Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 12, Issue No. 1, January 2008

Inside...

The PMPRB turns 20

It started with

Prior to 1987, Canada sought to moderate the prices of patented medicines by means of compulsory licenses to increase competition. With the 1987 amendments to the *Patent Act*, Canada strengthened patent protection of pharmaceutical products and created a quasi-judicial tribunal, the Patented Medicine Prices Review Board, as the "consumer protection" pillar of the patent law drug reform.

Stakeholders

Our stakeholders are consumer groups; Health Ministers; the pharmaceutical industry; and others, including health professionals, academics, and everyone who has an interest in drug prices.

Patentees

The *Patent 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.

Mandate

It ensures that prices charged by patentees for their patented medicines sold in Canada are not excessive, thereby protecting consumer interests; and reports on pharmaceutical trends of all medicines, and on R&D spending by pharmaceutical patentees, thereby contributing to informed decision and policy making.

The PMPRB at a Glance

Faced with the ever evolving complexities of pharmaceuticals management in Canada, the PMPRB has risen to the challenge and sought to engage its stakeholders on several issues over the last two decades. The Board has just released a Discussion Paper seeking feedback on Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines. The Board looks forward to continued transparent and open exchanges with all its stakeholders in the accomplishment of its mandate. ■

Celebrations of the 20th Anniversary of the PMPRB. From our Photo Gallery:

Gail Kohlmeyer, Compliance and Enforcement and Ginette Tognet, Director of Compliance and Enforcement

Robert Squires, Policy and Economic Analysis

Dr. Brien Benoit, Chairperson of the Board

Thomas (Tim) Armstrong, Member of the Board and Mary Catherine Lindberg, Vice-Chairperson of the Board

Matthew Bondy, Policy and Economic Analysis

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 charged by patentees for patented medicines sold in Canada are not excessive, thereby protecting consumers and contributing to Canadian health care.
Reporting - To report on pharmaceutical trends and on R&D spending by pharmaceutical patentees, thereby contributing to informed decisions and policy making.

Brien G. Benoit, MD
Chairperson

Message from the Chairperson

2007 has been a busy period for the PMPRB. Our attention was mainly focused on our regulatory mandate. From its inception, the PMPRB has been largely able to carry out its mandate with limited recourse to public hearings. This fact is not a sign of any reluctance on the part of the PMPRB to apply the law, but rather a measure of the effectiveness of the Board's Excessive Price Guidelines (Guidelines) and its Voluntary Compliance Policy.

The current Guidelines date from 1994. Initiatives such as the *Transparent Drug System for Patients Act, 2006*, in Ontario, amendments to the *Act respecting prescription drug insurance and other legislative provisions*, in Quebec (2005), and the federal/provincial/territorial (F/P/T) National Pharmaceuticals Strategy, have brought renewed attention to drug prices and cost trends. At the same time, the PMPRB was hearing concerns from its stakeholders about high introductory drug prices, among other issues. To respond to these concerns, the Board initiated a process to review its Guidelines, including consulting with key stakeholders as required by the *Patent Act*. As a result of their response, significant analytical work and face-to-face consultations took place in 2006. In 2007, there was further work on potential options for changing the Guidelines, along with bilateral consultations with industry, governments and consumers, with a view to completing the review of the Guidelines in the fall of 2008. The Board has just released its Discussion Paper – Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines on January 31 and is looking forward to receiving comments.

Also of importance in 2007 was the decision of the Federal Court of Canada in March 2007 in the LEO Pharma matter. This decision raised other concerns that the *Patented Medicines Regulations, 1994* (Regulations) and current Guidelines may create disincentives for patentees to offer various benefits to customers. The PMPRB is consulting on options to address these concerns in its Discussion Paper.

The PMPRB also pursued its reporting activities, and continued its work in collaboration with the Canadian Institute for Health Information (CIHI) and participating F/P/T drug plans to produce analyses and reports under the National Prescription Drug Utilization Information System (NPDUIS). As well, it continued the work it undertook at the request of the F/P/T Ministers of Health in the context of the National Pharmaceuticals Strategy, to monitor and report on non-patented prescription drug prices.

The PMPRB remains committed to fairness and transparency in the fulfillment of its mandate, as well as to actively engaging the views of its stakeholders. We look forward to a busy and productive year in 2008. ■

The PMPRB and the Government of Canada Workplace Charitable Campaign 2007 Results

"Building Bridges a Million Different Ways"

CONGRATULATIONS TO ALL

Once again, we are happy and proud to announce that the PMPRB has exceeded its goal by 20%.

Of course, this was ultimately a team effort. Congratulations to all who made a difference through generosity and compassion. You are to be commended!

We take this opportunity to thank Elaine McGillivray, our campaign leader. For years now, Elaine has been leading the PMPRB's successful campaigns. Once again, Elaine has shown tremendous commitment and devotion to the care of others. Well done! ■

Elaine McGillivray,
our team leader!

Since our last issue...

Our recent key events

November 14-16:	Barbara Ouellet attended the Annual Senior Financial Officers' Conference, in Montebello.
November 28:	The Board resumed its hearing into the matter of sanofi pasteur Limited and the medicines Quadracel and Pentacel.
December 3-4:	Barbara Ouellet gave a presentation at the Life Sciences Forum, in Montebello.
December 5:	Ginette Tognet gave a presentation at the Market Access Conference, in Toronto.
December 5:	The Human Drug Advisory Panel held a quarterly meeting by teleconference.
December 7:	The PMPRB marked its 20th Anniversary.
December 12-13:	The Board held its last meeting of the year. A summary of the Minutes are available on page 9.

2008

January 16-18:	The Board resumed its hearing into the matter of sanofi-aventis Canada Inc. and the medicine Penlac Nail Lacquer.
January 21:	The Board issued its decision on the Board's jurisdiction in the matter of the Celgene Corporation and the medicine Thalomid. The decision is available on our Web site under Hearings; Thalomid.
January 29:	Barbara Ouellet gave a presentation at the Telfer School of Management (University of Ottawa), as part of the Healthcare System Management Seminar Series.
January 31:	The Board released its Discussion Paper – Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines, for comments by March 3, 2008.
February 7:	Dr. Benoit and Barbara Ouellet appeared before the Standing Committee on Health in the context of its review on post-marketing surveillance of pharmaceuticals.

Comings and Goings

The PMPRB wishes best of luck and success to Ron Corvari, Director of Policy and Economic Analysis Branch and to Ravinder Dhillon, Director of Corporate Services Branch. Both have accepted positions to take on new challenges at the Competition Bureau at Industry Canada, and at the Canadian International Development Agency respectively. We take this opportunity to thank them both for their valuable contribution to the PMPRB.

Upon completion of her Financial Officer Recruitment Development (FORD) assignment with the Corporate Services Branch, Candice Popkie resumed her duties at Health Canada. Nadia Persaud has now joined this Branch to ensure continuity.

Renée Bergeron, left the Secretariat to join Heritage Canada in Vancouver. We wish her every success in her new endeavours.

We recently welcomed Marian Eagen as Director, Corporate Services Branch. Prior to joining the PMPRB team, Marian was Executive Director, Business Planning and Systems Management in the Human Resources Directorate at Health Canada. She brings with her over 12 years of private sector experience and 13 years of experience in the federal public service, including central agency and head office branch operations.

Luigi Formica, economist, formerly with Brogan Inc., has joined the NPDUIS team.

Suzanne Paré has returned to the Policy and Economic Analysis Branch, following a secondment at Health Canada. Welcome back!

Meaghan Massia-Lahey has joined the Legal Branch as Legal Assistant.

Best of luck everyone! ■

Update on Hearings

The PMPRB's regulatory mandate is to ensure that patentees' prices of patented medicines are not excessive, thereby protecting consumer interests and contributing to Canadian health care. 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.

Completed Proceedings

Thalomid, Celgene Corporation

On August 23, 2007, the Board heard the parties on the matter of its jurisdiction to regulate the price of the medicine Thalomid, a medicine sold in Canada under Health Canada's Special Access Programme.

The Panel issued its decision on January 21, 2008, and determined that it has jurisdiction to regulate the price of Thalomid. The patentee has 30 days from the date of issuance of the Panel's decision to appeal before the Federal Court.

The Panel's decision is available on our Web site under Regulatory; Hearings; Thalomid.

Ongoing Hearings

Quadracel – Pentacel, sanofi pasteur Limited

On November 28, 2007, the Board was scheduled to hear evidence in the matter of Quadracel – Pentacel. At the request of the Respondent, the proceeding was adjourned pending a hearing by the Federal Court of the Judicial Review Application filed by the Respondent with respect to the Hearing Panel's decision on the Respondent's Motion for an Order that Blake Cassels & Graydon (Blakes) step down as counsel to the Hearing Panel in this proceeding. The Federal Court heard sanofi pasteur's application on February 4, 2008 and its decision is pending.

The Hearing Panel's decision of November 23, 2007, is available on our Web site, under Regulatory; Hearings; Quadracel – Pentacel.

Penlac, sanofi-aventis Canada Inc.

Parties presented evidence to the Hearing Panel in this matter on January 16 to 18, 2008. Two additional sessions are being scheduled to complete the evidentiary portion of this proceeding and to hear final arguments.

Strattera, Eli Lilly Canada Inc.

A hearing date has yet to be scheduled in this matter.

Decisions Pending

The Board is scheduled to release its decisions in three matters: Shire BioChem Inc. and the medicine Adderall XR; Janssen-Ortho Inc. and the medicine Concerta; and Teva Neuroscience G.P.-S.E.N.C. and the medicine Copaxone.

Upon issuance of the Board's decisions in these matters, they will be posted on our Web site and the Board Orders will be filed with the Federal Court of Canada.

The Board's hearing calendar will be updated as soon as hearing dates have been confirmed. ■

Adderall XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD").

Concerta is indicated for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD").

Copaxone 20 mg/1.0 mL syringe is a new formulation of an existing compound (glatiramer acetate) indicated for use in ambulatory patients with Relapsing-Remitting Multitude Sclerosis to reduce the frequency of relapses.

Penlac is indicated as part of a comprehensive nail management program in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement.

Pentacel 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. It is sold in Canada in the form of a reconstituted product for injection combining one single dose vial of *Act HIB* (Lyophilized powder for injection) and one single (0.5 mL) dose ampoule of Quadracel (suspension for injection).

Quadracel 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.

Strattera is indicated for the treatment of Attention Deficit hyperactivity Disorder (ADHD) in children 6 years of age and over, adolescents and adults.

Further information on hearings is available on our Web site under Regulatory; Hearings.

All requests for information on hearings can also be addressed to the Secretary of the Board:

Sylvie Dupont
Secretary of the Patented Medicine Prices Review Board
Standard Life Centre, 333 Laurier Avenue West, Suite 1400
Ottawa ON K1P 1C1

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Discussion Paper-Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines

The Board is committed to working with its stakeholders to resolve the issues discussed during the ongoing review of the Excessive Price Guidelines (Guidelines), as well as those arising from the Federal Court of Canada decision in *LEO Pharma*. In keeping with this commitment, the Board has just released a document for public consultation entitled: the Excessive Price – Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines.

The purpose of the discussion paper is to seek written feedback from all stakeholders on both proposed changes to the Guidelines stemming from the Board's ongoing review, as well as on a range of options to address the issues arising from the Federal Court decision.

Written comments should be sent to Ms. Sylvie Dupont, Secretary of the Board, no later than March 3, 2008, at sdupont@pmprb-cepmb.gc.ca, or by mail at PMPRB, Box L40, Standard Life Centre, 333 Laurier Avenue West, Suite 1400, Ottawa, Ontario, K1P 1C1.

Your feedback is important in this process. It will help guide the Board's eventual decision-making on the proposed changes and options. All comments will be considered in the Board's deliberations, with decisions expected on the various proposals and options in the Spring of 2008.

As with previous consultations, all submissions received by the Board will be posted on our Web site as part of the PMPRB's commitment to openness and transparency. ■

All stakeholders are welcome to provide comments on the Discussion Paper, which can be found on the Board's Web site under Consultations.

Voluntary Compliance Undertaking

Under the Compliance and Enforcement Policy, patentees are given an opportunity to submit a Voluntary Compliance Undertaking (VCU) when Board Staff concludes, following an investigation, that the price set forth by the patentee for a patented medicine sold in Canada appears to have exceeded the Board's Excessive Price Guidelines (Guidelines).

A Voluntary Compliance Undertaking is a written undertaking by a patentee to adjust its price to conform to the Excessive Price Guidelines.

Dovobet, LEO Pharma Inc.

On January 19, 2008, the Chairperson of the Board approved a VCU submitted by LEO Pharma Inc., for the medicine Dovobet. This VCU comes as a result of the Board's recent Order requiring LEO Pharma to price Dovobet at a non-excessive level, and to offset the excess revenues derived from the sale of Dovobet in Canada from 2002 through to December 2005, by making a payment to the Government of Canada in the amount of $3,736,398.71.

For the period January 1, 2006 through December 31, 2006, Board Staff calculated the maximum non-excessive (MNE) price in accordance with the Board Order. The 2006 MNE price is $1.2963. In 2006, the average transaction price (ATP) of Dovobet exceeded the 2006 MNE price, resulting in excess revenues of $870,425.68.

To offset these excess revenues, LEO Pharma made a payment to the Government of Canada. ■

Dovobet is a dermatological drug administered for bringing psoriasis under control.

Patentees' Reporting on Research and Development (R&D) and Sales

The purpose of this article is to provide additional guidance on patentees´ requirements, under the *Patented Medicines Regulations, 1994* (Regulations), for the upcoming filing date of March 3, 2008. Please note that this clarification pertains to current filing requirements and is unrelated to any proposed amendments to the Regulations currently under consideration.

The *Patent 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.

As a result, all patentees (patent holders, licensees or others) are required to file Form 3 information on Revenues and R&D Expenditures. 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 medicines 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 medicines under the Board's jurisdiction.

Form 3, the template created by the PMPRB in order to help patentees file this information, under Legislation, Regulations and Guidelines; Patentee's Guide to Reporting, is now available on our Web site and may also be used to file electronically. ■

NPDUIS Update

Access to CIHI's data is pursuant to a Data Sharing Agreement between CIHI and the PMPRB signed in October 2007.

The National Prescription Drug Utilization Information System (NPDUIS) is a research initiative jointly conducted through a partnership between the PMPRB and the Canadian Institute for Health Information (CIHI). NPDUIS seeks to provide policy-makers with information and insights into Canada's drug reimbursement programs.

The NPDUIS team now has access to claims-level data via an internet portal created by our NPDUIS partner at CIHI. Staff have been trained in using the portal, and have begun working with claims data in the main NPDUIS database.

The NPDUIS Steering Committee met on January 31 and February 1, 2008, in Ottawa. This meeting focused on identifying major research priorities for 2008-2009.

Update on Projects

The next edition of the **Pharmaceutical Trends Overview Report** (PTOR) is well underway. It is expected this report will be available on our Web site by the end of March.

The next edition of the **New Drug Pipeline Monitoring Report** (NDPMR) is also currently in preparation. It is expected this report will be available on our Web site by the end of March.

The **Forecasting Drug Plan Expenditures** project is expected to be completed by the summer. ■

Human Drug Advisory Panel (HDAP) 2008 Schedule – Reminder

The HDAP is composed of three members who hold qualifications as physicians, pharmacists or other professional designation with recognized expertise in drug therapy and who have experience in clinical research methodology, statistical analysis and the evaluation of new drugs.

Date of HDAP Meeting / Conference Call	Information	Deadline
February 11, 2008	1 copy of product monograph or information similar to that included in a product monograph (if the product has not yet been approved for sale in Canada)	November 12, 2007
	7 copies of company submission	December 11, 2007
May 15, 2008 (Face-to-Face)	1 copy of product monograph or information similar to that included in a product monograph (if the product has not yet been approved for sale in Canada)	February 15, 2008
	7 copies of company submission	March 17, 2008
September 15, 2008	1 copy of product monograph or information similar to that included in a product monograph (if the product has not yet been approved for sale in Canada)	June 16, 2008
	7 copies of company submission	July 15, 2008
November 24, 2008	1 copy of product monograph or information similar to that included in a product monograph (if the product has not yet been approved for sale in Canada)	August 25, 2008
	7 copies of company submission	September 24, 2008

2007 CPI-Adjustment Factors

CPI-Adjustment Factors Based on Inflation Forecasts

The 2007 CPI-adjustment factors included in Table 1 were published in the April 2006 NEWSletter. These factors are based on forecasts of annual CPI-inflation rates for 2006 and 2007. The Base-CPI is the average of the monthly CPI figures, as published by Statistics Canada, for the benchmark year.

Table 1

2007 CPI-Adjustment Factors for All Patented Drug Products (CPI 1992=100)

	Benchmark Year		
	(1) 2004	(2) 2005	(3) 2006
Base-CPI	124.56	127.34	n/a
2007 Forecast CPI	132.75	132.75	132.75
2007 CPI-Adjustment Factor	1.066	1.042	1.019

The 2007 Forecast CPI was 132.75 (1992=100) and was based on the actual CPI figures for 2005 (127.34), as published by Statistics Canada, and the latest available inflation projections (2.3% for 2006 and 1.9% for 2007) from the federal Department of Finance.

Cap for 2007 =2.9% (1.5 x 1.9)

CPI-Adjustment Factors Based on Actuals

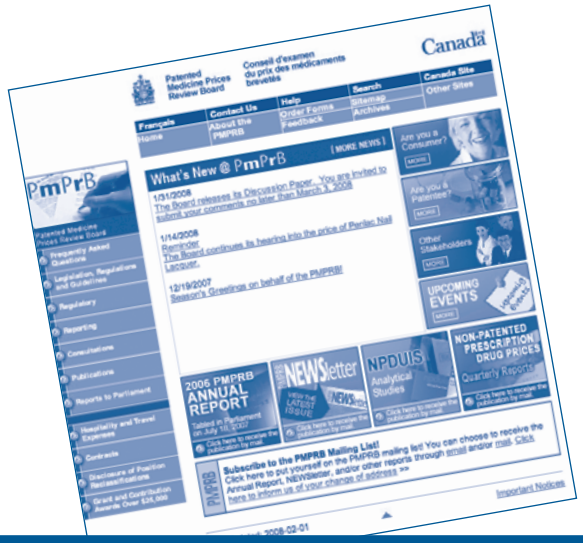
As of January 2008, Statistics Canada reports annual average CPI values of 129.90 and 132.67 for 2006 and 2007, respectively. Table 2 gives revised CPI-adjustment factors incorporating these actuals.

Table 2

2007 CPI-Adjustment Factors for All Patented Drug Products (CPI 1992=100)

	Benchmark Year		
	(1) 2004	(2) 2005	(3) 2006
Base-CPI	124.56	127.34	129.90
2007 Actual CPI	132.67	132.67	132.67
2007 CPI-Adjustment Factor	1.065	1.042	1.021

The actual 2007-over-2006 CPI-inflation rate was 2.1%. This implies a 2007-over-2006 price increase cap of 3.2% (= 1.5 x 2.1%). ■



What's New @ PMPRB

Readers are invited to check our Web site under What's New @ PMPRB for the latest information on the PMPRB's activities.

Questions and Comments

PMPRB E-bulletin

Readers who wish to receive PMPRB Electronic News bulletins are required to register by forwarding their e-mail address to pmprb@pmprb-cepmb.gc.ca.

Your cooperation in submitting changes to your e-mail and/or mailing address is also appreciated.

Please forward all subscriptions to the PMPRB e-mail or mailing lists, and requests for publications, to Elaine McGillivray at Elaine@pmprb-cepmb.gc.ca. For more information on our Web site, please contact our Communications Officer, Lyne Bélisle, at lbelisle@pmprb-cepmb.gc.ca.

List of New Drugs Introduced since the publication of the October 2007 NEWSletter

Since the publication of the October 2007 NEWSletter, 11 new DINs for human use (representing nine medicines) were added to the list of New Patented Medicines reported to the PMPRB for the period ending December 31, 2007. Six of these new medicines are new active substances, representing eight DINs.

The following table presents the new active substances reported to the PMPRB during the period October to December 2007. ■

Brand Name	Generic Name	Company	Therapeutic Use
Mycamine (50 mg/vial)	micafungin sodium	Astellas Pharma Canada Inc.	Antifungal
Vasovist (244 mg/ml)	gadofosveset trisodium	Bayer Inc.	Contrast agent
Aldurazyme (0.58 mg/ml)	laronidase	Genzyme Canada Inc.	Enzyme replacement therapy
Invega (3 mg/tab, 6 mg/tab, & 9 mg/tab)	paliperidone	Janssen-Ortho Inc.	Schizophrenia
Sebivo (600 mg/tab)	telbivudine	Novartis Pharmaceuticals Canada Inc.	Hepatitis B
Xyrem (500 mg/ml)	sodium oxybate	Valeant Canada Ltd.	Cataplexy

Report on New Patented Drug – Spriafil

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's Excessive Price Guidelines (Guidelines), for all new active substances introduced after January 1, 2002.

Brand Name: Spriafil

Generic Name: (*posaconazole*)

DIN: 02293404 (40mg/ml dose)

Patentee: Schering-Plough Canada Inc.

Indication – as per product monograph:

SPRIAFIL (posaconazole) is indicated for:

- prophylaxis of Aspergillus and Candida infections in patients, 13 years of age and older, who are at high risk of developing these infections, such as patients with prolonged neutropenia or hematopoietic stem cell transplant (HSCT) recipients.
- treatment of invasive aspergillosis in patients 13 years of age or older with disease that is refractory to amphotericin B or itraconazole, or in patients who are intolerant of these medicinal products. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.
- treatment of oropharyngeal candidiasis (OPC) in patients 13 years of age or older.

Date of Issuance of First Patent(s) Pertaining to the Medicine: January 23, 2007

Notice of Compliance: March 26, 2007

Date of First Sale: June 6, 2007

ATC Class: J02AC04

Antiinfectives for Systemic Use; Antimycotics for Systemic Use; Antimycotics for Systemic Use; Triazole Derivatives

Application of the Guidelines

Summary

The introductory price of Spriafil was found to be within the Guidelines because the price in Canada did not exceed the median of the prices of the same drug in those countries listed in the *Patented Medicines Regulations, 1994* (Regulations) in which Spriafil was sold.

Scientific Review

Spriafil is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Spriafil be classified as a category 2 new medicine. It provides a substantial improvement in the prevention of invasive fungal infections in immunocompromised patients, where current standard of prophylactic care confers inadequate protection.

The HDAP did not recommend any comparators for Spriafil; it is the first new active substance that offers significantly improved prophylactic coverage against invasive fungal infections.

Price Review

Under the Guidelines, the introductory price of a new category 2 drug product will be presumed to be excessive if it exceeds the prices of all comparable drug products, based on a Therapeutic Class Comparison (TCC) test, and the median of the international prices identified in an International Price Comparison (IPC) test. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines.

It was not possible to conduct a TCC test as the HDAP did not identify any comparator drug products. At introduction, the price of Spriafil was within the Guidelines as it did not exceed the median of the international prices identified in an IPC test. ■

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 medicines sold in Canada to ensure that such prices are not excessive. The publication of these reports is also part of the PMPRB's commitment to make its price review process more transparent.

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

Introductory Period (June - July 2007)

Country Price per Dose (CDN)	
Canada	$9.4095
France	n/a
Germany	$9.9034
Italy	$9.3453
Sweden	$9.5354
Switzerland	$9.4996
United Kingdom	$10.0192
United States	$4.8401
International Median	$9.5175

Source: Publicly available prices as per the *Patented Medicines Regulations, 1994*

Patented Medicine Prices Review Board – December 12, 2007 Meeting

At its meeting, the Board:

- Discussed and approved the outline of the Board's Discussion Paper on Options for Possible Changes to the *Patented Medicines Regulations, 1994* and the Excessive Price Guidelines.
- Received a progress report on the studies initiated by the PMPRB in the context of the National Prescription Drug Utilization Information System and its monitoring and reporting activities on Non-Patented Prescription Drug Prices.

The next Board meeting is scheduled for March 6-7, 2008. ■

For additional information, please contact the Secretary of the Board at: 1-877-861-2350, or (613) 954-8299, or at sdupont@pmprb-cepmb.gc.ca.

Summary of Board Meetings are available on our Web site under About the PMPRB.

Upcoming Events

February

February 11: HDAP Teleconference

February 27-28: Drug Patent Law and Patent Litigation Conference, Toronto

March

March 6-7: Board Meeting

April

April 10-11: National Business and Legal Guide to Life Sciences in Canada Conference, Ottawa

April 23-24: Pharmaceutical Pricing and Reimbursement Summit, London, UK

April 30: Release of the April 2008 NEWSletter

May

May 15: HDAP Face-to-Face Meeting, Ottawa

May 15-16: Board Meeting

May 31: Submission of the 2007 Annual Report to the Minister of Health

July

July 31: Release of the July 2008 NEWSletter

September

September 15: HDAP Teleconference

September 18-19: Board Meeting

October

October 31: Release of the October 2008 NEWSletter

November

November 24: HDAP Teleconference

December

December 11-12: Board Meeting

Upcoming Events are available on our Web site under Consultations; Events.

Readers' Corner

As of this year, a segment "Readers' Corner" will be dedicated to comments received from our readers. We will ensure that your comments are addressed and published.

We encourage you to submit your suggestions on topics you wish to see discussed in the NEWSletter.

We look forward to hearing from you.

Electronic PMPRB NEWSletter

Readers who wish to receive the NEWSletter electronically, please register by forwarding your E-mail address to pmprb@pmprb-cepmb.gc.ca.

To order our publications, call our toll-free number 1 877 861-2350

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 fax us your business card.

Name:

Title/Organization:

Address:

Postal Code:

Telephone: Fax:

E-mail:

Please return the completed form to the PMPRB:

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