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

Canada

NEWSletter

Since our last issue...

Volume 16, Issue No. 1, January 2012

Our recent key events

October 31–November 2:	Mary Catherine Lindberg and Michelle Boudreau held a series of meetings with provincial health officials in British Columbia and Alberta, representatives of In Initiative Inc., and the First Nations and Inuit Health Branch of Health Canada's Alberta Region.
November 4:	Mary Catherine Lindberg spoke at the 7th Annual Health Insurance Strategic Forum in Cambridge, Ontario.
November 5–8:	Mitchell Levine and Ginette Tognet participated in the International Society Pharmacoeconomics and Outcomes Research (ISPOR) 14th Annual European Congress in Madrid, Spain.
November 7:	The HDAP held its quarterly meeting.
November 14:	Michelle Boudreau and Robert Squires met with BIOTECanada.
November 15–16:	Michelle Boudreau spoke at the 10th Annual Market Access Summit in Toronto, Ontario.
December 8–9:	The Board held its quarterly meeting. The Board also held meetings with representatives of BIOTECanada, Canada's Research-Based Pharmaceutical Companies (Rx&D) and the Canadian Generic Pharmaceutical Association (CGPA), as well as with the Health Products and Food Branch, Health Canada.
December 12:	Michelle Boudreau and Ginette Tognet met with Rx&D's PMPRB subcommittee.
December 13:	Michelle Boudreau met with representatives of the Canadian Life and Health Insurance Association and with Sholom Glouberman, President of the Patients' Association of Canada.
December 20:	Michelle Boudreau, Ginette Tognet and Gregory Gillespie met with Jeff Poston, Executive Director of the Canadian Pharmacists Association.
December 29:	NPDUIS released a new analytical report entitled *Wholesale Up-charge Policies of Canada's Public Drug Plans, December 2011*.

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

Inside...

Board Members

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

Mary Catherine Lindberg, Chairperson

As it begins its 25th year of operation, the PMPRB remains committed to providing fairness and transparency in carrying out its mandate. In 2011, we focussed on assessing our direction in light of ongoing shifts in the health care environment. We are seeing important changes, domestically and internationally, as distribution practices evolve, sales models change, patentees introduce different types of benefit programs, and new types of drugs continue to reach the market. As well, other countries are adopting price control policies and voting on new legislation.

The PMPRB's objective to ensure that Canadians do not pay excessive prices for patented medicines is an important one. It impacts on public and private payers and on cash-paying customers. Our framework addresses affordability for consumers while supporting accessibility to drugs for all Canadians. As Chair of this Board since March 2011, it is my objective to ensure that the framework continues to have a positive impact for consumers while recognizing the value that innovative medicines offer to patients.

To that end, we have modified our engagement policy with stakeholders and enhanced our outreach to patentees. Our Guidelines Evaluation and Monitoring Plan has provided opportunities for a continued dialogue with patentees and allowed timely adjustments to our Guidelines. It is our intention that the Guidelines be responsive to changes in the environment that it regulates, in an appropriate timeframe. We will continue to adjust and amend the Guidelines, as required, in consultation with stakeholders. Enhancements to our engagement with stakeholders will also go a long way to meeting our long-standing commitment to a regulatory regime that is relevant, responsive and appropriate.

The decision issued by the Supreme Court of Canada on January 20, 2011, upholding key aspects of the Board's jurisdiction, provided an important clarification and affirmation of the PMPRB's consumer protection role.

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.

We have not lost track of our reporting role. Through the National Prescription Drug Utilization Information System (NPDUIS), we continue our partnership with the Canadian Institute for Health Information, Health Canada and the provinces and territories. We have published several reports in the past year and have initiated a number of studies which will provide policy makers and drug plan managers with information and insights on trends in prices, utilization and costs.

The Board remains committed to effectively meeting challenges, serving Canadians and contributing to the health care system. ■

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 Lynn Harrison, who joined the PMPRB from the Offices of the Information and Privacy Commissioners of Canada. Lynn will be working as a financial analyst with the Corporate Services Branch. ■

Workplace Charitable Campaign

Thanks to our contributors, this year the PMPRB almost doubled its goal for the Government of Canada Workplace Charitable Campaign. The staff enjoyed many fund-raising events including a pumpkin carving contest and sale, as well as the celebrated annual PMPRB breakfast. Staff members also participated in a chili contest and lunch cohosted by the Canadian International Trade Tribunal. Many thanks go to all of the volunteers for their time, energy and generous contributions. We are especially grateful to Elaine McGillivray for her continued leadership in the campaign. ■

Mary Catherine Lindberg, Chairperson
Michelle Boudreau, Executive Director
The PMPRB wishes everyone the best in 2012

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, 2012. 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, 2012, 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. ■

2011 CPI-Based Price-Adjustment Factors

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

Table 1 reproduces preliminary price-adjustment factors for 2011 published in the April 2010 *NEWSletter*. These factors were based on forecasted annual CPI-inflation rates of 1.7% and 2.2% for 2010 and 2011, respectively.

Table 1 Preliminary 2011 Price-Adjustment Factors for Patented Drug Products (Based on Forecast CPI-Inflation Rates for 2010 and 2011)

Benchmark Year	(1) 2008	(2) 2009	(3) 2010
Price-Adjustment Factor	1.043	1.039	1.022

These figures imply: (1) a maximum allowable cumulative price increase between 2008 and 2011 of 4.3% for patented drug products with Canadian sales in 2008 (that is, products whose "benchmark year" is 2008); (2) a maximum allowable cumulative price increase between 2009 and 2011 of 3.9% for products whose first Canadian sales occurred in 2009; and (3) a maximum allowable cumulative price increase between 2010 and 2011 of 2.2% for products whose first Canadian sales occurred in 2010.

In addition, the forecast inflation rate of 2.2% for 2011 implies a year-over-year price increase cap (applicable to all drug products, regardless of benchmark year) of 3.3% (= 1.5 x 2.2%) for 2011.

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

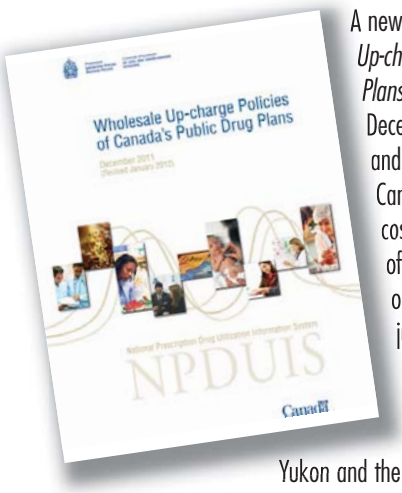
The actual rate of CPI inflation for 2010 of 1.8% was published in the January 2011 *NEWSletter*. The actual rate of CPI inflation for 2011 is now available and was 2.9%. These rates (along with the actual 2009 CPI-inflation rate of 0.3%) yield the following final price-adjustment factors.

Table 2 Final 2011 Price-Adjustment Factors for Patented Drug Products (Based on Actual CPI-Inflation Rates for 2010 and 2011)

Benchmark Year	(1) 2008	(2) 2009	(3) 2010
Price-Adjustment Factor	1.051	1.047	1.029

The final year-over-year price increase cap for 2011 is 4.4 % (= 1.5 x 2.9%). ■

NPDUIS – Release of Analytical Report



A new analytical report entitled *Wholesale Up-charge Policies of Canada's Public Drug Plans* was published by the PMPRB on December 29, 2011. The report identifies and summarizes the instruments used by Canada's public drug plans to manage costs related to the wholesale distribution of prescription drugs. The study focuses on the policies in place in the following jurisdictions: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, the Yukon and the national NIHB program.

Generally speaking there are few differences in how the public drug plans regulate charges. Once a jurisdiction decides to reimburse these costs, what changes from one plan to another is the amount (typically a percentage of the ingredient cost) that the plan is willing to reimburse a pharmacy. This maximum allowed up-charge amount is often established based on input from or negotiation with local pharmacy associations and, thus, reflects the realities of the local pharmaceutical market and the designs of individual reimbursement plans.

Drug plan policy is by its nature dynamic, reflecting the on-going demands of the respective pharmaceutical markets of Canada's provinces and territories. The policies described in this document reflect the environment as of December 2011 and are subject to change.

Through the NPDUIS initiative, the PMPRB provides critical analyses of price, utilization and cost trends in Canada to support drug plan policy decision making. NPDUIS is a partnership between the PMPRB and federal, provincial, territorial governments and the Canadian Institute for Health Information.

A link to the full report (as well as previously published analytical studies) is available on the PMPRB website on the NPDUIS or Publications page. ■

Guidelines Monitoring and Evaluation Plan — Initial Results

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 first annual assessment to the Board in December 2011. The results of this assessment are included in the GMEP, which can be found on the PMPRB website under Legislation, Regulations and Guidelines.

The next annual assessment will be presented to the Board in December 2012. ■

Launch of Web Application for New Patented Medicines Reported to the PMPRB

On January 31, 2012, the PMPRB launched its user-friendly Web application for New Patented Medicines Reported to the PMPRB. The application is now available on the PMPRB website under Regulating Prices.

With the implementation of the new Guidelines on January 1, 2010, the PMPRB decided to change the format of the information that it provides on the price review of new patented drug products and provide information on all new patented drug products reported as sold in the year.

This new application includes a complete list of medicines reported to the PMPRB since 1998 and is searchable by the year reported and by the status of the price review (for 2001 onward). In addition, a keyword search will enable users to refine their search results by company, brand name, chemical name, DIN, and/or therapeutic use.

Each medicine from 2010 onward that has a status classified as "Within the Guidelines" or "Does Not Trigger an Investigation" will have a link from the brand name to an individual Price Review Record. Price Review Records include information such as

- level of therapeutic improvement
- price test used to establish the maximum average potential price (MAPP)
- comparators and comparable dosage regimens used for price comparison
- comparator countries
- maximum average potential price

The record may also include additional explanations if applicable, for example, a rationale for establishing the level of therapeutic improvement or the evidence relied upon where secondary factors were relied upon in the case of moderate level of therapeutic improvement.

Price Review Records are currently available for almost all drug products reported in 2010 and will be gradually populated for 2011 over the next few months. For drug products reported prior to 2010, Summary Reports of the results of the price review for new active substances are available on the PMPRB website. Any additional information will be made available on a per request basis. ■

New Patented Medicines Reported to the PMPRB

New drug products first sold in 2011 will be reviewed based on the Guidelines implemented on January 1, 2010. As of December 31, 2011, a total of 104 new drug products (DINs) were reported to the PMPRB (representing 60 medicines). Information on these patented drug products can be found on the PMPRB website under Regulating Prices. ■

Core Control Audit of the PMPRB

The PMPRB continuously strives to be transparent and accountable in how it does business. Audits maintain and enhance the proper management of the public funds administered by the PMPRB. This is achieved by providing independent assurance that the resources, systems, processes, structures and operational tasks of the PMPRB are supporting the delivery of its programs in an economical, efficient and effective manner.

The objective of the Core Control Audit of the PMPRB performed by the Office of the Comptroller General (OCG), was to ensure that core controls over financial management within the PMPRB are effective and result in compliance with corresponding legislation, policies and directives. The PMPRB accepted the audit findings and provided the OCG with the PMPRB Management Action Plan for the Core Control Audit to address the OCG's detailed recommendations.

The OCG findings and the PMPRB plan are available on the website under Accountability. ■

Complaints Process on Prices of Patented Medicines Sold in Canada

The PMPRB regulates the ceiling prices that patentees charge wholesalers, hospitals and pharmacies for patented medicines sold in Canada, whether these medicines are prescribed or sold over the counter. The PMPRB does not regulate at the pharmacy level.

In order to better assist consumers, the PMPRB initiated a formal complaints process last spring, enabling any individual or group affected by the price of a patented medicine to submit a complaint. The process is described on the PMPRB website and a Complaint Form is available under Are you a Consumer and under Regulating Prices/Investigations.

Upon receipt of a complaint, we determine whether the drug product is patented and under the PMPRB's jurisdiction. We then look at the pricing information that patentees are required by law to file with the PMPRB, twice a year. If there appears to be an issue, the patentee will be asked to provide an explanation. Based on the information, we may open an investigation which could ultimately lead to an undertaking by the patentee to reduce the price of the patented drug or to a public hearing to determine whether the price is excessive and an order to reduce the price of the patented drug product.

Those who file a complaint will be informed of the outcome of the preliminary assessment within 10 days of receipt of the complaint.

For more information on the complaints process, please consult the website. ■

eBulletin and Subscriptions

The PMPRB *NEWSletter* is a free quarterly publication available electronically on the Web. As announced in the last issue, the *NEWSletter* is no longer distributed in hard-copy format. For immediate access to timely information, readers are invited to sign up for the email alert service.

Sign up for our **eBulletin alert** and you will be automatically notified as soon as the *NEWSletter* is published, with a link to the full electronic content. In addition, relevant news items and announcements will be sent to you directly upon their release.

To subscribe to this service, click on the link at the bottom of the PMPRB home page at www.pmprb-cepmb.gc.ca.

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). ■

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, two VCUs were accepted by the Chairperson for the patented medicines Thalomid and Dovobet. A VCU for the patented medicine Trinipatch had been approved by the Chair in June 2011 but had not yet been reported in the *NEWSletter*.

Trinipatch, Paladin Laboratories Inc.

On June 6, 2011, the Chairperson of the Board approved a VCU submitted by Paladin Laboratories Inc. regarding the price of Trinipatch. Under the terms of the VCU, Paladin reduced the average selling price of the three strengths of Trinipatch in order that they not exceed the agreed upon 2011 National Non-Excessive Average Price (N-NEAP). Paladin also offset cumulative excess revenues received from January 1, 2010, to December 31, 2010, by making a payment to the Government of Canada in the amount of $92,266.70.

Trinipatch is indicated for the prevention of anginal attacks in patients with stable angina pectoris associated with coronary artery disease.

Thalomid®, Celgene Corporation

On January 12, 2012, the Chairperson of the Board approved a VCU submitted by Celgene Corporation regarding the price of Thalomid. Under the terms of the VCU, Celgene is to make a payment in the amount of $10,000,000 to the Government of Canada no later than February 20, 2012, in order to comply with the Guidelines. Celgene will also ensure that the average transaction prices of Thalomid 50 mg, 100 mg and 200 mg in Canada are at or below the price agreed upon effective January 2012 and in each subsequent year while under the jurisdiction of the PMPRB. Finally, Celgene will maintain its compassionate programmes to provide eligible Canadian patients with access to its patented drug products Thalomid and Revlimid®.

Thalomid® brand drug (thalidomide capsules) in combination with melphalan and prednisone (MPT) is indicated for the treatment of patients with previously untreated multiple myeloma who are 65 years of age or older.

Dovobet, LEO Pharma Inc.

On January 17, 2012, the Chairperson of the Board approved a VCU submitted by LEO Pharma Inc. regarding the price of Dovobet. Under the terms of the VCU, the National Non-Excessive Average Prices (N-NEAPs) for Dovobet in 2010 and 2011 are $1.3710 and $1.4038, respectively. Also, to offset the cumulative excess revenues received by LEO Pharma during the period of January 1, 2010, to December 31, 2010, LEO Pharma will make a payment to the Government of Canada, no later than February 20, 2012, in the amount of $32,019.98.

Dovobet is an ointment containing 50 mcg/g of calcipotriol and 0.5 mg/g of betamethasone dipropionate, indicated for the topical treatment of psoriasis.

The prices of these drug products are to remain within the Guidelines in all future periods in which they are under the PMPRB's jurisdiction.

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.

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 pending**
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**
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 the PMPRB website under Hearings and Decisions/Decisions and Orders. ■

Backing-Out Formulas for Foreign Price Verification

In its January 2011 *NEWSletter*, the PMPRB committed to begin publishing the "backing-out" formulas it uses in carrying out foreign price verification. In the July 2011 *NEWSletter*, it noted that preliminary formulas were available on the PMPRB's website and that a finalized set of formulas would follow.

Significant changes to Sweden's formulary occurred in the late summer / early fall of 2011. As a result, the PMPRB has updated the backing-out formulas for Sweden for 2011. There were no changes to the backing-out formulas for France, Germany, Italy, Switzerland or the United Kingdom.

While formulary changes may occur at any time, the PMPRB recognizes that both it and patentees would benefit from a more predictable update of backing-out formulas that is better aligned with patentees' reporting cycle.

For this reason, the PMPRB has decided that it will check for formulary changes in December of each year and will publish any revisions to the backing-out formulas in January. These formulas will be valid for the entire calendar year (i.e., January through December).

More information on the PMPRB's foreign price verification process and a complete list of formulas for 2011 and 2012 is available on the PMPRB website listed under Reference Documents on the Are you a Patentee page. ■

Summary of December 8–9 Board Meeting

The Board continued its bilateral meeting series initiated last October. Board members met with representatives of the Health Products and Food Branch of Health Canada to discuss HPFB's activities and the modernization of Canada's drug approval process. They also met with representatives of the pharmaceutical industry, namely, BIOTECanada, Canada's Research-Based Pharmaceutical Companies (Rx&D) and the Canadian Generic Pharmaceutical Association, to discuss the current pharmaceutical environment in Canada.

Board members were briefed on several issues, including the ongoing monitoring and evaluation of the major changes to the Guidelines; analyses conducted in the context of the National Prescription Drug Utilization Information System (NPDUIS) and the report scheduled for release on December 29; and alternate dispute resolution mechanisms. The Board also approved a strategic planning action plan following the planning session it held in mid-October.

The Board's 2012 meeting schedule was confirmed, and the quarterly meetings will be held on: February 16; May 10–11; 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 the PMPRB website under About the PMPRB. ■

We Welcome Your Feedback

We want to hear from you. If you have any comments or suggestions for topics you wish to see covered in the *NEWSletter*, or if you would like more information on the PMPRB, contact us at:

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Upcoming Events

February

February 6:
HDAP meeting

February 16:
Quarterly Board Meeting

February 28:
PMPRB Outreach Sessions for patentees in Montreal

February 29:
PMPRB Outreach Sessions for patentees in Toronto

March

March 1:
Deadline for Patentees to file Form 3

March 20–23:
Michelle Boudreau will speak at the Pharma Pricing & Market Access Outlook Europe 2012 Conference in London, UK

May

May 7:
HDAP meeting

May 10–11:
Quarterly Board meeting

September

September 13–14:
Quarterly Board meeting

September 24:
HDAP meeting

December

December 13–14:
Quarterly Board Meeting

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