Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 15, Issue No. 3, July 2011

Inside...

Since our last issue...

Our recent key events

May 12–13:	The Board held its quarterly meeting.
May 16:	The HDAP held its quarterly meeting.
May 25–27:	Mary Catherine Lindberg attended the Life Sciences Invitational Forum in Cambridge, Ontario.
June 5–7:	Dr. Mitchell Levine, Vice-Chair, Sylvie Dupont and Martine Richard attended the 27th Annual Conference of the Council of Canadian Administrative Tribunals (CCAT) in Ottawa.
June 15:	Michelle Boudreau spoke at the 5th Annual Conference on Drug Pricing and Reimbursement in Toronto.
June 16:	The PMPRB's *Annual Report 2010* was tabled in Parliament.
July 12:	The Federal Court issued its decision on sanofi pasteur's application for Judicial Review of the Board's December 22, 2010 decision in the Quadracel and Pentacel matter, which was heard on January 16-17. ■

PMPRB speeches and presentations are available on the website at Publications/Speech Series.

National Public Service Week

National Public Service Week (NPSW) is an opportunity to celebrate the work and achievements of the individuals who make up the Public Service of Canada. It is a special occasion to recognize public servants and the important role we play in Canadian society. This year, the theme for National Public Service Week was **Be the Change**.

The PMPRB kicked off NPSW by distributing apples with a thank you message to all employees. Various activities were organized throughout the week, including a Changing Course Mini-Putt contest, a Recipe for Change Potluck, and a Change of Pace Scavenger Race. Catherine Morisset, a life wellness and performance coach who works with organizations to implement healthy workplace strategies, came to speak to staff about workplace change and how to make it work for each of us. Sundaes on Friday closed the week-long activities with senior managers serving ice cream sundaes to staff in thanks for everyone's hard work over the past year.

The Board thanks everyone for their commitment to the PMPRB and continued support throughout the year and offers its best wishes for success in the coming months. ■

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 the PMPRB moves towards 25 years of operations, its role has never seemed more pertinent. As the business environment of the pharmaceutical industry becomes ever more complex, and the needs of the health care system become more acute, the PMPRB plays an important role in contributing to the health care system and protecting consumers.

The Board has already identified enhancing our engagement with stakeholders and bolstering our outreach to patentees as priorities. This can already be felt in the implementation of the renewed Guidelines that came into effect on January 1, 2010. Exchanges with stakeholders are key to our long-standing commitment to a regulatory regime that is relevant, responsive and appropriate.

The tabling of the PMPRB's annual report in Parliament on June 16, 2011 was an opportunity to remind Members of Parliament and all Canadians about the important role of the PMPRB in ensuring Canadians do not pay excessive prices for patented medicines.

As the PMPRB moves forward in the fulfillment of its mandate, the Board remains committed to predictability, fairness, and transparency. ■

Mary Catherine Lindberg

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Director, Policy and Economic Analysis:
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Director, Corporate Services:
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2010 Annual Report

The PMPRB's annual report for the year ending December 31, 2010, was tabled by the Minister of Health with the Clerks of the House of Commons and Senate on June 16, 2011.

The report provides detailed information on sales and price trends of patented drugs sold in Canada, including international comparisons, patentees' compliance with the Board's price Guidelines, regulatory activities, and on pharmaceutical R&D expenditures.

In 2010, sales of patented drug products in Canada declined by 3.4% to $12.9 billion. The share of patented drug products as a percentage of total sales continued to decline, from 65.5% in 2009 to 58.0% in 2010. The prices of patented drug products sold by patentees, as measured by the Patented Medicines Price Index, fell by 0.4% from 2009 to 2010, while the Consumer Price Index rose by 1.8%. Canadian prices were the fourth highest of the seven comparator countries.

Patentees reported 68 new patented drug products to the PMPRB in 2010. A total of 1196 patented drug products for human use were under the PMPRB's jurisdiction in 2010. Up to May 31, 2011, the Board approved 16 Voluntary Compliance Undertakings (VCUs) and an amendment to one existing VCU. The Board issued decisions and/or orders effectively completing five matters: Adderall XR (Supplementary Order); Nicoderm; Penlac; Quadracel and Pentacel; and ratio-Salbutamol HFA. At the time of issuance of the July issue of the *NEWSletter*, decisions were pending in two matters: Copaxone (redetermination), on price, and Sandoz Canada Inc., on failure to file. Two proceedings are ongoing: Apotex Inc., on failure to file, and Apo-Salvent CFC Free, on price.

Patentees reported spending $1.18 billion on R&D, a decline of 7.4% over 2009. Members of Rx&D (Canada's Research-Based Pharmaceutical Companies) accounted for 84.8% of all reported R&D expenditures in 2010. The ratio of R&D-to-sales also declined from 7.5% in 2009 to 6.9% in 2010, while the R&D-to-sales ratio for members of Rx&D remained at 8.2%, the same as for 2009.

The Annual Report 2010 is available on the home page of the PMPRB website. ■

Human Drug Advisory Panel Process and 2012 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
- identifies significant uncertainties in the evidence that may affect the analysis on which its recommendations are based.

The HDAP is currently composed of five members with recognized expertise in drug therapy and 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* (Compendium).

The *Compendium of Policies, Guidelines and Procedures* is available on the PMPRB website at Regulatory.

The HDAP meets four times a year. The dates of the meetings for 2012 are as follows: February 6, May 7, September 24 and November 5.

To provide for fairness to the patentee, to ensure that a drug product will in fact be scheduled for discussion at a meeting and to 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.

Over the past couple of years, the deadline for filing submissions has been no later than three (3) months prior to the particular HDAP meeting. However, due to the fact that the majority of patentees and consultants filing on behalf of patentees have been filing on the last day, **the deadline for submission of the product monograph or information similar to that contained in a product monograph has been advanced by two weeks** to permit sufficient time to process all of the submissions for a particular meeting.

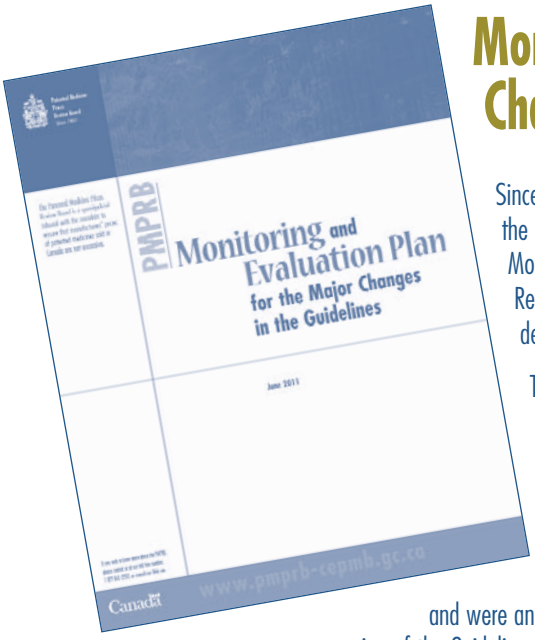
The patentee will be advised of the date of the HDAP meeting at which its submission will be considered.

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 10 weeks prior to the particular HDAP meeting. For more information on what should be included in a submission, please refer to Schedule 1, Submissions by Patentees on Level of Therapeutic Improvement, of the Compendium.

Although the actual submission on the level of therapeutic improvement is due no later than 10 weeks prior to the particular HDAP meeting, patentees are requested to indicate whether they intend 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**.

The following table provides the submission deadlines for the HDAP meetings in 2012.

HDAP Meeting/ Conference Call	Information	Deadline
February 6, 2012	• 1 copy of product monograph or information similar to that included in a product monograph (if drug product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement.	• **October 24, 2011**
	• 10 copies of patentee submission	• **November 24, 2011**
May 7, 2012	• 1 copy of product monograph or information similar to that included in a product monograph (if drug product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement.	• **January 24, 2012**
	• 10 copies of patentee submission	• **February 24, 2012**
September 24, 2012	• 1 copy of product monograph or information similar to that included in a product monograph (if drug product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement.	• **June 11, 2012**
	• 10 copies of patentee submission	• **July 11, 2012**
November 5, 2012	• 1 copy of product monograph or information similar to that included in a product monograph (if drug product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement.	• **July 23, 2012**
	• 10 copies of patentee submission	• **August 23, 2012** ■



Monitoring and Evaluation Plan for the Major Changes in the Guidelines

Since the implementation of the new Guidelines in January 2010, Board Staff has been monitoring and evaluating the application and impact of the major changes on an ongoing basis. In June 2011, the PMPRB published its Monitoring and Evaluation Plan for the Major Changes in the Guidelines on its website (under Legislation, Regulations and Guidelines). The plan explains the indicators (both qualitative and quantitative) that have been developed to measure the impact of each change, as well as results from some of the indicators.

This plan will assist the Board in assessing the impact and application of the major changes to the Guidelines. These impacts may not be immediately apparent due to the timing of the regulatory filings of patentees, the price review process of existing patented drug products which is based on a full calendar year, and the fact that it may take several reporting periods before any discernible trends become evident. The Board will monitor emerging issues to identify the need for any future amendments to the Guidelines or this plan.

Some adjustments, based on the monitoring plan and feedback from patentees, have already been made and were announced in various issues of the *NEWSletter*. These changes were summarized and included in an updated version of the Guidelines that was also published on the PMPRB website in June.

A summary of major changes, indicators and results will be updated and used to report annually on the monitoring and evaluation plan results, beginning in fall 2011. ■

Back-Out Methodology

"Backing-Out" Formulas for Foreign Price Verification

The *Patented Medicines Regulations* require patentees to report the ex-factory prices at which they sell their products in any of the seven comparator countries specified in the Regulations. It is critical patentees accurately report foreign prices because of the role these prices play in the price tests that the PMPRB applies when conducting its price reviews and reporting on pharmaceutical price trends. If patentees were to overstate foreign prices, this could lead the PMPRB to accept Canadian prices that are excessive in light of actual market conditions, to the detriment of Canadian consumers.

PMPRB staff routinely uses price information obtained from national formularies to validate the foreign prices patentees submit, in a process called Foreign Price Verification (FPV). This process typically involves a series of calculations needed to remove mark-ups and certain taxes embedded in formulary prices. Beginning with the manufacturer, the drug product may be sold to a wholesaler or directly to a pharmacy or hospital. As the drug travels through the distribution chain, the price may be marked up several times. In some countries, formulary prices also include a value-added-tax (VAT).

In the six European comparator countries that the PMPRB considers in its price reviews (i.e., France, Germany, Italy, Sweden, Switzerland and the United Kingdom), retail and wholesale mark-ups (as well as any sales taxes) are determined by means of publicly available formulas. With these formulas in hand, PMPRB staff can derive ex-factory prices from formulary prices. Staff then uses these derived ex-factory prices to perform FPV. (Similar calculations are not possible in the case of the United States, where wholesale and retail mark-ups are not regulated.)

Because the policies of foreign reimbursement plans can change from one year to the next, PMPRB staff, in consultation with appropriate officials in the comparator countries, update the FPV "backing-out" formulas in the second quarter of each year (that is, before patentees submit foreign prices for the first six months of that year).

In its January 2011 *NEWSletter*, the PMPRB committed to begin publishing the "backing-out" formulas it uses in carrying out FPV. Preliminary formulas for 2011 are available on the PMPRB's website (under Regulatory). A finalized set of formulas will be posted in September. ■

Notice and Comment – Rules of Practice and Procedure

As announced in its April 2011 *NEWSletter* and as part of its consultation process, the Board recently sought comments on proposed amendments to its Rules of Practice and Procedure for Hearings through its Notice and Comment process. This Notice and Comment followed a consultation, last December, of selected lawyers who appear regularly before administrative tribunals, including the PMPRB.

The Board would like to thank Rx&D for its submissions on behalf of the industry. The Board will move to pre-publication of the draft Rules in Part I of the *Canada Gazette* over the coming months. This pre-publication gives various interested groups, individuals and Canadians in general the opportunity to comment on a proposed regulation before it is adopted. As well, it provides interested parties that have already been consulted the opportunity to see how the final proposal is in keeping with previous drafts.

The May 2011 proposed revised Rules of Practice and Procedure are posted on the PMPRB website at Consultation/Notice and Comments/Rules of Practice and Procedure.

The Rules of Practice and Procedure for Hearings constitute a published standard set of procedures for all participants to follow in proceedings before the Board. The Rules set out the Board's procedures in accordance with the requirement under the *Patent Act* to resolve matters before it as informally and expeditiously as the circumstances and considerations of fairness permit. They provide a fair opportunity for interested parties to participate in the Board's hearings. ■

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 second quarter, two VCUs were accepted for the patented medicines Technescan MAG3® and Niaspan.

Technescan MAG3® (technetium), Lantheus Medical Imaging

On May 16, 2011, the Chairperson of the Board approved a VCU submitted by Lantheus Medical Imaging (Lantheus) regarding the price of TechneScan MAG3®. Under the terms of the VCU, Lantheus offset excess revenues received from January 1, 2004 to April 27, 2010 (date of patent expiry) in the amount of $34,800.59 by making a payment to the Government of Canada on June 15, 2011.

Technescan MAG3® (technetium) is a radiopharmaceutical agent used in the diagnosis of diseases.

Niaspan, Sepracor Pharmaceuticals, Inc.

On May 16, 2011, the Chairperson of the Board approved a VCU submitted by Sepracor Pharmaceuticals, Inc. (Sepracor) regarding the price of Niaspan. Under the terms of the VCU, Sepracor reduced the price of Niaspan 500 mg tablet so that it does not exceed the 2011 National Non-Excessive Price (N-NEAP) of $1.1920 for the remainder of 2011. In addition, Sepracor offset the cumulative excess revenues it received from January 2009 to December 2010 by making a payment to the Receiver General of Canada in the amount of $76,554.47. Sepracor will also offset any excess revenues it received from January 1, 2011 to the date of the implementation of the price reduction (no later than September 2, 2011) by making a further payment to the Receiver General of Canada.

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

Niaspan (extended-release niacin) is indicated as an adjunct to diet for reduction of elevated total cholesterol, low-density lipoprotein cholesterol, apolipoprotein B and triglyceride levels, and to increase high density lipoprotein cholesterol in patients with primary hypercholesterolaemia and mixed dyslipidaemia, when the response to an appropriate diet and other non-pharmacological measures have been inadequate.

VCUs are available on the PMPRB website at Regulatory/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 Neuroscience G.P.-S.E.N.C.	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	Board Decision: December 21, 2009 Board Order: March 16, 2010	**Federal Court decision: July 12, 2011**
ratio-Salbutamol HFA	Relief of chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs	ratiopharm Inc.	Board Decision: May 27, 2011 Board Order: pending	**Federal Court Judicial Review Application filed June 27, 2011** **Federal Court Hearing date to be announced**

Patentee	Issue	Date of Notice of Application	Status
Apotex Inc.	Failure to file (jurisdiction)	March 3, 2008	**Ongoing**
ratiopharm Inc.	Failure to file (jurisdiction)	August 28, 2008	**Board Decision: June 30, 2011** **Board Order: June 30, 2011**
Sandoz Canada Inc.	Failure to file (jurisdiction)	March 8, 2010	**Board decision pending**

Board decisions and orders are available on the PMPRB website at Hearings. ■

Comings and Goings

A few employees have joined the PMPRB since the last *NEWSletter*. Joel Weber has taken on a new role as a Regulatory Officer with Regulatory Affairs and Outreach. Mélanie Leroux accepted the position of Administrative and Human Resources Assistant with the Corporate Services Branch. We would like to take this opportunity to thank Mélanie for her hard work as Assistant to the Director in the Policy and Economic Analysis Branch.

We extend our best wishes to Joelle Cousineau, who recently left the PMPRB. ■

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 June 30, 2011, a total of 43 new drug products (DINs) were reported to the PMPRB (representing 32 medicines). Information on these patented drug products can be found on the PMPRB website at Regulatory/Patented Medicines/New Medicines Introduced In/2011. ■

Summary Report on Patented Drugs

In 2002, the PMPRB began publishing the results of the price review of new patented drug products where the price was within the Guidelines. These reports are available on the PMPRB website under Regulatory/Patented Medicines/Reports on New Patented Drugs for Human Use.

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 will include:

- Information on the new drug product
- Level of therapeutic improvement (including rationale for breakthough, substantial improvement and moderate improvement, information on evidence where secondary factors considered for moderate improvement)
- Comparators and comparable dosage regimens
- Comparator countries
- Maximum average potential price

The new format will be published this fall. ■

Summary of May 12-13 Board Meeting

At its May meeting, the Board approved the PMPRB's annual report for the year ending December 31, 2010. As in previous years, the report was to be submitted to the Minister of Health on May 31 with a recommendation that it be tabled in Parliament prior to the summer recess.

The Board also approved the publication of the Monitoring and Evaluation Plan for the Major Changes in the Guidelines, along with the release of the updated *Compendium of Policies, Guidelines and Procedures*. The Compendium will be updated annually in June.

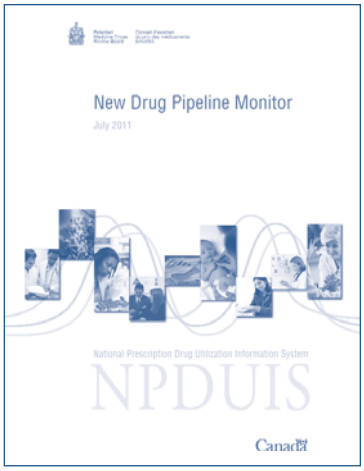
The Board was briefed on analyses being conducted in the context of the National Prescription Drug Utilization Information System (NPDUIS) and on the issue of price review of biologics.

The Board's next meeting is scheduled for October 13-14, 2011.

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 at About PMPRB. ■

New Drug Pipeline Monitor Report



The latest edition of the New Drug Pipeline Monitor (NDPM) is now available on the PMRPB website (under Publications/Study Series and Discussion Papers). This web-based publication summarizes information on new drugs that are expected to be launched in Canada within the next two to five years and that could potentially have a significant impact on federal, provincial and territorial drug plan expenditures.

The NDPM is intended to support informed decision-making by providing information on drugs that are in the latter phases of research and could have a significant impact in terms of therapeutic value. These drugs have the potential to either change clinical practice or treat a condition with no existing treatment, a life-threatening condition, or a rare disease affecting a small population. ■

Subscription Information and Services

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

E-bulletin alert: sign up for an email 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.

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For any other questions or comments on our publications, call our toll-free number 1-7877-861-2350 ior send an email message to pmprb@pmprb-cepmb.gc.ca.

Please note that beginning January 2012, paper copies of publications will be made available by request only. ■

Congratulations to Muhammad Mamdani

On behalf of the Board Members and PMPRB staff, we wish to congratulate Dr. Muhammad Mamdani on winning the Top 40 Under 40 award.

Established in 1995 by Doug Caldwell, the Top 40 Under 40 awards annually celebrate the achievements of young Canadians.

Dr. Mamdani was appointed Director of the Applied Health Research Centre of the Li Ka Shing Knowledge Institute of St. Michael's Hospital in 2007 and is also an associate professor in the department of Health Policy, Management and Evaluation of the Faculty of Medicine, and the Leslie Dan Faculty of Pharmacy at the University of Toronto. He joined the Human Drug Advisory Panel of the PMPRB in January 2010. ■

Congratulations to Marie-Sophie Jobin

On behalf of the Board Members and PMPRB staff, we wish to congratulate Marie-Sophie Jobin and her co-authors, who published a study entitled "Factors associated with the appropriate use of asthma drugs" in the Canadian Respiratory Journal.

Canadian Respiratory Journal is the official journal of the Canadian Thoracic Society and serves as a major venue for the results of Canadian research, society guidelines and continuing medical education. This internationally recognized journal contains peer-review material pertinent to specialists and general practitioners and addresses all aspects of respiratory medicine.

Marie-Sophie Jobin has been a Scientific Officer at the PMPRB since 2007. ■

Upcoming Events

August

August 8:
Michelle Boudreau to make a presentation to the Global HTA and CER Forum 2011

September

September 8:
HDAP meeting

September 21:
Mary Catherine Lindberg to speak at the Canadian Association for Healthcare Reimbursement (CAHR) Conference in Ottawa

October

October 13–14:
Board meeting

October 25–26:
Canadian Institute's 10th Annual Forum on Pharma Patents in Toronto

October 28:
October *NEWSletter*

November

November 1–3
3rd Annual Market Access Canada Summit in Toronto

November 7:
HDAP meeting

November 5–8:
Mitch Levine and Ginette Tognet to attend International Society Pharmacoeconomics and Outcomes Research (ISPOR) 14th Annual European Congress in Madrid, Spain

November 15–16:
Michelle Boudreau to speak at the 10th Annual Market Access Summit in Toronto

December

December 8–9:
Board meeting

Upcoming Events are available on the PMPRB website at Consultations/Events ■

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