Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 14, Issue No. 3, July 2010

Inside...

Since our last issue...

Our recent key events

May 6:	Barbara Ouellet delivered a presentation, *A Modern Regulator for a Changing Industry*, at the Drug Patents in Canada conference in Toronto.
May 10:	The HDAP held its quarterly meeting.
May 11:	Greg McComb presented the results of an NPDUIS study, *Public Drug Plan Professional Fees: A Cost-Driver Analysis*, at the 2010 Annual Conference of the Canadian Association for Health Services and Policy Research (CAHSPR) in Toronto.
May 13:	The Board held its quarterly meeting.
May 26–28:	Mary Catherine Lindberg and Barbara Ouellet participated in the Northwind Professional Institute's 2010 Life Sciences Invitational Forum held in Cambridge, Ontario.
May 27:	The NPDUIS Steering Committee held a teleconference call in which PMPRB Staff provided a status update on current research projects and announced the launch of a secure network to provide Steering Committee members with access to NPDUIS-related information.
June 15:	Barbara Ouellet delivered a presentation, *A Responsive Regulator in a Time of Change*, at The Canadian Institute's 4th Annual Drug Pricing & Reimbursement in Toronto.
June 16:	The 2009 PMPRB Annual Report was tabled in Parliament. Mary Catherine Lindberg announced the appointment of a new Executive Director, Michelle Boudreau, who will be joining the PMPRB on August 30, 2010.
June 18:	The Board issued a Notice and Comment seeking comments on its proposal to approve a Voluntary Compliance Undertaking in respect to the price of the patented medicine FASLODEX, on or before September 17, 2010.
July 22:	The NPDUIS Steering Committee held a teleconference call in which PMPRB Staff provided a status update on current research projects and discussed plans for a fall meeting in Ottawa. ■

PMPRB speeches and presentations are available on the Web site at Publications/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 Web site.

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.

ISSN 1920-3705

News from the Vice-Chairperson

As I take on new responsibilities delegated to me by the departure of Dr. Brien Benoit as Chair, I would like to take a moment to thank Dr. Benoit for his many lasting contributions to the PMPRB. His dedication and hard work during our lengthy stakeholder consultations over the new Guidelines have given the Board a solid foundation to build on. His term saw considerable changes in the industry, but under his leadership, the Board has been able to set a course that benefits the industry, the Board, and Canadians as a whole.

Mary Catherine Lindberg, Vice-Chairperson

I would also like to acknowledge the energy and dedication of Barbara Ouellet, who retired as Executive Director in June after a long and successful career in the public service, including five years at the PMPRB. Her successor, Michelle Boudreau, joins the PMPRB with a long list of accomplishments at Health Canada and an impressive background that includes intellectual property law and pharmacy. We are delighted to welcome her aboard.

The tabling of the PMPRB's Annual Report in Parliament on June 16, 2010, was an opportunity to remind Members of Parliament and all Canadians about the important role of the PMPRB in ensuring that Canadians do not pay excessive prices for patented medicines. The success of this organization in meeting the mandate that Parliament has given it is clear.

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

Mary Catherine Lindberg

Senior Staff

Executive Director:
Michelle Boudreau
(effective August 30, 2010)

Director, Regulatory Affairs and Outreach:
Ginette Tognet

Director, Policy and Economic Analysis:
Gregory Gillespie

Director, Corporate Services:
Marian Eagen

Director, Board Secretariat and Communications:
Sylvie Dupont

General Counsel:
Martine Richard

Comings and Goings

A few new employees have joined us since the last NEWSletter. Tom Kloppenburg and Carol McKinley are the newest members of the Board Secretariat and Communications Branch. Mark Leger recently joined the Corporate Services Branch as the new Manager of Information Management. ■

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, from June 13 to 19, the NPSW celebrated the theme "Together, shaping Canada's future."

The PMPRB celebrated NPSW by distributing small mementos to all employees. On June 14, we held a delicious lunch. Everyone enjoyed the meal and the opportunity to mingle informally with their colleagues.

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

Barbara Ouellet celebrates her retirement from the Public Service at a reception on June 18.

New Executive Director

The Board is very pleased to welcome Michelle Boudreau to the position of Executive Director of the PMPRB. Ms. Boudreau will officially begin her term on August 30, 2010.

Michelle Boudreau comes to the PMPRB from Health Canada where she was Director General of the Natural Health Products Directorate since September 2008. She has extensive experience in the development of government policy. She worked on legislative and regulatory changes in the area of copyright policy at Canadian Heritage and in the development of patent and biotechnology policy at Industry Canada. Ms. Boudreau was legal counsel with the Health Canada Legal Services Unit and Director of the Compliance and Enforcement Division within the Health Products and Food Branch Inspectorate. She also worked as Executive Advisor to the Deputy Minister of Health.

Ms. Boudreau holds a Bachelor of Science in Pharmacy from Dalhousie University and a Bachelor of Laws from the University of Ottawa. ■

2009 Annual Report

The PMPRB Annual Report for the year ending December 31, 2009, was tabled by the Minister of Health with the Clerks of the House of Commons and Senate on June 16, 2010.

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 spending on pharmaceutical R&D spending.

In 2009, sales of patented drugs in Canada increased by 2.8% to $13.3 billion, representing 62.4% of all drug sales, a slight decrease from 2008. Prices of patented drugs (as measured by the Patented Medicines Price Index) rose on average by 0.3% in 2009, while the Consumer Price Index was also 0.3% during the same period. Canadian prices ranked third of the seven comparator countries, lower than the U.S. and Germany.

Patentees reported 81 new patented drug products to the PMPRB in 2009, including 22 new active substances. A total of 1,177 patented drug products for human use were under the PMPRB's jurisdiction in 2009. As of the date of the release of the 2009 Annual Report, investigations were ongoing into the prices of 90 patented drugs.

While the vast majority of prices remained within the Board's Guidelines, the Board approved, to the end of May 2010, 17 Voluntary Compliance Undertakings worth more than $43 million in order to reduce prices and reimburse excess revenues. The Board also completed five price hearings and issued two Notices of Hearing. Decisions are pending in three matters, and four proceedings are ongoing.

Spending on pharmaceutical R&D continued to decline in 2009. Patentees reported spending $1.2 billion on R&D, a drop of 2.9% over 2008. Members of Rx&D (Canada's Research-Based Pharmaceutical Companies) accounted for 89.1% of all reported R&D expenditures. The ratio of R&D investment to sales also declined to 7.5% from 8.1% in 2008, while the R&D-to-sales ratio for members of Rx&D was 8.2%, down from 8.9% in 2008.

The Annual Report is available on the PMPRB Web site Home page. ■

May 13 Board Meeting

The Board met on May 13, 2010, to approve the 2009 Annual Report. Board Members thanked Dr. Benoit for his hard work and leadership as his term as Chairman came to an end.

The Board's next meeting is scheduled for September 16, 2010.

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 Web site at About 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.

In the last quarter, four VCUs were accepted for: Busulfex, Dicetel, Levemir and Adenoscan.

Busulfex, Otsuka America Pharmaceutical Inc.

On June 15, 2010, the Vice-Chairperson approved the VCU submitted by Otsuka America Pharmaceutical Inc. for the medicine Busulfex. In order to comply with the PMPRB Guidelines, Otsuka agreed to offset excess revenues received during the period of March 8, 2008, to December 31, 2009, by making a payment to the Government of Canada in the amount of $22,092.48.

Busulfex is indicated for use in combination with other chemotherapeutic agents and/or radiotherapy as a conditioning regimen prior to hematopoietic progenitor cell transplantation. Otsuka began selling Busulfex following acquisition of the product on March 7, 2008.

Dicetel, Solvary Pharma

On May 13, 2010, the Chairman approved the VCU submitted by Solvay Pharma Inc. for the medicine Dicetel. Under the terms of the VCU, Solvay Pharma offset cumulative excess revenues received from January 1, 2008, to December 31, 2009, by making a payment to the Government of Canada in the amount of $31,287.32. Solvay will make an additional payment to the Government of Canada for any excess revenues received from January 1, 2010, to the date of the acceptance of this VCU as calculated by Board Staff, or before August 30, 2010.

Dicetel (pinaverium bromide) is indicated for the treatment and relief of symptoms associated with irritable bowel syndrome (IBS), abdominal pain, bowel disturbances and intestinal discomfort; as well as the treatment of symptoms related to functional disorders of the biliary tract.

Levemir, Novo Nordisk

On May 8, 2010, the Chairman approved the VCU submitted by Novo Nordisk Canada Inc. Under the terms of the VCU, Novo Nordisk offset cumulative excess revenues received from January 3, 2006, to December 31, 2009, by making a payment to the Government of Canada in the amount of $6,035,903.54. Novo Nordisk Canada also made an additional payment to the Government of Canada for excess revenues received from January 1 to March 31, 2010, based on its filing of price and sales data for the said period in the amount of $432,336.79.

Levemir is a soluble, long-acting basal insulin analogue with a flat and predictable action profile with a prolonged duration of action for blood glucose control. It is supplied as an injectable solution in a 3 mL cartridge in a strength of 100 IU/mL of insulin detemir in pack sizes of 5 cartridges.

Adenoscan, Astellas Pharma Canada Inc.

On May 8, 2010, the Chairman of the Board approved the VCU submitted by Astellas Parma Canada Inc. for the medicine Adenoscan. Under the terms of the VCU, Astellas offset the cumulative excess revenues received from 1996 to August 4, 2009, in the amount of $34,545.32 by making a payment to the Government of Canada.

Adenoscan (adenosine injection) is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.

The prices of these drugs will remain under the Board's jurisdiction for the duration of their respective patents. ■

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.

Email 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, please send your email address to pmprb@pmprb-cepmb.gc.ca

Requests for publications and/or additional information concerning subscriptions can be made to Elaine McGillivray at elaine@pmprb-cepmb.gc.ca.

Readers are reminded to send all updates to their contact information to the above address. ■

Hearings – Update

The PMPRB's regulatory mandate is to ensure that prices at which patentees sell their patented medicines 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 multitude sclerosis to reduce the frequency of relapses	Teva Neuroscience G.P.-S.E.N.C.	May 8, 2006	**Hearing dates: Oct. 4–5, 2010**
Penlac	Part of a comprehensive nail management program in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement	sanofi-aventis Canada Inc.	March 26, 2007	**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.	July 18, 2008	**Board decision pending**

Patentee	Issue	Date of Notice of Hearing	Status
Apotex Inc.	Failure to File (jurisdiction)	March 3, 2008	**Ongoing**
ratiopharm Inc.	Failure to File (jurisdiction)	August 28, 2008	**Board decision pending**
Sandoz Canada Inc.	Failure to File (jurisdiction)	March 8, 2010	**Hearing dates: Dec. 6–8, 2010**

Redetermination of the Copaxone Matter

The Board issued a Notice of Hearing in the matter of Copaxone on May 8, 2006. After having heard the matter, the Hearing Panel issued its decision and reasons on February 25, 2008, and its Order on May 12, 2008. The Respondent filed an application for judicial review with the Federal Court. In its decision of November 12, 2009, the Federal Court set aside the Board's decisions and returned the matter to the Board for redetermination, preferably by a different panel.

Accordingly, the matter was remitted and a second panel was struck to hear the matter. Counsel to Teva and Board Staff were so informed on February 4, 2010.

On April 9, 2010, Teva submitted a Voluntary Compliance Undertaking (VCU) for consideration by the Chairperson. Board Staff objected to having the Chairperson consider the VCU and argued that the (second) Panel should consider the VCU. Given this dispute, the Panel was not made privy to the content of the VCU and directed that the parties make written submissions on the issue.

After considering the written submissions, the Panel determined that the Chairperson would consider the VCU. Parties were then asked to file written submissions in support of their positions on the VCU. On May 18, 2010, the term of the Chairperson expired, and since a new Chairperson had not yet been appointed, subsection 93(3) of the *Patent Act* provides that the Vice-Chairperson has all the powers and functions of the Chairperson during the vacancy, and as such, the Vice-Chairperson considered the appropriateness of the VCU.

On June 24, 2010, the Vice-Chairperson declined the VCU. The redetermination of this case is scheduled to be held October 4 and 5, 2010.

Supplementary Order in the Matter of Shire Canada Inc. and the Medicine Adderall XR

On August 27, 2008, the Hearing Panel issued an Order for the price reduction of Adderall XR and the offset of excess revenues accrued by Shire Canada from the sale of the medicine.

Shire complied with the Board Order by reducing the price of Adderall XR and offsetting excess revenues received for the period of September 12, 2002, to December 31, 2007, by making a payment of $5,622,863.63 to the Government of Canada.

As for excess revenues accrued for the period of January 2008 to September 15, 2008, the date on which the price reduction of Adderall XR came into effect, Shire was ordered to pay Her Majesty in Right of Canada a further amount equal to the amount of the excess revenues estimated by the Board to have been derived by Shire from the sale of Adderall XR in its 5, 10, 15, 20, 25 and 30 mg strengths at excessive prices and to make the payment within 30 days of receipt of a notification from the Board of its estimate of excess revenues based on the information filed with the Board.

Shire subsequently requested that the amount it owed for the period from January 2008 to September 12, 2008, when the price reductions came into effect for the 5, 10, 15 and 20 mg strengths, be reduced to reflect credits that it provided for stock of said strengths sold before September 12, 2008, at the price which was found to be excessive, even though these credits were given after September 12, 2008.

Board Staff calculated the amount of excess revenue owing, net of the credits, for the period January 1, 2008, to December 31, 2008. Furthermore, Board Staff and Shire reached an agreement with regard to further calculations of excess pricing and requested that same be reflected in a Supplementary Order.

As a result, the Panel issued a Supplementary Order on May 10, 2010, requiring Shire to pay the total sum of $544,931.22 to the Government of Canada, with which Shire complied.

Matter Before the Supreme Court of Canada

On April 22, 2010, Celgene Corporation was granted leave to appeal to the Supreme Court of Canada in the Thalomid matter. After a hearing in August 2007, the Board issued its decision in January 2008 asserting its jurisdiction over the price of Thalomid. That decision was appealed to the Federal Court and then to the Federal Court of Appeal, which upheld the Board decision. Celgene Corporation was granted leave to appeal to the Supreme Court of Canada. The hearing has been set for November 10, 2010. ■

Notice and Comment on the Price of the Medicine FASLODEX

On June 18, 2010, the Board issued a Notice and Comment on the price of the patented medicine FASLODEX. The purpose of a Notice and Comment is to provide Ministers of Health in the provinces and territories of Canada and other interested persons with an opportunity to make submissions on the appropriateness of accepting a Voluntary Compliance Undertaking with respect to the price proposed by a patentee for a specific patented medicine.

Interested parties have until September 17, 2010, to submit their comments to the Board. For more details, including contact information for filing a submission, see the PMPRB Web site at What's New.

FASLODEX Notice and Comment Timetable

Patented Drug Product	Indication / Use	Patentee	Notice and Comment	Submission Deadlines
FASLODEX	Hormonal treatment of locally advanced or metastatic breast cancer in post-menopausal women, regardless of age, who have disease progression following prior endocrine therapy	AstraZeneca	Issued June 18, 2010 Published in *Canada Gazette* July 17, 2010	**Interested parties:** September 17, 2010 **Board Staff and AstraZeneca – in response to written submissions:** October 1, 2010 ■

New Patented Medicines Reported to the PMPRB

New drug products first sold in 2010 will be reviewed based on the Guidelines implemented on January 1, 2010. As of June 30, 2010, a total of 28 new drug products (DINs) were reported to the PMPRB (representing 22 medicines). Information on these patented drug products can be found on the PMPRB Web site at Regulatory/Patented Medicines/New Medicines Introduced in/2010.

New patented drug products come under the PMPRB's jurisdiction once they are both patented and sold in Canada. If a patented drug product was first sold during the patent pending period (after the date when the patent was laid open for public inspection and before patent grant), the PMPRB's policy is to review the price of the product back to the date of first sale. ■

Human Drug Advisory Panel Process and 2011 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 that may affect the analysis on which its recommendations are based.

The HDAP is composed of six 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. Mitchell Levine, 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 Web site at Regulatory.

The HDAP meets four times a year. The dates of the meetings for 2011 are as follows: February 7, May 16, September 8 and November 7.

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 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 of the Compendium, Submissions by Patentees on Level of Therapeutic Improvement.

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 2011.

HDAP Meeting/ Conference Call	Information	Deadline
February 7, 2011	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 25, 2010
	10 copies of patentee submission	November 25, 2010
May 16, 2011	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	February 2, 2011
	10 copies of patentee submission	March 2, 2011
September 8, 2011	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	May 25, 2011
	10 copies of patentee submission	June 27, 2011
November 7, 2011	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 25, 2011
	10 copies of patentee submission	August 25, 2011 ■

Report on New Patented Drugs – Pristiq

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drug products conducted by Board Staff for purposes of applying the Board's pre-2010 Guidelines for all new active substances introduced in Canada after January 1, 2002.

Brand Name: Pristiq

Generic Name: (*desvenlafaxine succinate*)

DIN: 02321092 (50 mg tablet)
02321106 (100 mg tablet)

Patentee: Wyeth Pharmaceuticals

Indication – as per product monograph: For the symptomatic relief of major depressive disorder.

Date of Issuance of First Patent Pertaining to the Medicine: October 17, 2006

Notice of Compliance: February 4, 2009

Date of First Sale: March 5, 2009 (DIN 02321092)
March 6, 2009 (DIN 02321106)

ATC Class: N06AX23
Nervous system; psychoanaleptics; antidepressants; other antidepressants.

Application of the Guidelines

Summary

The introductory prices of Pristiq were found to be within the pre-2010 Guidelines because the cost of therapy did not exceed the cost of therapy of existing drug products in the therapeutic class comparison and did not exceed the range of prices of the same drug products in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) in which Pristiq was sold.

Scientific Review

Pristiq is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Pristiq be classified as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable existing drug products).

The Therapeutic Class Comparison (TCC) test of the pre-2010 Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drugs that treat the same disease or condition. Comparators are generally selected from among existing drug products in the same 4th level of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system that are clinically equivalent in addressing the approved indication. See the PMPRB's *Compendium of Guidelines, Policies and Procedures "up to 2009"* for a more complete description of the Guidelines and the policies on TCCs.

The HDAP recommended venlafaxine (Effexor XR), trazodone (Desyrel), mirtazapine (Remeron RD), buproprion (Wellbutrin) and duloxetine (Cymbalta) as the appropriate comparators to Pristiq. They all share the same 4th level ATC class and the same indication as Pristiq. There were no comparative trial data to support the inclusion of drug products outside the 4th level ATC.

The pre-2010 Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The recommended comparable dosage regimens for Pristiq and the comparable drug products were based on the respective product monographs and supported by clinical literature.

Price Review

Under the pre-2010 Guidelines, the introductory price of a category 3 new drug product will be presumed to be excessive if it exceeds the price of all the comparable drug products based on the TCC test or if it exceeds the range of prices of the same drug product sold in the seven countries listed in the Regulations.

The introductory prices of Pristiq were within the pre-2010 Guidelines as the cost per treatment did not exceed the cost per treatment of the comparable drug products as shown in the following table.

Introductory Period (March to June 2009) – Pristiq 50 mg per tablet and 100 mg per tablet

Brand Name (Generic Name)	Strength	Dosage Regimen (per day)	Unit Price	Cost per Treatment (per day)
Pristiq (desvenlafaxine succinate)	50 mg/tablet	1 tablet	$2.5700[1]	$2.5700
Desyrel Dividose (trazodone HCl)	150 mg/tablet	2 2/3 tablets	$0.5812[2]	$1.5499
Remeron RD (mirtazapine)	45 mg/tablet	1 tablet	$1.1700[2]	$1.1700
Wellbutrin SR (bupropion)	150 mg/tablet	1 tablet	$0.8260[2]	$0.8260
Wellbutrin XL (bupropion)	150 mg/tablet	1 tablet	$0.5190[2]	$0.5190
Effexor XR (venlafaxine)	75 mg/capsule	3 capsules	$1.6110[2]	$4.8330
Effexor XR (venlafaxine) + Effexor XR (venlafaxine)	150 mg/capsule + 75 mg/capsule	1 capsule + 1 capsule	$1.7039[2] + $1.6110[2]	$3.3149
Cymbalta (duloxetine)	60 mg/capsule	1 capsule	$3.5600[2]	$3.5600
Pristiq (desvenlafaxine succinate)	100 mg/tablet	1 tablet	$2.5700[1]	$2.5700
Desyrel Dividose (trazodone HCl)	150 mg/tablet	4 tablets	$0.5812[2]	$2.3248
Remeron RD (mirtazapine)	30 mg/tablet	2 tablets	$0.7800[2]	$1.5600
Remeron (mirtazapine)	30 mg/tablet	2 tablets	$1.2400[2]	$2.4800
Wellbutrin SR (bupropion)	150 mg/tablet	2 tablets	$0.8260[2]	$1.6520
Wellbutrin XL (bupropion)	300 mg/tablet	1 tablet	$1.0380[2]	$1.0380
Cymbalta (duloxetine)	60 mg/capsule	1 capsule	$3.5600[2]	$3.5600
Remeron RD (mirtazapine) + Remeron RD (mirtazapine)	45 mg/tablet + 15 mg/tablet	1 tablet + 1 tablet	$1.1700[2] + $0.3900[2]	$1.5600
Effexor XR (venlafaxine)	150 mg/capsule	2 capsules	$1.7039[2]	$3.4078

Sources:
1 PPS Pharma, 2010
2 Association québécoise des pharmaciens propriétaires, 2009

In 2009, both strengths of Pristiq were sold in one country listed in the Regulations, namely, the United States. In compliance with the Guidelines, the prices of Pristiq in Canada did not exceed the prices of the same drug product in this country.

The publication of Summary Reports is part of the PMPRB's commitment to make its price review process more transparent.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by the HDAP for the purpose of carrying out the PMPRB's regulatory mandate, which is to review the prices of patented drug products sold in Canada to ensure that such prices are not excessive.

The PMPRB reserves the right to exclude from the therapeutic class comparison test any drug product it has reason to believe is being sold at an excessive price.

In Summary Reports under the pre-2010 Guidelines, the PMPRB refers to the publicly available prices of comparators, provided that such prices are not more than 10% above a non-excessive price, in which case no price will be made available. Publication of these prices is for information only and should not be construed as indicating that the public prices are considered to be within the pre-2010 Guidelines.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than stated and is not to be interpreted as an endorsement, recommendation or approval of any drug product, nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner.

This report, including the references, is available on the PMPRB Web site at Regulatory/Patented Medicines/Reports on New Patented Drugs for Human Use/Pristiq ■

Upcoming Events

September

September 9 (to be confirmed): NPDUIS Steering Committee teleconference call

September 15: HDAP meeting

September 16: Board meeting

October

October 4–5: Redetermination Hearing in the matter of Teva Neuroscience and the medicine Copaxone

Market Access Canada Summit, Toronto

October 6–8: Market Access World USA conference, Washington, D.C.

October 7: Sedgwick County Health Care Roundtable Seminar, Wichita, Kansas

October 27: Risk Sharing Americas 2010

October 30: October NEWSletter

November

November 1: CIHI's NPDUIS Database Advisory Group meeting

November 2: NPDUIS Steering Committee meeting in Ottawa

November 4–5: 9th Annual Conference on Market Access, Toronto

November 4–5: 9th Annual Forum on Pharma Patents, Toronto

November 4–5: DIA Annual Canadian Meeting, Ottawa

November 17: HDAP meeting

November 23–24: Gestion des risques associés à la conformité réglementaire dans le domaine pharmaceutique, Montréal

December

December 2–3: Canadian Pharmaceutical Pricing and Reimbursement Conference, Toronto

December 6–8: Hearing in the matter of Sandoz Canada Inc.

December 9: Board meeting

Upcoming Events are available on the PMPRB Web site at Consultations/Events ■

What's New @ PMPRB

Readers are invited to check our Web site for the latest information on our activities!

To order our publications, call our toll-free number 1-877-861-2350 or email us at elaine@pmprb-cepmb.gc.ca

Comments

We want to hear from you. If you have any comments, ideas or suggestions on topics you wish to see covered in the NEWSletter, please let us know.

Mailing List

To ensure that our mailing list is up to date and that we better serve our readers, please take a few moments to complete this form or email us your business card.

Name: _____

Title/Organization: _____

Address: _____

Postal Code: _____

Telephone: _____ Fax: _____

Email: _____

Please return the completed form to the PMPRB:

Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Email: elaine@pmprb-cepmb.gc.ca

Fax: 613-952-7626