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

Canada

NEWSletter

Inside...

Board Members

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Since our last issue...

Volume 16, Issue No. 3, July 2012

Our recent key events

May 3-4:	Marian Eagen, Director, Corporate Services, participated in the Deputy Chief Financial Officers (DCFO) Annual General Meeting in Cornwall.
May 7:	The Human Drug Advisory Panel (HDAP) held its quarterly meeting.
May 15:	The Board held its quarterly meeting.
May 29-30:	Greg McComb delivered a poster presentation at the Canadian Association for Health Services and Policy Research Conference in Montreal.
June 6:	Michelle Boudreau, Executive Director, met with the Chinese Delegation at Health Canada. The delegation headed by Mr. Sun Zhigang, Vice Chairman of the Chinese National Development and Reform Commission (NDRC), was on a fact finding mission to learn more about pharmaceutical distribution, including pricing of drugs.
June 6-7:	Michelle Boudreau and Gregory Gillespie, Director, Policy and Economic Analysis, participated in the Canadian Diabetes Association Sponsored National Summit on the Future of the Common Drug Review.
June 20:	The PMPRB's *2011 Annual Report* was tabled in Parliament.
July 26:	Michelle Boudreau met with Jim Keon, President of the Canadian Generic Pharmaceutical Association (CGPA) and Jody Cox, Director of Federal Government Relations.
July 30:	Due date for regulatory filing of price and sales information data (Form 2: Information on the Identity of Prices of the Medicine).

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

Comings and Goings

Two new employees have joined the PMPRB since the last *NEWSletter*. Isabelle Matte-LeBlanc joined the Communications team as a Text Editor, replacing Shirin Paynter while she is away on maternity leave. Amber McNeely joined the Regulatory Affairs & Outreach Branch as an Executive Assistant taking over for Linda Payant who moved to a new role in the Policy & Economic Analysis Branch.

The PMPRB would like to congratulate Sylvie Seguin on her retirement from the public service. ■

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

This last quarter we were pleased to welcome the newest member of the Board, Mr. Normand Tremblay, for a five-year term.

Mr. Tremblay teaches at the Université du Québec in Trois-Rivières, in the area of strategic management. He brings to the Board a vast experience in strategic and operational planning and organizational development. His experience and his knowledge of the pharmaceutical industry provide a valuable combination for the Board.Furthermore, the experience gleaned as member of the National Research Council of Canada from 2007 to 2010 will no doubt enhance the Board's ability to deal with varied and complex issues developing in the pharmaceutical industry. I look forward to working with Mr. Tremblay, as do my colleagues and Staff, in meeting the Board's mandate for the benefit of all Canadians.

In June, we published our Annual Report, providing detailed information on the PMPRB's activities, the pharmaceutical price trends and R&D expenditures by patentees for the year 2011. While prices of patented drug products sold in Canada remained on average unchanged from 2010, the Consumer Price Index rose by 2.9%. Canadian prices were the fourth highest among the seven comparator countries listed in the *Patented Medicines Regulations*, lower than prices in Switzerland, Germany and the United States. In the area of R&D, the downward trend continued.

Mary Catherine Lindberg, Chairperson

More recently, we released the updated version of the Compendium of Policies, Guidelines and Procedures, which incorporates all the clarifications made to the Guidelines through the past year. As well, the Board's proposed Rules of Practice and Procedure for public hearings were pre-published in the *Canada Gazette*, Part I for comments. I would like to take this opportunity to thank all of those who participate in the Board's consultations and assist us in advancing ways of meeting our regulatory and reporting mandate.

We look forward to the Fall as we continue our work in examining alternate dispute resolution models, exploring ways to reduce regulatory burden for patentees and completing a number of studies initiated under the National Prescription Drug Utilization Information System (NPDUIS) for publication this fiscal year.

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

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

The PMPRB's Compendium is updated

The *Compendium of Policies, Guidelines and Procedures* was updated at the end of June to include all clarifications on the Guidelines that were published during the year. A list of all updates to the Compendium can be found at section 18 of the document on the PMPRB's website. ■

National Public Service Week – June 10–16, 2012

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.

The PMPRB kicked off NPSW by distributing apples with a thank you message to all employees. Later in the week employees were invited to indulge in a feast of fajitas. The food was delicious and fun was had by all.

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. ■

2011 Annual Report

The PMPRB's Annual Report for the year ending December 31, 2011, was tabled by the Minister of Health with the Clerks of the House of Commons and Senate on June 20, 2012.

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.

This year, the PMPRB published a summarized form of the Annual Report. The PMPRB *Annual Report 2011: In Brief* was published and distributed to subscribers in both electronic and hard copy. Its purpose is to provide stakeholders and subscribers with all of the pertinent information contained within the Annual Report in a condensed form while reducing distribution costs and our carbon footprint.

In 2011, sales of patented drug products in Canada increased by 1.7% to $13.1 billion. The share of patented drug products as a percentage of total sales rose slightly, from 58.0% in 2010 to 59.1% in 2011. The prices of patented drug products sold by patentees, as measured by the Patented Medicines Price Index, remained on average unchanged while the Consumer Price Index rose by 2.9% Canadian prices were the fourth highest of the seven comparator countries.

Patentees reported 109 new patented drug products to the PMPRB in 2011. A total of 1282 patented drug products for human use were under the PMPRB's jurisdiction in 2011. Up to May 31, 2012, the Board approved 15 Voluntary Compliance Undertakings (VCUs). The Board issued decisions and/or orders effectively completing three matters: ratiopharm Inc.; ratio-Salbutamol HFA; and Copaxone Redetermination. Just recently, the Hearing Panel released its decision in the matter of 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 total R&D expenditures of $991.7 million, a decline of 15.8% over 2010. Members of Rx&D (Canada's Research-Based Pharmaceutical Companies) reported $901.2 million in R&D expenditures, a 9.9% decline over 2010. The ratio of R&D-to-sales also declined from 6.9% in 2010 to 5.6% in 2011, while the R&D-to-sales ratio for members of Rx&D declined from 8.2% in 2010 to 6.7% in 2011.

The *Annual Report 2011* and *Annual Report 2011: In Brief* are available on the home page of the PMPRB website. ■

Board's Proposed Rules of Practice and Procedure for Hearings

The Board's *Rules of Practice and Procedure* (Rules) 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. The Rules provide a fair opportunity for interested parties to participate in the Board's hearings.

Although the current Rules had generally fulfilled their intended purpose, the Board proceeded with amending its Rules in order that they better reflect current practices in recent proceedings and facilitate case management. The proposed Rules were drafted to codify the Board's practices and procedures and to take into consideration relevant current practices in other federal administrative tribunals and Courts.

The proposed Rules were pre-published in the *Canada Gazette*, Part 1. Interested parties had 30 days to submit comments on the proposed Rules. The comment period closed on July 16 at which time no comments had been filed. The Board will be seeking enactment of the Rules and their publication in *Canada Gazette*, Part II this Fall.

Information on the Board's proposed revised *Rules of Practice and Procedure* is available on the PMPRB website at Consultations/Notice and Comment. ■

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 advises 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 is 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. ■

Summary of May 15, 2012 Board Meeting

At its meeting, the Board approved its Annual Report for the year ending December 31, 2011. As in previous years, the report was submitted to the Minister of Health on May 31. The Minister tabled the Report in Parliament on June 20.

The Board approved the proposed amendments to the Compendium of Policies, Guidelines and Procedures. As reported in the April NEWSletter, a Notice and Comment was posted on April 16 inviting stakeholders to comment on the proposed changes by May 14. Comments received supported the proposed amendments. The updated Compendium was posted on the PMPRB website at the end June. As well, the Board received the final report of the Working Group on the application of the DIP Methodology, which is now available on the website.

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 are scheduled for September 11 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. ■

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, three VCUs were accepted by the Chairperson for the patented medicine Diflucan, Trileptal and Pariet.

Diflucan, Pfizer Canada Inc.

On April 27, 2012, the Chairperson of the Board approved a VCU submitted by Pfizer Canada Inc. regarding the price of Diflucan. Under the terms of the VCU, Pfizer Canada Inc. agreed, among other things, to reduce the price of Diflucan 2 mg/mL in order that it does not exceed the 2012 National Non-Excessive Average Price (N-NEAP) of $0.3756. Also, Pfizer has offset cumulative excess revenues received from January 1, 2005 to December 31, 2011 by making a payment to the Government of Canada in the amount of $30,951.51. In addition, to offset any excess revenues received during the period of January 1, 2012 to the date of reduction of the price of Diflucan, Pfizer will make a further payment on or before August 29, 2012 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.

Diflucan (fluconazole) 2mg/mL – DIN 891835 is an antifungal antibiotic used to treat infections caused by fungus, which can invade any part of the body.

Trileptal® (oxcarbazepine), Novartis Pharmaceuticals Canada Inc.

On May 2, 2012, the Chairperson of the Board approved a VCU submitted by Novartis Pharmaceuticals Canada Inc. regarding the price of Trileptal® (oxcarbazepine). Under the terms of the VCU, Novartis agreed, among other things, to reduce the prices of Trileptal 300 mg and 600 mg in order that they do not exceed the National Non-Excessive Average Prices (N-NEAPs) of $1.2124 and $2.4249 respectively. Novartis has offset alleged cumulative excess revenues received between April 2002 and December 31, 2011 by making a payment to the Government of Canada in the amount of $1 million.

In addition, Novartis will further reduce the price of Trileptal 300 mg and 600 mg tablets by 27% below their respective 2012 N-NEAPs until December 15, 2015 in order to offset alleged remaining excess revenues in the amount of $2,471,084.02. Any of these excess revenues and any additional excess revenues received by Novartis from January 1, 2012 to the date of the implementation of the price reduction that have not been offset by December 31, 2015 are to be offset by a further payment to the Government of Canada on or before March 2, 2016.

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

Trileptal® is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults and in children and adolescents aged 6 to 16 years.

Pariet, Janssen Inc.

On May 14, 2012, the Chairperson of the Board approved a VCU submitted by Janssen Inc. regarding the price of Pariet. Under the terms of the VCU, Janssen Inc. agreed, among other things, to reduce the national average transaction price of Pariet 20mg tablet to the 2012 National Non-Excessive Average Price (N-NEAP) before December 31, 2012. In the event that the national average price of Pariet is not within the Guidelines on December 31, 2012, Janssen will make a payment to the Government of Canada for such further amount as calculated by Board Staff, on or before March 1, 2013. Janssen has also offset the cumulative excess revenues it received from January 1, 2011 to December 30, 2011 by making a payment to the Government of Canada in the amount of $217,413.07.

Pariet (rabeprazole sodium) is indicated for the treatment of conditions where a reduction of gastric secretion is required.

VCUs are available on the PMPRB website at Voluntary Compliance Undertakings. ■

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. ■

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 any 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 Neuroscience G.P.-S.E.N.C. (now Teva Canada)	New panel struck February 2010	**Order: February 23, 2012 Application for judicial review: March 20, 2012** ***Hearing date to be announced***
Pentacel and Quadracel	Immunization	sanofi pasteur Limited	March 27, 2007	**Order: June 14, 2012 on reconsideration of the remedy as instructed by the Federal Court on July 12, 2011**
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***

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 pending**

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

Human Drug Advisory Panel Process and 2013 Schedule

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

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

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

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

The HDAP meets four times a year. The dates of the meetings for 2013 are as follows: **February 4**, **May 6**, **September 16** and **November 4**.

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

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

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

The table below provides the submission deadlines for the meetings of the HDAP in 2013.

HDAP Meeting/ Conference Call	Information	Deadline
February 4, 2013	• 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 26, 2012
	• 10 copies of patentee submission	• November 26, 2012
May 6, 2013	• 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 25, 2013
	• 10 copies of patentee submission	• February 25, 2013
September 16, 2013	• 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 10, 2013
	• 10 copies of patentee submission	• July 8, 2013
November 4, 2013	• 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 26, 2013
	• 10 copies of patentee submission	• August 26, 2013 ■

Upcoming events

September

September 11:
Quarterly Board meeting

September 13:
Michelle Boudreau to attend the Canadian Life and Health Insurance Association Roundtable discussion of Prescription Drug Coverage

September 24:
HDAP meeting

September 25:
Michelle Boudreau to speak at the 2nd Annual Canadian Healthcare Reimbursement Day in Ottawa

October

October 18-19:
Pharmaceutical Pricing and Reimbursement Information Network Meeting in Brussels, Belgium

November

November 7-9:
Michelle Boudreau to speak at the Annual Health Insurance Invitational Forum in Cambridge, ON

November 8–10:
Mary Catherine Lindberg to attend the 2012 Canadian Health Policy Assembly in Banff, AB.

November 13–14:
Gregory Gillespie to speak at the 11th Annual Market Access Summit in Toronto

December

December 13–14:
Quarterly Board meeting

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