources while remaining open and transparent. ■

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

We are pleased to welcome Marie-Anne Clancy to the Corporate Services Branch. Marie-Anne will be replacing Josée Boucher as the Administrative Assistant in Finance during her maternity leave. Marie-Anne comes to the PMPRB from Industry Canada.

We would like extend our best wishes to Derek Jones who recently left the NPDUIS group at the PMPRB. We wish him good luck in his future endeavours. ■

Updates to the Patentee's Guide to Reporting

The updated Patentee's Guide to Reporting is now posted on our website under Are you a Patentee?/Frequently Requested Items.

The updates clarify the process for completing and filing Forms 1 and 2, which became mandatory under the amended *Patented Medicines Regulations* (the Regulations). The amended Regulations require patentees to submit the completed forms in electronic format to compliance@pmprb-cepmb.gc.ca.

The updated Patentee's Guide to Reporting also reflects changes in reporting over-the counter and veterinary drug products, as well as the new schedule for reporting the first day of sales. ■

Proposed Changes to the Compendium

Notification

The Board is proposing two changes to the *Compendium of Policies, Guidelines and Procedures*.

The first change proposes to eliminate the 5% investigation trigger at the national level for existing patented drug products. The second change proposes to replace the 3-year period to offset *de minimus* excess revenues through a Voluntary Compliance Undertaking (VCU) with the requirement to offset in a timely manner.

The side-by-side document detailing the changes along with the Notice and Comment was posted on our website on April 16, 2012, under Consultations/Notice and Comments.

The deadline for written feedback on these proposed changes is May 14, 2012. ■

Clarification on the Guideline on "Any Market" Price Reviews

The PMPRB is also providing a clarification for the application of "Any Market" Price Reviews.

The application of "Any Market" Price Reviews, for new and existing drug products, will be generally limited to patented drug products *first sold* in Canada on or after January 1, 2010.

The Board views market-specific price review as part of its mandate. At the same time, the Board is committed to continuing to be a responsive, effective and efficient regulator that recognizes the effects of its policies on the operational requirements and resources of patentees, as well as on its own limited resources. The Board believes that retroactively applying this new policy to all existing drugs would represent a significant administrative burden to patentees and to Board Staff. The Board is, therefore, clarifying that the "Any Market" Price Reviews will generally apply only to new and existing patented drug products first sold on or after January 1, 2010. ■

CPI-Based Price-Adjustment Factors for 2013

The *Patent Act* specifies the factors to be used by the PMPRB in determining whether the price of a patented drug product sold in Canada is excessive. One of these factors is the Consumer Price Index (CPI). The Board's *Compendium of Policies, Guidelines and Procedures* requires the cumulative increase in a product's price over any three-year period be no more than the increase in the CPI over the same period. The Compendium also sets a cap on year-over-year price increases equal to one and one-half times the CPI-inflation rate for the year in question.

To allow patentees to set prices in advance, the Board's CPI-Adjustment Methodology provides for the calculation of the CPI-adjustment factors based on forecast changes in the CPI. The Board informs patentees of these CPI-adjustment factors each year in its April *NEWSletter*.

The following table provides CPI-adjustment factors for 2013. These factors were based on forecasts of annual CPI-inflation rates of 2.1 % and 2.0% for 2012 and 2013, respectively, as well as the actual 2011 CPI-inflation rate of 2.9%. CPI inflation rates are provided by Finance Canada (see Government of Canada, *Budget 2012: Jobs, Growth and Long-Term Prosperity*, March 29, 2012, Table 2.1).

Forecast 2013 Price-Adjustment Factors for Patented Drug Products

Benchmark Year	(1) 2010	(2) 2011	(3) 2012
Price-Adjustment Factor	1.072	1.041	1.020

These figures imply (1) a maximum allowable cumulative price increase between 2010 and 2013 of 7.2% for patented drug products with Canadian sales in 2010 (that is, products whose "benchmark year" is 2010); (2) a maximum allowable cumulative price increase between 2011 and 2013 of 4.1% for products whose first Canadian sales occurred in 2011; and (3) a maximum allowable cumulative price increase between 2012 and 2013 of 2.0% for products whose first Canadian sales occurred in 2012.

In addition, the forecast inflation rate of 2.0% for 2013 implies a year-over-year price increase cap (applicable to all drug products regardless of benchmark year) of 3.0% (= 1.5 x 2.0%) for 2013. ■

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.

In the last quarter, one VCU was accepted for the patented medicine Precedex.

Precedex, Hospira Healthcare Corporation (Canada)

On March 6, 2012, the Chairperson of the Board approved a VCU submitted by Hospira Healthcare Corporation (Canada) for the price of Precedex.

Under the terms of the VCU, Hospira agreed upon the 2008 to 2009 maximum non-excessive (MNE) prices and the 2010, 2011 and 2012 National Non-Excessive Average Price (N-NEAP) for Precedex. Hospira also agreed to file data for the period from January to February 2012 to confirm the excess revenues that accrued over that period.

The terms of the VCU also required Hospira to offset excess revenues received from July 10, 2008, to February 2012 in the amount of $807,490, plus any additional amount identified by the review of January and February 2012 data, by lowering the price of another patented medicine, Docetaxel. The price of Docetaxel will remain at the discounted price until all Precedex excess revenues have been offset, no later than December 31, 2012.

In the event that the full amount of the excess revenues has not been offset by December 31, 2012, Hospira will make a payment to the government of Canada on or before January 30, 2013.

Precedex (dexmedetomidine hydrochloride for injection) is indicated for intensive care unit sedation and for conscious sedation.

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

The VCU is available on our website under Voluntary Compliance Undertakings. ■

eBulletin and Subscriptions

The PMPRB *NEWSletter* is a free quarterly publication available electronically on the Web. For immediate access to timely information, readers are invited to sign up for the **eBulletin alert**.

To subscribe to this service, click on the link at the bottom of the PMPRB home page at www.pmprb-cepmb.gc.ca. Readers are reminded to update their contact information when required.

Note that although we will not be offering ongoing print subscriptions, if you require a single printed copy of any of our publications, please contact us by email at pmprb@pmprb-cepmb.gc.ca or by phone at 613-952-3300 (toll free: 1-877-861-2350; TYY: 613-957-4373). ■

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.

Status of Board Proceedings

Patented Drug Product	Indication / Use	Patentee	Date of Notice of Hearing	Status
Apo-Salvent CFC-Free	Relief of chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs	Apotex Inc.	July 8, 2008	**Ongoing**
Copaxone – Redetermination	Use in ambulatory patients with relapsing–remitting multiple sclerosis to reduce the frequency of relapses	Teva Canada	New panel struck February 2010	**Board Decision and Order: February 23, 2012** **Subject of judicial review before the Federal Court**
Pentacel and Quadracel	Pentacel is a co-marketing of two licensed vaccines: Act-HIB (the lyophilized Haemophilus b Conjugate Vaccine (Tetanus Protein-Conjugate) to be reconstituted with Quadracel. It is indicated for the routine immunization of all children between 2 and 59 months of age against diphtheria, tetanus, whooping cough (pertussis), poliomyelitis and *Haemophilus influenzae type b disease*. Quadracel is a Component Pertussis Vaccine and Diphtheria and Tetanus Toxoids Adsorbed combined with Inactivated Poliomyelitis Vaccine. It is indicated for the primary immunization of infants, at or above the age of 2 months, and as a booster in children up to their 7th birthday against diphtheria, tetanus, whooping cough (pertussis) and poliomyelitis.	sanofi pasteur Limited	March 27, 2007	**Federal Court Decision: July 12, 2011** **Matter (remedy) returned to the Hearing Panel for reconsideration** **Board Decision pending**
ratio-Salbutamol HFA	Relief of chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs	ratiopharm Inc. (now Teva Canada)	July 18, 2008	**Board Decision: May 27, 2011** **Board Order: October 17, 2011** **Subject of judicial review before the Federal Court**

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 Decision: June 30, 2011** **Board Order: June 30, 2011; amended October 17, 2011** **Subject of judicial review before the Federal Court**
Sandoz Canada Inc.	Failure to file (jurisdiction)	March 8, 2010	**Board Decision pending**

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

PMPRB now on Twitter @PMPRB_CEPMB

To further enhance communications with our stakeholders, the PMPRB recently launched a Twitter account @PMPRB_CEPMB.

This not only provides another means for the PMPRB to disseminate information, but encourages a forum for open, two-way communication by connecting with other institutions, organizations and individuals.

In conjunction with the eBulletin service, as well as the "What's New?" section of our website, the PMPRB's Twitter account will advise users of new material posted on the website and of upcoming activities, such as,

- Announcements of Voluntary Compliance Undertakings, Board Decisions and Orders
- Notices of new publications including the *NEWSletter* and analytical studies
- Notices of consultations
- Conference presentations, speeches, news releases and other communication activities
- Notices of any changes to the website
- Other PMPRB updates including changes to policies, guidelines, services and initiatives

We have activated one bilingual account, which is monitored daily by our Communications Team. Each announcement will be tweeted simultaneously but separately in French and English.

We are always looking to add to our growing number of followers! Sign on to Twitter and check it out. ■

New Patented Medicines Reported to the PMPRB

New drug products first sold in 2012 will be reviewed based on the Guidelines implemented on January 1, 2010. Information on new patented drug products in 2012, along with those from previous years, can be found on our website under Regulating Prices/New Patented Medicines Reported to PMPRB. ■

Summary of February 16 Board Meeting

Board members received the final report and approved the recommendations of the Working Group on the DIP Methodology. The Working Group was struck in 2011 to examine the application of the methodology following concerns expressed by the industry, namely, with respect to the resource-intensive nature of this measure and onerous evidence requirements.

Proposed changes to the *Compendium of Policies, Guidelines and Procedures* were discussed by the Board. As a result, a Notice and Comment was posted on our website on April 16 inviting stakeholders to comment on the proposed changes by May 14. Following a thorough review of the comments received, a consolidated updated version of the Compendium will be released in June. This work is in line with the Board's commitment to provide an annual updated version of its Guidelines.

Board members discussed other issues, including the Program Evaluation, patient engagement in the PMPRB's regulatory process and alternative dispute resolution.

The Board's next quarterly meetings will be held on May 14, September 13–14, and December 13–14.

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

April 30–May 1:
Pharma Pricing, Reimbursement and Market Access, St. Andrew's Club and Conference Centre, Toronto

May

May 4–5:
2012 National Health Law Conference, Toronto

May 7:
HDAP Meeting

May 13–15:
Sylvie Dupont to attend the Council of Canadian Administrative Tribunals' (CCAT) 28th Annual Conference, Calgary

May 14:
Quarterly Board meeting

May 29–30:
Annual Conference of the Association of Professional Executives of the Public Service of Canada, Ottawa

May 29–31:
Greg McComb to present a poster at the Canadian Association for Health Services and Policy Research (CAHSPR) Annual Conference, Montreal

May 31:
PMPRB Annual Report for 2011 to be submitted to the Minister of Health for tabling in Parliament

June

June 11–12:
Michelle Boudreau to speak at the 6th Annual Drug Pricing and Reimbursement in Canada Forum, Toronto

June 11–15:
National Public Service Week

September

September 12–13:
Quarterly Board meeting

September 24:
HDAP meeting

November

November 8–10:
Mary Catherine Lindberg and Michelle Boudreau to attend the 2012 Canadian Health Policy Assembly, Banff, Alta.

December

December 13–14:
Quarterly Board meeting

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