Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 13, Issue No. 1, January 2009

Inside...

Since our last issue...

Our recent key events

November 12:	the Human Drug Advisory Panel (HDAP) held a quarterly teleconference.
November 21:	the Board resumed its hearing in the matter of sanofi-aventis Canada Inc. and the medicine Nicoderm.
November 25-27:	the Board completed the evidentiary portion of its proceedings in the matter of sanofi pasteur Limited and the medicines Quadracel and Pentacel.
November 26:	Barbara Ouellet gave a presentation on the role of the PMPRB, at the *Procurity* Conference, in Scottsdale, Arizona.
December 3:	Barbara Ouellet gave a presentation on the review of the Board's Excessive Price Guidelines, at the 7th Annual Market Access Conference, in Toronto.
December 19:	the Rx&D-PMPRB Ad-Hoc Committee met to discuss the draft revised Excessive Price Guidelines.
2009	
January 6:	the Board heard closing arguments in the matter of sanofi pasteur Limited and the medicines Quadracel and Pentacel. The Board decision in this matter is pending.
January 13:	the Board met to continue its review of stakeholders' comments on the draft revised Excessive Price Guidelines issued in August 2008.
January 29:	the Rx&D-PMPRB Ad-Hoc Committee continued its discussion on the draft revised Excessive Price Guidelines. ■

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

Report on the PMPRB's contribution to the Workplace Charitable Campaign in 2008

"Be a star in someone's life; together we can make a difference."

We wish to thank our dedicated team of volunteers and our generous contributors, including our friends from the Canadian International Trade Tribunal who participated in the McGillivray breakfast! Again this year, we have, by far, exceeded our goal, with contributions totaling more than 38% over the target set at the beginning of the campaign.

Thank you all for your generosity! ■

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 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.

News from the Chairperson

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

The Board is completing the review of its Excessive Price Guidelines. On behalf of my colleagues, I wish to thank all stakeholders who provided feedback on the August 2008 Notice and Comment on the Draft Revised Excessive Price Guidelines. Your input has been of great assistance in helping us shape our decisions.

As part of the feedback, some stakeholders indicated that certain aspects of the draft revised Guidelines were either unclear or required additional discussion. The Board remains committed to providing clarity, transparency and predictability in its price review process. In order to better understand some of the feedback received, the Board met with representatives of the Ontario Public Drug Programs on December 13, 2008, and with representatives of the Canadian Generic Pharmaceutical Association (CGPA) on January 13, 2008. In addition, representatives of the Board and Canada's Research-Based Pharmaceutical Companies (Rx&D) met on December 19, 2008, and on January 29, 2009, as part of an ad-hoc committee to discuss key issues of the innovative pharmaceutical industry.

Brien G. Benoit, MD, Chairperson

We are nearing finalization of our review of the feedback on the draft revised Guidelines on which we consulted in August. We have noted that in many areas, stakeholders offered few if any comments and generally signalled the proposed changes represent an improvement to the Guidelines. There are a few areas where stakeholders' comments were more significant and where the Board is now focussing its efforts. We continue to be most appreciative of the contributions of stakeholders to the Guidelines Review and wish to maintain an open dialogue as we look to release a new version of the draft revised Guidelines for final Notice and Comment in March. Following the Board's review and consideration of stakeholder feedback, the final text of the revised Guidelines is planned for release around the end of May, with implementation expected on July 1, 2009.

In August 2008, the Board also released a Communiqué on the plans to enforce mandatory reporting by patentees of all benefits as part of net prices or net revenue. The Federal Court of Canada will consider the two Judicial Review Applications filed by Pfizer Canada Inc. and Rx&D et al., on this matter on June 16-17. Given the dates of the judicial reviews, the Federal Court decision is not likely prior to July 1, 2009, and as such mandatory reporting of benefits will be suspended to January 1, 2010.

The PMPRB remains committed to transparency and fairness in the fulfillment of its mandate. ■

Submissions on the Draft Revised Excessive Price Guidelines are available on our Web site under Consultations.

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.

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

2008 CPI-Based Price-Adjustment Factors

Preliminary Price-Adjustment Factors (Based on Forecast Inflation Rates)

Table 1 reproduces preliminary price-adjustment factors for 2008 published in the April 2007 NEWSletter. These factors were based on annual forecast CPI-inflation rates of 1.6% and 2.0% for 2007 and 2008, respectively, as well as the actual 2006 CPI-inflation rate of 2.0%.

Table 1

Preliminary 2008 Price-Adjustment Factors for Patented Drug Products (Based on Forecast CPI-Inflation Rates)

	Benchmark Year		
	(1) 2005	(2) 2006	(3) 2007
Price-Adjustment Factor	1.057	1.036	1.020

These figures imply: (1) a maximum allowable cumulative price increase between 2005 and 2008 of 5.7% for patented drug products with Canadian sales in 2005 (that is, products whose "benchmark year" is 2005); (2) a maximum allowable cumulative price increase between 2006 and 2008 of 3.6% for products whose first Canadian sales occurred in 2006; and a maximum allowable cumulative price increase between 2007 and 2008 of 2.0% for products whose first Canadian sales occurred in 2007.

In addition, the forecast inflation rate of 2.0% for 2008 implies a year-over-year price increase cap of 3.0% (= 1.5 x 2.0%) for 2008.

Final Price-Adjustment Factors (Based on Actual Inflation Rates)

The actual rate of CPI inflation for 2007 of 2.1% was published in the January 2008 NEWSletter. The actual CPI inflation for 2008 is now available and is 2.4%. These rates (along with the actual 2006 CPI-inflation rate of 2.0%) yield the following final price-adjustment factors.

Table 2

Final 2008 Price-Adjustment Factors for Patented Drug Products (Based on Actual CPI-Inflation Rates)

	Benchmark Year		
	(1) 2005	(2) 2006	(3) 2007
Price-Adjustment Factor	1.066	1.045	1.024

The final year-over-year price increase cap for 2008 is 3.6% (= 1.5 x 2.4%).

In June 2007, Statistics Canada updated the base year of its Consumer Price Index (CPI) from 1992 to 2002. This change merely involved a rescaling of the series. Historical rates of growth in the CPI have not been affected.

The PMPRB will henceforth use the new base year in its calculations. The PMPRB anticipates no impact on patentees. In particular, the change in base year will require no revision of previously published CPI-based price-adjustment factors, or affect the calculation of maximum non-excessive prices.

Patentees who want more information on the CPI base year or any other aspect of the CPI should consult the Statistics Canada publication *Your Guide to the Consumer Price Index* (Catalogue No. 62-557-XPB), which is available online at www.statcan.gc.ca. ■

Comings and Goings

We welcomed new employees over the last few months: Salma Pardhan and Nelson Millar joined the Policy and Economic Analysis Branch, while Lama Abi Khaled and Anne Tardif joined the Compliance and Enforcement Branch and Legal Services respectively. Welcome all! ■

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.

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

Under the *Patented Medicines Regulations* (Regulations), all patentees 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 a drug 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 drugs under the Board's jurisdiction.

Patentees are reminded that the deadline for filing Form 3 information on revenues and R&D expenditures is March 2, 2009.

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.

Form 3, the template created by the PMPRB to help patentees file this information, is contained in the *Patentee's Guide to Reporting* (which can be downloaded from the "Legislation, Regulations and Guidelines" page of the Board's Web site or by clicking on http://www.pmprb-cepmb.gc.ca/CMFiles/Form_3_-_English38KHS-3192008-6581.xls.

Failure to File

If a patentee fails to file complete information by March 2, 2009, the patentee will be advised in writing that the information required to be filed under the Regulations has not been received by the PMPRB and will be given a further seven (7) days to provide the information. Should the patentee not file within the further period, Board Staff shall request that the Board issue an order pursuant to section 88 of the *Patent Act* requiring that the patentee file the required information.

Orders issued by the Board are reported in the PMPRB's publications and posted on its Web site. ■

List of New Patented Drugs Reported since the Publication of the October 2008 NEWSletter

Eleven new DINs for human use (representing eight medicines) were added to the list of Patented Medicines reported to the PMPRB for the period ending December 31, 2008. Three of these new medicines are new active substances representing five DINs.

The following Table presents the new active substances reported to the PMPRB during the period October to December 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 December 31, 2008

Brand Name	Generic Name	Company	Therapeutic Use
Xarelto (10 mg/tablet)	rivaroxaban	Bayer Inc.	Venous Thromboembolism
Catena (150 mg/tablet)	idebenone	Santhera Pharmaceuticals (Canada) Inc.	Symptomatic management of Friedreich's ataxia
Tridural (100 mg/tablet, 200 mg/tablet, 300 mg/tablet)	tramadol hydrochloride	Paladin Labs Inc.	Analgesic

Report on New Patented Drug – Revlimid

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.

Brand Name: Revlimid

Generic Name: *lenalidomide*

DIN: 02304899 (5 mg capsule)
02304902 (10 mg capsule)

Patentee: Celgene Corporation

Indication – as per product monograph:

For the treatment of patients with transfusion-dependent anemia due to low or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

Date of Issuance of First Patent(s) Pertaining to the Medicine: August 16, 2005

Notice of Compliance: January 17, 2008

Date of First Sale: February 27, 2008

ATC Class: L04AX
Antineoplastic and Immunomodulating Agents; Immunosuppressive Agents; Immunosuppressive Agents; Other Immunosuppressive Agents

Application of the Guidelines

Summary

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

Scientific Review

Revlimid is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Revlimid be classified as a category 2 new medicine (a breakthrough or 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.

Revlimid 5 mg capsule
Introductory Period (February – June 2008)

Country	Price (In Canadian Dollars)
Canada	No public price available
France	No public price available
Germany	$370.5675
Italy	
Sweden	$372.8405
Switzerland	$306.6748
United Kingdom	$348.4357
United States	$276.1366
Median	$348.4357

Sources:
Germany: *Rote Liste*, January 2008
Sweden: *Prislista*, June 2008
Switzerland: Medwin Web site, July – December 2008
United Kingdom: MIMS, April 2008
United States: Federal Supply Schedule (FSS), January – June 2008; Thomson Micromedex Wholesale Acquisition Cost (WAC), April 2008

Revlimid 10 mg capsule
Introductory Period (February – June 2008)

Country	Price (In Canadian Dollars)
Canada	No public price available
France	No public price available
Germany	$391.2956
Italy	
Sweden	$393.5572
Switzerland	$322.7308
United Kingdom	$368.9321
United States	$288.9801
Median	$368.9321

Sources:
Germany: *Rote Liste*, January 2008
Sweden: *Prislista*, June 2008
Switzerland: Medwin Web site, July – December 2008
United Kingdom: MIMS, April 2008
United States: Federal Supply Schedule (FSS), January – June 2008; Thomson Micromedex Wholesale Acquisition Cost (WAC), April 2008

As no comparators were identified for the purposes of conducting a TCC test, the introductory prices of Revlimid were considered within the Guidelines as they did not exceed the median of the international prices identified in an IPC test – Revlimid was sold in six of the seven countries listed in the Regulations. For purposes of publication, the Tables above do not include prices for Canada and one of these countries (France) in which Revlimid was sold in the introductory period as there were no publicly available sources for the prices. The prices of Revlimid in Canada were also below the median price of the five comparator countries for which a public price was available. ■

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.

Board Meeting

The Board met on December 11, 2008 and on January 13, 2009, to continue its review of stakeholders' submissions on the Draft Revised Excessive Price Guidelines.

The next Board meeting is scheduled for February 25, 2009. ■

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.

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.

Upcoming Events

February

February 2:
Patentees' Form 2 filings

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

February 19:
HDAP meeting

February 25:
Board meeting

March

March 2:
Patentees' Form 3 filings

March 3:
Federal Court hearing of the Judicial Review Application by Celgene Corporation of the Board's decision in the matter of Thalomid

March 5-6:
Hearing – Penlac, sanofi-aventis Canada Inc.

March 27: (to be confirmed)
Release of the Draft Revised Excessive Price Guidelines for final Notice and Comments

April

April 24:
Submissions on the Revised Excessive Price Guidelines

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

April 30:
April 2009 NEWSletter

May

May 15:
HDAP meeting

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

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

May/June:
Release of the Board's Excessive Price Guidelines 2009

June

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

July

July 31:
Patentees' Form 2 filings

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.

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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