Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 12, Issue No. 4, October 2008

Inside...

News from the Chairperson

This past August, the Board released a Notice and Comment on its draft revised Excessive Price Guidelines, soliciting submissions from its stakeholders by October 6, 2008. These draft revised Guidelines come on the heels of extensive consultations with stakeholders over the last three years.

The Board received a total of 44 submissions, all of which are posted on our Web site.

To assist stakeholders, Board Staff held information sessions in mid-September to summarize the Board's positions reflected in the draft revised Guidelines as well as those recommendations of the various Working Groups that the Board did not pursue. It was also an opportunity to clarify the content of the draft revised Guidelines and to respond to questions stakeholders may have had on the document.

It has been the Board's objective to ensure that the Guidelines remain relevant and appropriate in the context of an ever evolving pharmaceutical environment. The Board remains committed to provide transparency and predictability in its price review process, important elements to offering guidance to patentees. To that end, the Board met with the Board of Directors of Rx&D on October 21, 2008 and with representatives of BIOTECanada on October 22, to further discuss the draft revised Guidelines and issues which remain of concern to the industry.

On October 22, the Board also met to review the submissions and discuss next steps. The Board is continuing with its assessment of the submissions and will update stakeholders of its progress through the Web site and in upcoming issues of the NEWSletter.

On behalf of my colleagues, I take this opportunity to thank all those who have taken the time to review the draft revised Guidelines and provide the Board their thoughtful and valuable feedback. ■

Brien G. Benoit, MD, Chairperson

Submissions on the draft revised Guidelines are available by clicking on **http://www.pmprb-cepmb.gc.ca/english/view.asp?x=1103** – or under Consultations; Consultations on the Board's Excessive Price Guidelines; Draft Revised Excessive Price Guidelines.

Since our last issue…

Our recent key events

August 18	The Board released a Communiqué to update stakeholders on its work in regard to the *Patented Medicines Regulations* and to announce the release of its draft revised Excessive Price Guidelines on August 20th, 2008.
August 20	The Board released its Notice and Comment on the draft revised Excessive Price Guidelines. The deadline for submission was October 6, 2008. The Board resumed its hearing in the matter of sanofi-aventis Canada Inc. and the medicine Penlac Nail Lacquer.
September 11	The Human Drug Advisory Panel held a teleconfence.
September 4, 9, 12, 15, 19	Board Staff held information sessions with stakeholders on the draft revised Excessive Price Guidelines.
October 6	The Board heard the parties on preliminary issues in the matter of Apotex Inc. as a patentee under the jurisdiction of the PMPRB. The Hearing Panel's decision, dated October 27, 2008, is available on our Web site.
October 21	The Board met with the Board of Directors of Rx&D on the draft revised Excessive Price Guidelines.
October 22	The Board met with representatives of BIOTECanada on the draft revised Excessive Price Guidelines. The Board met to review and discuss stakeholders' submissions on the Notice and Comment on the draft revised Excessive Price Guidelines.
October 27	The Board held a pre-hearing conference in the matter of ratiopharm Inc. and the medicine ratio-Salbutamol.
October 28	Delia Lewis participated at the Canadian Institute's 8th Annual "*Advanced Administrative Law and Practice*" Conference, Ottawa.
October 28-29	Ginette Tognet and Barbara Ouellet did a presentation on the price review process and the draft revised Excessive Price Guidelines, at the Brogan Advanced Training Seminars held in Montréal and in Toronto.
October 30	Sylvie Dupont did a presentation to a delegation of the Department of Health of Tunisia on the regulatory role of the PMPRB.

Comings and Goings

Over the last quarter, we were pleased to have Patricia Hum return to the Legal Branch. Robin Main joined our Corporate Services Branch as Records Manager. In November, Gregory Gillespie will be joining the PMPRB as Director of the Policy and Economic Analysis Branch. Also, Ruth Keays will join the Compliance and Enforcement Branch.

We would also like to offer our best wishes to Lyne Bélisle, Communications Officer, who left the PMPRB to take on new challenges with the Canadian Intellectual Property Office (CIPO) and to Marta Rivas, who joined the administrative arm of the RCMP.

Finally, we would like to congratulate Frank Parisotto, who retired after 35 years in the Public Service, and thank him for his valuable contribution to the PMPRB. All the very best for a well deserved retirement Frank! ■

Senior Staff

Executive Director:
Barbara Ouellet

Director of Compliance and Enforcement:
Ginette Tognet

Director of Policy and Economic Analysis:
Gregory Gillespie

Director of Corporate Services:
Marian Eagen

Senior Counsel:
Martine Richard

Secretary of the Board:
Sylvie Dupont

The PMPRB's speeches and presentations are available on our Web site under Publications; Speech Series.

Hearings

The PMPRB's regulatory mandate is to ensure that patentees' prices for patented drugs 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 to reduce the price and to offset revenues received as a result of excessive prices. The Board's decisions are subject to judicial review in the Federal Court (FC).

Adderall XR, Shire Canada Inc.

The Board issued an Order on August 27, 2008 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 paying $5,622,863.63 to Her Majesty in Right 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 shall pay to 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 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.

The Board Order is posted on our Web site.

Apotex Inc.

The Board heard the parties on preliminary matters on October 6, 2008 and issued its decision under date of October 27. The Panel will release a detailed schedule on this proceeding in the next few weeks.

Apo-Salvent CFC Free, Apotex Inc.

In its decision, dated October 27, the Board granted ratiopharm Inc. leave to intervene in this matter. The full text of the decision is available on our Web site. A revised schedule in this matter will be released shortly and posted on our Web site.

Copaxone, Teva Neuroscience G.P.-S.E.N.C.

On May 12, 2008, the Board issued an Order and reasons in the matter of Teva Neuroscience G.P.-S.E.N.C. and its medicine Copaxone. Teva has filed applications for judicial review of the Board's decision and Order in this matter with the Federal Court (FC). No hearing date has yet been scheduled.

Nicoderm, sanofi-aventis Canada Inc.

On July 3, 2008, the Board heard the parties on their joint submission to conclude this proceeding. The Panel issued its decision on July 21 to resume the hearing into the price of Nicoderm. sanofi-aventis Canada Inc. filed an application with the Federal Court for judicial review of the Board's July 21 decision. The FC has not yet scheduled a date to hear the application. The Board's hearing in the Nicoderm matter resumes on November 21.

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

Apo-Salvent CFC Free is a new DIN of an existing dosage form of an existing bronchodilator medicine (salbutamol sulphate) which relieves chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs.

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 Multiple Sclerosis to reduce the frequency of relapses.

Nicoderm is a transdermal smoking cessation patch. Penlac is indicated as part of a comprehensive nail mana - gement program in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement.

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.

ratio-Salbutamol HFA is a new DIN of an existing dosage form of an existing bronchodilator medicine (salbutamol sulphate) which relieves chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs.

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

Penlac, sanofi-aventis Canada Inc.

At its August 20 hearing in this matter, the Panel agreed to hear Board Staff's Motion for the issuance of two orders, the first for the production of data and studies by sanofi-aventis, and the second, to seek leave to call expert reply evidence on this new data.

The Board granted a variation on the relief sought on the Motion and issued an Order on August 20. The hearing in this matter is set to resume on December 8.

Quadracel – Pentacel, sanofi pasteur Limited

The hearing is set to resume on November 25-27, 2008. The final session in this matter is scheduled for January 5-7, 2009.

ratiopharm Inc.

This matter is on hold, pending the Board's decision on ratiopharm's motion for the consolidation of this matter and that of ratio-Salbutamol. Upon release of the Board's decision, a revised schedule will also be issued.

ratio-Salbutamol, ratiopharm Inc.

The pre-hearing conference in this matter was held on October 27, 2008. The Panel will release its decision on preliminary matters, including the consolidation of this matter and that of ratiopharm's failure to file, in the next few weeks.

Strattera, Eli Lilly Canada Inc.

The hearing in this matter will resume on January 27, 2009. ■

Further information on hearings, including Board decisions and orders, 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:

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Human Drug Advisory Panel (HDAP) 2009 Schedule

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.

HDAP Meeting/ Conference Call	Information	Deadline
February 19, 2009	1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada)	November 19, 2008
	7 copies of company submission	December 19, 2008
May 15, 2009	1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada)	February 16, 2009
	7 copies of company submission	March 16, 2009
September 17, 2009	1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada)	June 17, 2009
	7 copies of company submission	July 17, 2009
November 19, 2009	1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada)	August 19, 2009
	7 copies of company submission	September 19, 2009

List of New Drugs Introduced Since the Publication of the July 2008 NEWSletter

Twenty-two new DINs for human use (representing 19 medicines) were added to the list of Patented Medicines reported to the PMPRB for the period ending September 30, 2008. Seven of these new medicines are new active substances representing 10 DINs.

The following table presents the new active substances reported to the PMPRB during the period July to September 2008. ■

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 just 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 September 30, 2008

Brand Name	Generic Name	Company	Therapeutic Use
Lucentis (3 mg/vial)*	*ranibizumab*	Novartis Pharmaceuticals Canada Inc.	Treatment of Neovascular (wet) Age-Related Macular Degeneration (AMD)
Myozyme (50 mg/vial)	*alglucosidase alfa*	Genzyme Canada Inc.	Treatment of Pompe's Disease
Nimotuzumab (50 mg/vial)	*nimotuzumab*	YM Biosciences Inc.	Cancer Treatment
Pradax (75 mg/capsule, 110 mg/capsule)	*dabigatran etexilate*	Boehringer Ingelheim (Canada) Inc.	Venous Throembolic Events (VTE)
Revlimid (5 mg/capsule, 10 mg/capsule)	*lenalidomide*	Celgene Corporation	Anemia
Volibris (5 mg/tablet, 10 mg/tablet)	*ambrisentan*	GlaxoSmithKline Inc.	Pulmonary Arterial Hypertension
Zevalin (3.2 mg/vial)	*ibritumomab tiuxetan*	Bayer Inc.	Treatment of Non-Hodgkins Lymphoma

* Summary Report on this drug product is published in this NEWSletter.

Questions and Comments

PMPRB E-bulletin

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

Please forward all **subscriptions** to the PMPRB mailing lists, and requests for publications to Elaine McGillivray at Elaine@pmprb-cepmb.gc.ca.

Report on New Patented Drug — Lucentis

Under its transparency initiative, 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.

Generic Name: *ranibizumab*

DIN: 02296810 (10 mg/mL)

Patentee: Novartis Pharmaceuticals Canada Inc.

Indication – as per product monograph:

For the treatment of neovascular (wet) age-related macular degeneration (AMD).

Date of Issuance of First Patent Pertaining to the Medicine: June 10, 2008

Notice of Compliance: June 26, 2007

Date of First Sale: July 26, 2007

ATC Class: S01LA

Sensory Organs; Ophthalmologicals; Ocular Vascular Disorder Agents; Antineovascularisation Agents

Application of the Guidelines

Summary

The introductory price of Lucentis 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 in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) in which Lucentis was sold.

Scientific Review

Lucentis is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Lucentis be classified as a category 2 new medicine (a breakthrough or provides a substantial improvement over comparable existing medicines). 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 the comparable drug products based on the 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.

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

Introductory Period (July to December 2007)

Country	Price (In Canadian Dollars)
Canada	$1,575.0000
France	$1,775.5884
Germany	$1,858.3958
Italy	$1,939.0296
Sweden	$1,659.5728
Switzerland	$1,737.1947
United Kingdom	$1,595.5728
United States	$2,336.0069
Median	$1,775.5884

Sources:
Canada: Ontario Formulary Online Edition Version 1.4, August 2007
France: Sempex, August 2007
Germany: *Rote Liste*, July 2007
Italy: *L'informatore farmaceutico*, December 2007
Sweden: *Prislista*, December 2007
Switzerland: Medwin website, Jul-Dec07
UK: MIMS, December 2007
US: Federal Supply Schedule (FSS), Jul-Dec07;
Thomson Micromedex Wholesale Acquisition Cost (WAC), October 2007

The publication of the Summary Reports is part of the PMPRB's commitment to make its price review 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 medicines sold in Canada to ensure that such prices are not excessive.

The PMPRB reserves the right to exclude from the therapeutic class comparison list any drug product if it has reason to believe it 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, nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner.

NPDUIS Update

The National Prescription Drug Utilization Information System (NPDUIS) is a research initiative jointly conducted by the PMPRB and the Canadian Institute for Health Information. 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).

A meeting of the NPDUIS Steering Committee was held on October 3rd in Ottawa. An update on current NPDUIS projects was provided. Work is progressing well on two projects that are looking respectiveley at the impacts of demographic changes and dispensing fees on public drug plan expenditure. Ongoing methodological work is focusing on the use of Defined Daily Dose (DDD) in drug costs and utilization analyses, and more detailed cost decomposition using day supply data. The NPDUIS Steering Committee provided very valuable feedback on work underway.

Two NPDUIS projects are nearing completion:

- The second edition of the *New Drug Pipeline Monitor (NDPM)* will be posted on our Web site in November, 2008. In addition to highlighting new pipeline drugs, this edition will profile the five cancer drugs that were identified in the first edition. Furthermore, in conjunction with the release of this second edition, the PMPRB will release an interactive drug list which will provide accurate and up-to-date information on the drugs that have been selected.
- The development of a standard methodology and guidelines for producing reliable short to medium term forecasts of drug plan pharmaceutical expenditure is well underway. It is expected that the *Guidelines for Forecasting Program Expenditure for Canadian Public Drug Plans* will be published in early 2009. ■

NPDUIS studies and reports are posted on our Web site under Reporting; NPDUIS.

Board Meeting

The Board met on October 22, to review and discuss stakeholders submissions on the Notice and Comment on the Draft Revised Excessive Price Guidelines.

The next Board meeting is scheduled for December 11, 2008 ■

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 the PMPRB.

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.

Upcoming Events

November 2008

November 5-7: DIA's 6th Canadian Annual Meeting – *Benefit and Risk Management: An Evolution in Progress*, Ottawa

November 11: World Generic Medicines Congress Americas 2008 – *The Business of Affordable Medicines*, Washington, DC

November 12: HDAP Teleconference

November 21: Hearing – Nicoderm, sanofi-aventis Canada Inc.

November 24-27: Procurity Conference, Scottsdale, Arizona

November 25-27: Hearing – Quadracel and Pentacel, sanofi pasteur Limited

December

December 3-4: 7th Annual Market Access Conference, Toronto

December 4-5: 2008 Life Sciences Invitational Forum – *Is Canada Competitive in the Life Sciences*, Montebello

December 8: Hearing – Penlac, sanofi-aventis Canada Inc.

December 11: Board Meeting, Ottawa

January 2009

January 5-7: Hearing – Quadracel and Pentacel, sanofi pasteur Limited

January 27-29: Hearing – Strattera, Eli Lilly Canada Inc.

February 2009

February 11-13: Hearing – Strattera, Eli Lilly Canada Inc.

April

April 29-30: *Pharmaceutical Pricing Summit*, London, UK

May/June

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

May/June 31-1-2: Canadian Council of Administrative Tribunals (CCAT) 25th Annual Conference, Halifax

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

Readers' Corner

This segment "Readers' Corner" is 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.

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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.

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.

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