Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 12, Issue No. 2, April 2008

Inside...

Amendments to the *Patented Medicines Regulations* are published in the *Canada Gazette*, Part II

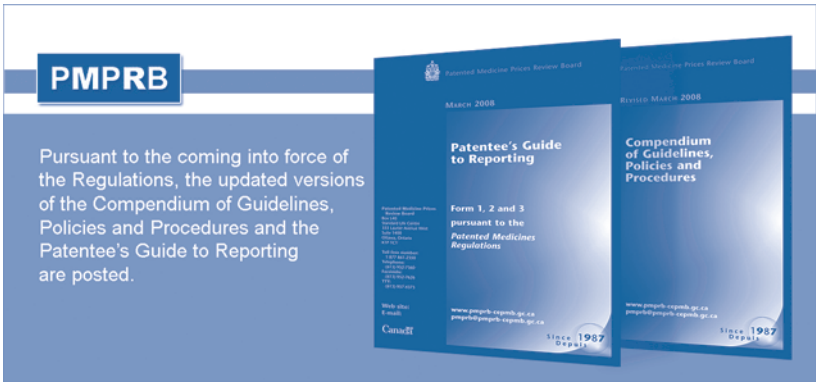
The Board is pleased to announce that its regulatory amendments to the *Patented Medicines Regulations, 1994* (Regulations) were registered on March 6, 2008 and received final publication in the *Canada Gazette*, Part II, on March 19, 2008. These amendments modernize the Regulations by increasing efficiency and timeliness in the price review process for patented medicines.

This regulatory initiative began in January 2005 with the publication of a Notice and Comment proposal to amend the Regulations, followed by the initial pre-publication of the proposed regulatory amendments in the *Canada Gazette*, Part I, on December 31, 2005. Following extensive stakeholder consultations a revised regulatory package was pre-published in the *Canada Gazette*, Part I, on October 6, 2007. Several stakeholder submissions were received during the second pre-publication consultation period. These submissions are posted on our Web site for the information of all interested parties.

In response to stakeholder concerns, the final amendments contain two changes from the proposed amendments which were pre-published on October 6, 2007. First, the proposed requirement that patentees must identify the type of reductions used in the calculation of average price per package or net revenue from sales has been removed. Second, the date of the coming into force of the electronic filing requirement has been changed from January 1, 2009 to July 1, 2008, as the electronic forms will no longer have to be revised to accommodate the filing of reduction information by type.

Patentees must comply with the amended Regulations as of their final publication on March 19, 2008, with the exception of the electronic filing requirement which must be complied with as of July 1, 2008. The Board has already begun communicating with patentees to explain how to fully comply with the regulatory amendments, and will be offering information sessions for patentees in May and June 2008 to further discuss changes to the filing requirements. Patentees will be receiving more information about these workshops in the near future. ■

The amendments to the Regulations are available at **http://canadagazette.gc.ca/partII/index-e.html**



Comings and Goings

The Compliance and Enforcement Branch is pleased to announce the appointments of Larissa Lefebvre, Christina Conlin, Kirk Stanley and Jarrett Todd as Statistical Research Assistants. Congratulations to all.

We welcome Bill Simon to the PMPRB as Chief, Human Resources.

The PMPRB wishes best of luck and success to Marie-Sophie Jobin, Marcin Szumski and Liliane Kayirere who left the PMPRB recently to take on new challenges. We take this opportunity to thank them for their valuable contribution. ■

Brien G. Benoit, MD
Chairperson

Message from the Chairperson

The Board wishes to thank all stakeholders who have participated to date in its consultations on the Excessive Price Guidelines and the *Patented Medicines Regulations*, since the review was initiated in May of 2006.

With the release of the January 2008 Discussion Paper on possible options to amend the Guidelines and the Regulations, and the feedback received from a wide range of stakeholders, we have moved towards meeting our goal of ensuring that the Guidelines are relevant and appropriate in today's health care environment.

At our March Board meeting, we reviewed and discussed the submissions received, met with the Working Groups on *Therapeutic Improvement* and on *International Therapeutic Class Comparison* and discussed their preliminary findings. We also finalized the terms of reference of the working group on *Price Tests* which met for the first time on April 9.

We are sensitive to the considerable ongoing variability among key stakeholder groups regarding the merits of the various scenarios and options presented in the Discussion Paper. As a result, we have directed Staff to undertake further analysis of the significance of the underlying problems these options were designed to address, and to develop further details as to how the options might be implemented.

We are concentrating our efforts on developing a comprehensive package of proposed changes to the Guidelines for consultation during the summer and we look forward to the continued input of our stakeholders. ■

Since our last issue...

Our recent key events

February 11:	The Human Drug Advisory Panel (HDAP) held its first 2008 meeting by teleconference.
February 27:	Barbara Ouellet gave a presentation at the *Drug Patent Law and Patent Litigation* Conference in Toronto.
March 6-7:	The Board held its first 2008 meeting. Summary of the Minutes are available on page 9.
March 19:	The *Patented Medicines Regulations* were published in the *Canada Gazette*, Part II.
March 19-20:	Martine Richard and Ria Mykoo gave a presentation at the University of Ottawa, Faculty of Law, on the regulatory mandate of the PMRPB.
April 1:	Sylvie Dupont gave a presentation at the Canadian Teachers' Federation – Group Insurance/Pension Meeting – on the *Role and Responsibilities of the PMPRB*, in Ottawa.
April 10:	Barbara Ouellet gave a presentation at the *National Business and Legal Guide to Life Sciences Business and Legal Guide to Product Life Cycle Management* Conference, held in Ottawa.
April 17:	Martine Richard gave a presentation at the *Université Laval*, MBA Programme, on the regulatory mandate of the PMPRB.
April 23-24:	Dr. Brien Benoit and Barbara Ouellet attended the Pharmaceutical Pricing Summit in London, U.K. Dr. Benoit gave a presentation *The PMPRB and Pharmaceutical Price Regulation.*
April 28-29:	Members of the NPDUIS Team made presentations at the CADTH Invitational Symposium – *Beyond the Evidence: Making Tough Decisions*, held in Edmonton. For more details on the presentations, see page 9 under National Prescription Drug Utilization Information System or access our Web site under Reporting; NPDUIS.

The PMPRB's speeches and presentations are available under Publications; Speech Series.

Discussion Paper-*Options for Possible Changes*

Stakeholder Feedback on the January 2008 Discussion Paper

On January 31, 2008, the PMPRB released a Discussion Paper entitled *Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines*. The Board received 43 submissions on the Discussion Paper.

> The PMPRB Discussion Paper – *Options for Possible Changes* to the *Patented Medicines Regulations, 1994 and the Excessive Price Guidelines* and the submissions received can be found on our Web site under Consultations; Consultations on the Board's Excessive Price Guidelines.

At the Board meeting on March 6-7, 2008, considerable discussion was held on the submissions received on the Discussion Paper. The Board values the input of its stakeholders and was pleased to receive a wealth of responses from a wide range of organizations and individuals. The following is a summary of the major proposals and options found in the Discussion Paper, as well as stakeholder feedback and preliminary responses from the Board.

Any Market Price Review

Proposal: The Board was seeking comments on four proposed circumstances when a price review at the level of "any market" (i.e., class of customer or province/territory) would be conducted.

Stakeholder Feedback: In general, representatives of the pharmaceutical industry were opposed to the proposed circumstances for any market price review, believing the approach to be unwarranted and unnecessary. On the other hand, most consumers, federal/provincial/territorial (FPT) governments and other respondents felt the PMPRB should exercise its authority to undertake price review in any market in order to limit significant price disparities.

Board Response: In principle, the Board agrees that price reviews at the level of any market should be conducted as part of its mandate to ensure that the prices charged by patentees for patented medicines sold in Canada are not excessive, thereby protecting consumers and contributing to Canadian health care.

The Board believes the proposed circumstances for any market price review are reasonable, will not pose an undue burden on patentees or Board Staff, and will contribute positively to the Canadian health care system by ensuring that individual customer classes and jurisdictions do not pay excessive prices. The Board will be giving further consideration to the specific methodology for conducting price reviews at the level of any market.

Re-Setting the MNE Price

Proposal: The Board proposed three circumstances when it would be appropriate to consider re-setting the maximum non-excessive (MNE) price on a case-by-case basis (i.e., based on: the cost of "making" and "marketing" a drug product, new scientific information or evidence, or when the medicine is sold in too few countries when introduced in Canada).

Stakeholder Feedback: In general, respondents from the pharmaceutical industry did not support the proposed circumstances for re-setting the MNE price, stating the proposals would limit the circumstances in which a price could be re-set and increase uncertainty in prices. Other respondents were more supportive of these provisions, but all stakeholders felt that clear definitions were needed for the cost of "making" and "marketing" and that "triggers" for when prices would be re-set based on new scientific information or evidence, needed to be identified. The vast majority of respondents were opposed to lowering the number of countries, or changing the number of years, before an "interim" price is re-set.

Board Response: The Board's intention for the proposals in the Discussion Paper was not to limit the circumstances for possible re-setting the MNE price, but to elaborate on likely situations where re-setting may be considered. By incorporating the proposed circumstances into the Guidelines, Board Staff would have more latitude to address the re-setting of a price, without having to bring the matter before the Board in the context of a hearing (which is the current situation). Other case-by-case circumstances could also arise in which patentees may argue that the price should be re-set, and would be open to consideration by the Board in a hearing.

The Board agrees with respondents that clear definitions are needed for the cost of "making" and "marketing" and that clearly identified triggers are needed for MNE price re-setting based on new scientific information or evidence. The Board will therefore defer its final decision on the circumstances for re-setting, pending the report of the expert consultant that has been contracted to prepare a paper on activities to be included or excluded from the definition of making and marketing, which will be reviewed by the Working Group on Making and Marketing (ss. 85(2) of the *Patent Act*). Triggers for re-setting the MNE price based on new scientific information or evidence will be developed by Board Staff in consultation with scientific experts, as needed. The current number of countries and number of years before an "interim" price is re-set will be retained.

Options to Address Issues Arising from the Federal Court of Canada Decision in LEO Pharma

Regulatory Changes

Options: The Board put forward a range of possible regulatory change options to mitigate concerns arising from the Federal Court of Canada decision. The options consisted of a number of possible regulatory changes designed to modify, and/or clarify, what information patentees would need to report as part of their regulatory obligations related to net average prices, as well as an option that would permit the Board to exclude certain in under limited circumstances.

Stakeholder Feedback: Overall, the majority of the feedback focused on the option to exempt patentees from the requirement to report benefits (payments) provided to third-party payers (i.e., Option 2), as well as the option permitting the Board to disallow benefits in limited circumstances (i.e., Option 6).

Respondents from the pharmaceutical industry supported Option 2, which was also supported by some respondents representing provincial drug benefit plans. Other respondents did not support this option, emphasizing that all benefits should be taken into consideration in the determination of the net average price. Representatives of the pharmaceutical industry opposed Option 6, although it was supported by a number of other non-industry representatives that chose to respond.

Board Response: The Board does not take the option of regulatory amendments lightly, and will be giving further consideration to proposed amendments over the next few weeks.

Guidelines Changes Relating to CPI

Options: The Board put forward two options for possible Guidelines changes affecting the CPI-Adjustment Methodology for determining the MNE price.

Stakeholder Feedback: In general, respondents from the pharmaceutical industry favored the option establishing the MNE price by using the greater of the introductory MNE price and the CPI-adjustment methodology, using the highest previous non-excessive average price (i.e., Option 2), but did not feel the option sufficiently addressed the issues at hand. The majority of respondents from the pharmaceutical industry requested that the Board consider an alternative option, where, if the average actual introductory price was below the introductory MNE price, the MNE price at introduction would increase by CPI on an annual basis and at any time patentees could increase their average price to this level. Other respondents supported both options put forward in the Discussion Paper, but only if there was a constraint placed on maximum single-year price increases.

Board Response: The Board believes that, in principle, both options in the Discussion Paper have merit, but shares the concerns of many respondents regarding the potential impact of a single year price increase, and the complexity and inter-connectedness of these options with other issues (e.g., any market price review, re-setting the MNE). The Board will therefore defer its decision on these Guidelines options, until other aspects of the Guidelines Review exercise are further advanced and all options can be considered in a more comprehensive manner.

Additional Updates from the Board Meeting on March 6-7, 2008

The Working Groups on Therapeutic Improvement and on the International Therapeutic Class Comparison presented their preliminary findings to the Board on March 6, 2008, and submitted their reports on April 4, 2008.

The Board would like to thank the members of both Working Groups for their considerable efforts.

> The final reports of the Working Groups on Therapeutic Improvement and International Therapeutic Class Comparison are posted on our Web site under Consultations; Consultations on the Board's Excessive Price Guidelines as are the Terms of Reference for all Working Groups.

The Board also endorsed the Terms of Reference and membership of the Working Group on Price Tests, which held its first meeting on April 9, 2008.

Next Steps

The Board remains committed to its goal to have the Guidelines Review exercise completed by the fall of 2008. To this end it expects to issue a *Stakeholder Communiqué* later this spring on its decisions with regard to some outstanding issues, and to further consult with stakeholders during the summer on a comprehensive package of proposed changes to the Guidelines. If the Board decides to pursue regulatory changes, further information will be included in the spring *Communiqué*.

The Board looks forward to the continued support and input of all its stakeholders in this review exercise. ■

CPI-Adjustment Factors for 2009

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 periods.

The CPI-adjustment factors for 2009 are as follows:

The Base CPI is the average of the monthly CPI figures, as published by Statistics Canada, for the benchmark year.

The 2009 Forecast CPI is 138.30 and is based on the actual CPI figures for 2007 (132.67), as published by Statistics Canada and the latest available inflation projections (2.2% for 2008 and 2.0% for 2009) from the federal Department of Finance.

Table 1

2009 CPI-Adjustment Factors for All Patented Drug Products (CPI 1992=100)

	Benchmark Year		
	(1) 2006	(2) 2007	(3) 2008
Base-CPI	129.90	132.67	NA
2009 Forecast CPI	138.30	138.30	138.30
2009 CPI-Adjustment Factor	1.065	1.042	1.020

Calculations: Latest actual available Base-CPI (DEC 2007) = 132.67

Forecast CPI for 2008 = 132.67 x 1.022 = 135.59
Forecast CPI for 2009 = 135.59 x 1.020 = 138.30

Cap for 2009 = 1.5 x 2.0% = 3.0% ■

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. The Board's decisions are subject to judicial review in the Federal Court of Canada (FC).

In the January 2008 issue of the NEWSletter, we reported on the status of several hearings. Here is an update of the Board's quasi-judicial activities over the last quarter.

Adderall XR, Shire BioChem Inc.

The Hearing Panel issued its decision in this matter on April 10. The parties have until May 10 to submit a joint proposed Order.

Apotex Inc.

The Board issued a Notice of Hearing in the matter of Apotex Inc. on March 3, 2008, requiring information concerning Apotex' status as a patentee and the filing of all statutory information required of a patentee pursuant to the *Patent Act* and the *Patented Medicines Regulations, 1994*.

Concerta, Janssen-Ortho Inc.

The Board's decision is pending.

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

On February 25, 2008, the Hearing Panel issued its decision and reasons in this matter. In its decision, the Panel instructed the parties to file a joint proposed Board Order by March 25. The Panel received separate submissions on which it is scheduled to rule in the coming weeks.

Teva Neuroscience has filed a Notice of Application with the FC seeking a judicial review of the Board's decision of February 25. A hearing date has not yet been set.

Nicoderm, Hoechst Marion Roussel Canada

A Notice of Hearing in this matter was issued in April 1999. Following proceedings before the FC, the matter was returned before the Board. A hearing has been scheduled for July 3, 2008 for disposition.

Penlac, sanofi-aventis Canada Inc.

The hearing in this matter will resume on July 14 and 15. The Hearing Panel will hear final arguments on August 20.

Quadracel – Pentacel, sanofi pasteur Limited

On February 4, 2008, the FC heard sanofi pasteur on the matter of the Hearing Panel's decision to deny the Respondent's Motion for an Order seeking to have Blake Cassels & Graydon removed as counsel to the Hearing Panel in this proceeding. The application for judicial review was dismissed. The Panel will reconvene this hearing on June 13, 2008.

Strattera, Eli Lilly Canada Inc.

Hearing dates have not yet been scheduled in this matter.

Thalomid, Celgene Corporation

Celgene Corporation has filed a Notice of Application with the FC for a judicial review of the Panel's January 21, 2008 decision. A court date has not yet been announced. ■

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 is indicated for use in ambulatory patients with Relapsing-Remitting Multitude Sclerosis to reduce the frequency of relapses.

Nicoderm is a transdermal smoking cessation patch.

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.

Thalomid does not have an Notice of Compliance but patients in Canada have been purchasing Thalomid from Celgene since 1995 (through Health Canada's Special Access Programme). Thalomid has been particularly successful in slowing the progress of multiple myeloma, a form of cancer.

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:

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

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

Voluntary Compliance Undertaking

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust its price to conform to the Excessive Price 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 medicine sold in Canada appears to have exceeded the Board's Excessive Price Guidelines (Guidelines).

Vaniqa, Barrier Therapeutics Canada Inc.

Vaniqa (*eflornithine hydrochloride*) is indicated for slowing the growth of unwanted facial hair in women. It is recommended as an adjunct to any hair removal technique.

On February 28, 2008, the Chairperson of the Board approved a VCU submitted by Barrier Therapeutics Canada Inc. for the medicine Vaniqa.

Barrier reimbursed the excess revenues accrued over the period of November 2005 to December 2007, by making a payment to the Government of Canada, in the amount of $70,860.59.

Vaniqa is no longer sold in Canada.

Lantus, sanofi-aventis Canada Inc.

Lantus (*insulin glargine*), is indicated for once-daily subcutaneous administration in the treatment of adult patients with Type 1 or Type 2 diabetes mellitus and pediatric patients (age 6-17 years) with Type 1 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

On March 14, 2008, the Chairperson of the Board approved a VCU submitted by sanofi-aventis Canada Inc. for the medicine Lantus.

In addition to reducing the price of Lantus to a non-excessive level, sanofi-aventis offset the cumulative excess revenues it received from sales of Lantus as of September 18, 2006 by making a payment to the Government of Canada in the amount of $694,239.50 and reducing the price of another medicine, ALTACE HCT. In the event that the full amount of excess revenues, totaling $3,969,554.83, has not been completely offset by December 31, 2008, sanofi-aventis has undertaken to make a further payment to the Government of Canada. ■

Human Drug Advisory Panel (HDAP)

We bid farewell to Dr. James McCormack as a member of the Human Drug Advisory Panel (HDAP). His expert advice and invaluable contribution to the scientific review of new patented medicines since 2002 will be long remembered. We wish him success in his future endeavours.

We also welcome Dr. Adil Virani as a member of the HDAP. Director of Pharmacy Services at the Fraser Health Authority and Assistant Professor at the Faculty of Pharmaceutical Sciences at the University of British Columbia, Dr. Virani brings extensive experience in drug evaluation and therapeutic assessment. We look forward to Dr. Virani's participation in the scientific review process of new patented medicines. ■

Reporting Ex-factory Prices of Medicines sold in Countries listed in the *Patented Medicines Regulations*

The *Patented Medicine Regulations* (Regulations) set out the information that patentees are required to report in respect of paragraphs 80(1)(*b*) and 80(2)(*b*) of the *Patent Act*. Paragraph 4(1)(*f*)(iii) of the Regulations requires the submission of publicly available ex-factory prices for each dosage form, strength and package size in which the medicine was sold to each class of customer in France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.

When completing the Form 2 *Information on the identity and price of the medicine*, Block 5 *Publicly available ex-factory prices for Canada and other countries*, patentees must report foreign price information even if the patented drug product is being sold in another country by another company. However, it is important to note that the information reported must pertain to the same patented drug product. It is not permitted to include prices relating to the same chemical entity, for example, that is not covered by the same patent. ■

Report on New Patented Drug – Replagal

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

Brand Name: Replagal

Generic Name: *agalsidase alfa*

DIN: 02249057 (3.5 mg/vial)

Patentee: Shire Human Genetic Therapies

Indication – as per product monograph:

Long term enzyme replacement therapy in patients with confirmed diagnosis of disease (alfa-galactosidase A deficiency)

Date of Issuance of First Patent(s) Pertaining to the Medicine: June 26, 2007

Notice of Compliance: NOC/c on February 6, 2004

Date of First Sale: July 2004

ATC Class: A16AB03

Alimentary Tract and Metabolism; Other Alimentary Tract and Metabolism Products; Enzymes

Application of the Guidelines

Summary

The introductory price of Replagal 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* (Regulations) in which Replagal was sold.

Introductory Period (July – December 2004)

Country	Price per 3.5 mg/vial
Canada	no public price available
France	$2,840.4358*
Germany	$3,040.0173*
Italy	$2,693.1091*
Sweden	$2,820.6223*
Switzerland	no public price available
United Kingdom	no public price available
United States	not sold
Median	$2,830.5290

*Derived based on methodology set out in Verification of Foreign Patented Drug Prices (2000), PMPRB Study Series S-0215

Sources:
France: *Sempex*, August 2004
Germany: *Rote Liste*, July 2004
Italy: *L'informatore farmaceutico*, September 2004
Sweden: *Preslista*, September 2004

Scientific Review

Replagal is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Replagal be classified as a category 2 new medicine (provides a breakthrough or substantial improvement). It is a breakthrough medicine as it is the first one to be sold in Canada that treats effectively a particular illness or addresses effectively a particular indication, i.e. the management of Fabry disease.

The HDAP did not identify any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

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 higher of the highest price of all of the comparable drug products based on the TCC test, and the median of the international prices of the medicine 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 Replagal was within the Guidelines as it did not exceed the median of the international prices identified in an IPC test. Replagal was sold in six of the seven countries listed in the Regulations. The table does not include prices for Canada and some of the countries in which Replagal was sold in the introductory period as there were no publicly available sources for the prices. ■

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 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 that 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 being considered within the Guidelines.

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

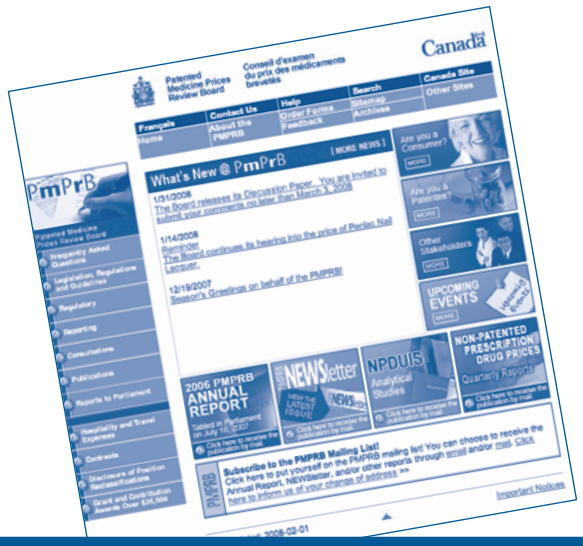
List of New Drugs Introduced since the publication of the January 2008 NEWSletter

Since the publication of the January 2008 NEWSletter, 18 new DINs for human use (representing 11 medicines) were added to the list of New Patented Medicines reported to the PMPRB for the period ending March 31, 2008. Four of these new medicines are new active substances, representing eight DINs.

The following table presents the new active substances reported to the PMPRB from January to March 2008. ■

As of March 31, 2008

Brand Name	Generic Name	Company	Therapeutic Use
Celsentri (150 mg/tab & 300 mg/tab)	*maraviroc*	Pfizer Canada Inc.	HIV Type I Therapy
Emend (80 mg/capsule, 125 mg/capsule & 125mg / 80mg tripak)	*aprepitant*	Merck Frosst Canada Ltd.	Prevention of nausea & vomiting due to chemotherapy
Isentress (400 mg/tablet)	*raltegravir potassium*	Merck Frosst Canada Ltd.	HIV Therapy
Rasilez (150 mg/tablet & 300 mg/tablet)	*aliskiren*	Novartis Pharma Canada Inc.	Hypertension



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.

National Prescription Drug Utilization Information System

The 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 Canada's drug reimbursement programs.

NPDUIS projects currently underway include a new edition of the Pharmaceutical Trends Overview Report, the second Drug Pipeline Monitor Report, which provides information on upcoming new drug products, and a methodology and tool for forecasting Drug Plan Expenditures, to name a few. As well, at the January meeting of the NPDUIS Steering Committee, several potential research priorities for 2008-2009 were discussed and a number of new projects were initiated, including research examining: the potential impact of long-term demographic change on public drug plans; recent trends in dispensing fees reimbursed by drug plans; and, methodological alternatives for measuring volumes of treatment in utilization analysis.

Detailed information on these projects, and others, will be published on our Web site as they progress.

The NPDUIS Team was invited to present some of its research projects at the 2008 Invitational Symposium of the Canadian Agency for Drugs and Technologies in Health (CADTH), on April 27-29. The following projects were presented: New Drug Pipeline Monitor, WHO Defined Daily Dose and the Drug Trend Report.

These presentations are available on our Web site under Reporting; NPDUIS and under Publications; Speech Series (2008).

The PMPRB saw its reporting role further evolve in 2005, when it was directed by the Minister of Health, on behalf of himself and his provincial and territorial colleagues, to also begin monitoring and reporting on the prices of non-patented prescription drugs. Funding for this initiative and for NPDUIS had been provided separately by Health Canada, but both activities have now been merged under the umbrella of NPDUIS. To the extent possible and appropriate, future NPDUIS studies will analyze issues from the perspective of both patented and non-patented drugs. ■

Studies published under the guise of NPDUIS are available on our Web site under Reporting; NPDUIS.

Patented Medicine Prices Review Board – March 6-7, 2008 Meeting

At its meeting, the Board

Received:

- A detailed update of the review of the Board's Excessive Price Guidelines
- The stakeholders' submissions on the Board's January 31, 2008 Discussion Paper: *Options for Possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines*
- The preliminary findings of the Working Groups on Therapeutic Improvement and on International Therapeutic Class Comparison

Approved:

- The Terms of Reference of the Working Group on Price Tests
- The next steps in the review of the Guidelines and the work plan

The next Board meeting is scheduled for May 14-16, 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

May

May 14-16: Board Meeting, Ottawa

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

May 22-23: Post Market Drug Safety and Effectiveness Workshop, University of Ottawa

May 30: Submission of the 2007 Annual Report to the Minister of Health

June

June 9: Medium Workshop, Ontario Pharmacists' Association – Drug Information and Research Centre, Toronto

June 24-25: Drug Pricing & Reimbursement in Canada Conference, Toronto

July

July 3: Hearing on Nicoderm

July 10-11: *Pharmaceutical Innovation,* International Working-Level Meeting hosted by Health Canada, in Montréal

July 14-15: Hearing on Penlac

July 31: Release of the July 2008 NEWSletter

August

August 20: Hearing on Penlac

September

September 15: HDAP Teleconference

September 18-19: Board Meeting, Ottawa

October

October 6: Hearing on Apotex

October 31: Release of the October 2008 NEWSletter

November

November 24: HDAP Teleconference

December

December 11-12: Board Meeting, Ottawa

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

Readers' Corner

The "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 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.

Name:

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