Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 13, Issue No. 2, April 2009

Inside...

Since our last issue...

Our recent key events

February 12	Brien G. Benoit and Barbara Ouellet appeared before the Standing Committee on Health relating to Supplementary Estimates. For more information on the Chairman's appearance before the Committee, click on http://www2.parl.gc.ca/content/hoc/Committee/402/HESA/Evidence/EV3679528/HESAEV04-E.PDF.
February 19	The HDAP held its quarterly meeting. The Board approved a Voluntary Compliance Undertaking (VCU) in the matter of Eli Lilly Canada Inc. and the patented drug product Strattera, concluding the proceedings initiated in December 2005. More details on this VCU are available on page 3, under Hearings – Recent Developments.
February 23	The Chairman approved a VCU submitted by Bristol-Myers Squibb Canada Co. for the patented drug product Vepesid. For more details, please turn to page 4.
February 25	The Board completed its review of stakeholders' submissions on the August 2008 Notice and Comment on Draft Revised Excessive Price Guidelines, and decided on next steps.
March 3	The Federal Court of Canada (FC) heard the parties on the Board's jurisdiction in the matter of Celgene Corporation and the patented drug product Thalomid. On March 17, the FC issued its decision, setting aside the Board's decision of January 21, 2008. The Attorney General of Canada is appealing the decision.
March 4	The Rx&D-PMPRB Ad Hoc Committee met to discuss the draft revised Excessive Price Guidelines. The Chairman approved a VCU submitted by sanofi-aventis Canada Inc. for the patented drug product Suprax. For more details on this VCU, please turn to page 4.
March 5	The Board heard the parties' final oral arguments in the matter of sanofi-aventis Canada Inc. and the patented drug product Penlac. The Hearing Panel is currently deliberating on this matter.
March 16	The Board issued a Notice of Hearing into the price of the patented drug product Neulasta, a product of Amgen Canada Inc. More details on this matter are available under Hearings, on page 3.
March 17-19	Gregory Gillespie participated in the First Pan-American Seminar on the Economic Regulation of Pharmaceuticals, organized by the Pan-American Health Organization (PAHO) and the Brazilian Health Surveillance Agency (ANVISA). The Seminar was held in Brasilia, Brazil.
March 26	The Board released its final Notice and Comment on the Draft Revised Excessive Price Guidelines for stakeholders' comments.

Stakeholders' submissions are posted on our Web site under Consultations; Consultations on the Board's Excessive Price Guidelines.

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 drug products sold in Canada are not excessive, thereby protecting consumer interests 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.

April 8-15	Board Staff held a series of information sessions with stakeholders on the Notice and Comment on the Draft Revised Excessive Price Guidelines.
April 20	The Chairman of the Board approved a VCU submitted by sanofi-aventis Canada Inc. for the patented drug product Eligard. For more information on this VCU, please turn to page 4.
April 23	The Rx&D-PMPRB Ad Hoc Committee met to discuss the Draft Revised Excessive Price Guidelines.
April 23-24	Mary Catherine Lindberg and Barbara Ouellet attended the 2009 Life Sciences International Forum – *Is Canada Competitive in the Life Sciences*, in Cambridge, Ontario.
April 24	The Board approved a VCU in the matter of Janssen-Ortho Inc. and the patented drug product Concerta, concluding the proceedings initiated in July 2006. For more details on this matter, see Hearings – Recent Developments, on page 3.
April 29	The Chairman made a presentation at the Pharma Pricing & Market Access Outlook conference in London, UK. His presentation, *Canada's Patented Medicine Prices Review Board – Moving Forward*, will be available on our Web site on May 4, under Publications; Speech Series 2009. ■

News from the Chairman

Update on the revision of the Board's Excessive Price Guidelines

On March 26, 2009, the Board issued its final Notice and Comment on the Draft Revised Excessive Price Guidelines.

In early April, Board Staff held a series of briefing sessions with stakeholders, summarizing the proposed changes incorporated in the Draft Revised Guidelines since the August package and offering stakeholders an opportunity to raise questions and obtain clarification on the final draft of the Guidelines. In total, 30 stakeholders took part in the final phase of our consultation process by submitting written comments on the March Draft Revised Guidelines.

The Board is currently reviewing the submissions and will be releasing the revised Guidelines in early June with implementation planned to take effect on July 1, 2009.

These new revised Guidelines come after a long period of consultation initiated in 2005. On behalf of my colleagues, I wish to thank all who have taken part in these consultations. Your time and efforts in providing thoughtful comments on the perspectives of your constituency are most appreciated. ■

Brien G. Benoit, MD, Chairman

Senior Staff

Executive Director:
Barbara Ouellet

Director, Regulatory Affairs and Outreach*:
Ginette Tognet

Director, Policy and Economic Analysis:
Gregory Gillespie

Director, Corporate Services:
Marian Eagen

Secretary of the Board:
Sylvie Dupont

Senior Counsel:
Martine Richard

* The Compliance and Enforcement Branch has been renamed the *Regulatory Affairs and Outreach Branch*, to better reflect both its regulatory activities and proactive interactions with pharmaceutical patentees.

Submissions on the March 2009 Notice and Comment on the Draft Revised Excessive Price Guidelines are available on our Web site under Consultations; Consultations on the Board's Excessive Price Guidelines.

Comings and Goings

Marta Rivas, Records Officer and Steve Eyamie, IT Support Technician have recently returned to the PMPRB. Welcome back!

Rebecca Szilagyi is leaving the PMPRB on May 1 to take on new challenges at Health Canada. We wish her the best of luck in her new endeavours. ■

What's New @ PMPRB

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

CPI-Adjustment Factors for 2010

The *Patent Act* specifies the factors to be used by the PMPRB in determining whether the price of a patented drug product sold in Canada is excessive. One of these factors is the Consumer Price Index (CPI). The Excessive Price Guidelines limit price increases to changes in the CPI over a three-year period.

To allow patentees to set prices in advance, the Board's CPI-Adjustment Methodology provides for the calculation of the CPI-Adjustment factors based on forecast changes in the CPI. The Board informs patentees on an annual basis of the CPI-adjustment factors for future pricing period.

These factors (provided by Finance Canada) were based on annual forecast CPI-inflation rates of 0.7% and 1.9% for 2009 and 2010, respectively, as well as the actual 2008 CPI-inflation rate of 2.36%.

The CPI-adjustment factors for 2010 are as follows:

Table 1

Forecast 2010 Price-Adjustment Factors for Patented Drug Products

Benchmark Year	(1) 2007	(2) 2008	(3) 2009
Price-Adjustment Factor	1.050	1.026	1.019

These figures imply: (1) a maximum allowable cumulative price increase between 2007 and 2010 of 5.0% for patented drug products with Canadian sales in 2007 (that is, products whose "benchmark year" is 2007); (2) a maximum allowable cumulative price increase between 2008 and 2010 of 2.6% for products whose first Canadian sales occurred in 2008; and (3) a maximum allowable cumulative price increase between 2009 and 2010 of 1.9% for products whose first Canadian sales occurred in 2009.

In addition, the forecast inflation rate of 1.9% for 2010 implies a year-over-year price increase cap of 2.9% (= 1.5 x 1.9%) for 2010. ■

Hearings

The PMPRB's regulatory mandate is to ensure that patentees' prices of patented drug products sold in Canada are not excessive, thereby protecting consumer interests and contributing to Canadian health care. In the event that the price of a patented drug product 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 for the reduction of the price and the offsetting of revenues received by the patentee as a result of excessive prices. The Board's decisions are subject to judicial review in the Federal Court (FC).

Notice of Hearing issued in the matter of Amgen Canada Inc. and the patented drug product Neulasta

On March 16, 2009, the Board issued a Notice of Hearing into the price of the patented drug product Neulasta. The purpose of this hearing is to determine whether Amgen Canada Inc. is selling or has sold Neulasta in any market in Canada at a price that, in the Board's opinion, is or was excessive and if so, what order, if any, should be made.

A pre-hearing conference in this matter has been scheduled for June 3, 2009.

Neulasta (pegfilgrastim) is a new active substance indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with cancer receiving myelosuppressive chemotherapy.

Recent Developments

Two hearings have been concluded to date this year, with the Board's approval of VCUs in the matter of Eli Lilly Canada Inc. and the patented drug product Strattera, and in the matter of Janssen-Ortho Inc. and the patented drug product Concerta.

Eli Lilly Canada Inc. and the patented drug product Strattera

The Board approved a VCU for Strattera on February 19, 2009, thereby concluding the proceeding in this matter commenced with the issuance of a Notice of Hearing on December 15, 2006. The terms of the VCU require that the prices of Strattera not exceed the 2009 maximum non-excessive (MNE) prices and that Eli Lilly offset excess revenues in the amount of $15,326,066.49 by making a payment to the Government of Canada.

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

Janssen-Ortho Inc. and the patented drug product Concerta

The Board approved a VCU for Concerta on April 24, 2009, thus concluding the Board's proceeding commenced in this matter with the issuance of a Notice of Hearing on July 24, 2006. The terms of the VCU require, among other things, that Janssen-Ortho offset excess revenues in the amount of $1,464,441.58 by making a payment to the Government of Canada.

Concerta (methylphenidate hydrochloride) is indicated for the treatment of ADHD. ■

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 Excessive Price Guidelines (Guidelines). Under the Compliance and Enforcement Policy, 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.

Vepesid, Bristol-Myers Squibb Canada Co.

On February 23, 2009, the Chairman approved a VCU submitted by Bristol-Myers Squibb for the patented drug product Vepesid. Among other things, Bristol-Myers Squibb was required to offset excess revenues of $53,161.48 by making payments to customers that previously purchased Vepesid at excessive prices.

Vepesid (etoposide) is used in combination with other established antineoplastic agents in the treatment of neoplastic diseases.

Suprax, sanofi-aventis Canada Inc.

The Chairpman approved a VCU from sanofi-aventis for the patented drug product Suprax 400 mg/tablet. Among other things, sanofi-aventis is to reduce the price of Suprax so that it does not exceed the 2009 MNE price. It will also offset excess revenues received by making a first payment to the Government of Canada in the amount of $97,900.30 for the period of July 1, 2007 to June 30, 2008. A payment for the July – December 2008 period will also be required.

Suprax 400 mg/tablet (cefixime) is an antibiotic used in the treatment of infections caused by susceptible strains of designated micro-organisms.

Eligard, sanofi-aventis Canada Inc.

On April 20, 2009, the Chairman approved a VCU submitted by sanofi-aventis for the patented drug product Eligard. In addition to reducing the price of Eligard in the majority of provinces based on 2009 MNE prices determined as of December 31, 2009, sanofi-aventis will offset the cumulative excess revenues received from January 2005 to December 2008 by making a payment to the Government of Canada, in the amount of $13,127,953.14. Payments to offset excess revenues accrued during the 2009 period will be made directly to hospitals, cancer clinics and cancer boards that purchased Eligard.

Eligard (leuprolide acetate) is indicated for the palliative treatment of advanced prostate cancer.

VCUs are posted on our Web site under Regulatory; Voluntary Compliance Undertakings. ■

Failure to File R&D

Under subsection 89(3) of the *Patent Act*, the PMPRB is required to report the identity of patentees who failed to file information before March 2, 2009, as per section 88 of the Act.

One company, Biogen Idec Canada Inc., failed to file information on their revenues and R&D expenditures by the above date. A Board Order was issued to Biogen Idec on March 27, 2009.

Biogen Idec filed its R&D information on April 9, 2009. ■

Electronic PMPRB NEWSletter

If you wish to receive the NEWSletter electronically, please register by forwarding your e-mail address to: pmprb@pmprb-cepmb.gc.ca.

Readers who have changed e-mail address recently are invited to send us their new coordinates if they wish to keep receiving the NEWSletter.

Summary of Minutes – February 25, 2009 Board Meeting

The Board met on February 25, 2009 to complete its review of the stakeholders' submissions on the August 2008 Notice and Comment on the Draft Revised Excessive Price Guidelines and to determine next steps in finalizing the review of the Guidelines.

The next Board meeting will be held on May 5, 2009, at which time the Board Members will review the submissions on the March 2009 consultative package and finalize the revised Guidelines. The Board will also meet on May 19 to approve the 2008 Annual Report. ■

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

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

NPDUIS

The National Prescription Drug Utilization Information System (NPDUIS) is a research initiative by the PMPRB in partnership with the Canadian Institute for Health Information (CIHI). NPDUIS seeks to provide policy-makers with information and insights on trends in prices, utilization and costs of interest to participating public drug plans (all federal and provincial drug plans participate in NPDUIS except Québec).

NPDUIS research projects currently being finalized for publication include:

- the analysis of the use of the World Health Organization (WHO) defined Daily Dose (DDD) in Canadian drug utilization and cost analyses
- an analysis of the baby-boomer effect on prescription costs and number of transactions
- the 2nd edition of the New Drug Pipeline Monitor.

Two trend reports pertaining to non-patented drugs in Canada will be published this summer: Price Trends and International Price Comparisons; as well as Market Structure – Trends and Impacts.

In addition, there are a number of important research endeavours currently underway. Of interest to policy makers is a comparative analysis of the recent trends in professional fee expenditures observed in Canadian public drug plans. Another important study focuses on the development of the methodology for decomposing program expenditure growth in the context of claims-level data. Also, a standardized methodology for producing short-term and medium-term forecasts of Canadian public drugs plan costs is being developed in the form of Guidelines for Forecasting Program Expenditures. Finally, NPDUIS is in the process of enhancing and updating the Pharmaceutical Trends Overview Report, which examines the recent drug price trends in public drug programs.

The NPDUIS Steering Committee held conference calls in January and March, providing valuable input into the development of the study design on two newly initiated projects: an analysis of the impact of generic entry on the utilization of the ingredient; as well an assessment of projected Canadian expenditures on generic drugs if generic drugs in Canada had been priced at international levels.

The NPDUIS Steering Committee comprises representatives of public drug plans and Health Canada. It advises the PMPRB on priorities for new analytical studies and advises CIHI on NPDUIS database development.

The NPDUIS team looks forward to engaging the NPDUIS Steering Committee members in a face-to-face meeting in Ottawa on May 21-22. The purpose of this meeting is to report on the status and present the results of the ongoing studies, and to identify future research priorities.

The PMPRB has a longstanding history of cooperation with CIHI through the NPDUIS initiative. As part of ongoing efforts to strengthen relations, the members of the NPDUIS team met with representatives of CIHI on data to share information and perspectives on challenges, best practices, and future directions. ■

List of New Drugs introduced since the publication of the January 2009 NEWSletter

Since the publication of the January 2009 NEWSletter, four new DINs for human use (representing four patented drug products) were added to the list of Patented Drug Products reported to the PMPRB for the period ending March 31, 2009. One of these new patented drug products is a new active substance representing one DIN.

The following table presents the new active substance reported to the PMPRB during the period January to March 2009. ■

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.

As of March 31, 2009

Brand Name	Generic Name	Company	Indication
Nevanac – 1 mg/mL	nepafenac	Alcon Canada Inc.	Pain and inflammation following cataract eye surgery

Report on New Patented Drug — Relistor

The PMPRB publishes the results of the reviews of new patented drug products by Board Staff, for purposes of applying the Board's *Excessive Price Guidelines* (Guidelines) for all new active substances introduced in Canada after January 1, 2002.

Brand Name: Relistor

Generic Name: *methylnaltrexone bromide*

DIN: 02308215 (20mg/vial)

Patentee: Wyeth Pharmaceuticals

Indication – as per product monograph: For treatment of opioid-induced constipation in patients with advanced illness, receiving palliative care. When response to laxatives has been insufficient, Relistor should be used as an adjunct therapy to induce prompt bowel movement.

Date of Issuance of First Patent Pertaining to the Patented drug product: April 6, 1993

Notice of Compliance: March 28, 2008

Date of First Sale: May 22, 2008

ATC Class: A06AX
Alimentary Tract and Metabolism; Laxatives; Laxatives; Other Laxatives

Application of the Guidelines

Summary

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

Scientific Review

Relistor is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Relistor be classified as a category 2 new patented drug product (a breakthrough or a substantial improvement over comparable existing drug products). The HDAP did not recommend any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

Price Review

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

As no comparators were identified for purposes of conducting a TCC test, the introductory price of Relistor was considered within the Guidelines as it did not exceed the median of the international prices identified in the IPC test. Relistor was sold in one country listed in the Regulations.

When an IPC test is being conducted to determine the median price, an interim median international price will be used in cases when the drug product is sold in fewer than five countries at the time of its introduction. Unless it is excessive, the introductory price will be treated as the interim benchmark price. The interim benchmark price may be reviewed at the end of three years or when the drug product is sold in at least five countries, whichever comes first.

Introductory Period (May to June 2008)

Country and Median	Price (in Canadian dollars)
Canada[1]	$38.00 per vial
France	Not sold
Germany	Not sold
Italy	Not sold
Sweden	Not sold
Switzerland	Not sold
United Kingdom	Not sold
United States[2]	$39.8634 per vial
Median	$39.8634 per vial

Sources:
1 PPS, July 2008
2 Federal Supply Schedule, June 2008 and Direct Price, Red Book, July 2008

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 its Summary Reports, the PMPRB will also refer to the publicly available prices of comparators provided such prices are not more than 10% above a non-excessive price in which case no price will be made available. As a result, the publication of these prices is for information purposes only and should not be relied upon as indicating the public prices are considered within the Guidelines.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than that 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 our Web site under Regulatory; Patented Drug Products; Reports on New Patented Drugs for Human Use; Relistor. ■

Upcoming Events

May

May 5:
Board meeting

May 12:
Appearance of the PMPRB and Health Portfolio agencies before the Standing Committee on Health on the Main Estimates

May 14:
Appearance of the Minister of Health before the Standing Committee on Health on the Main Estimates

May 15:
HDAP meeting

May 19:
Board meeting

May 21-22:
Brogan Seminars, Montréal and Toronto

May 28:
Drug Patent and Legal Forum Conference, Toronto

May 29:
2008 PMPRB Annual Report to the Minister of Health

May 31-June 3:
Canadian Council of Administrative Tribunals (CCAT)
25th Annual Conference, Halifax

June

Date to be confirmed:
Publication of the Board's Excessive Price Guidelines 2009

June 3:
Pre-Hearing conference in the matter of Amgen Canada Inc. and the patented drug product Neulasta

June 16-17:
Drug Pricing and Reimbursement Conference, Toronto

June 16-17:
Federal Court hearing of the Judicial Review Applications filed by Rx&D *et al* and Pfizer Canada Inc., on the Board's August 18, 2008 Communiqué on mandatory reporting of benefits

June 17-18:
Regulatory Affairs and Outreach Branch information sessions with patentees on the new Guidelines, Toronto and Montréal

June 23-24:
Third Annual Canadian Summit on Biologics, Toronto

July

July 1:
Implementation of the Board's Excessive Price Guidelines 2009

July 6-10:
Hearing in the matter of ratiopharm Inc. and the patented drug product ratio-Salbutamol

July 30:
Patentees' Form 2 filing deadline

July 31:
July 2009 NEWSletter

September

September 17:
HDAP meeting

September 17-18:
Board meeting

October

October 30:
October 2009 NEWSletter

November

November 19:
HDAP meeting

December

December 3-4:
Board meeting

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

Questions and Comments

PMPRB E-bulletin

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To order our publications, call our toll-free number 1 877 861-2350 or e-mail 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.

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Please return the completed form to the PMPRB:

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

E-mail: elaine@pmprb-cepmb.gc.ca

Fax: (613) 952-7626