Patented Medicine Prices Review Board

PMPRB NEWSletter

Volume 11, Issue No. 2
April 2007

Inside...

Board Members

The PMPRB is an independent quasi-judicial body with a dual mandate.

Regulatory - To protect consumers and contribute to Canadian health care by ensuring that prices charged by patentees for patented medicines are not excessive.

Reporting - To contribute to informed decisions and policy making, by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.

Since our last issue...

Here are some of the key events that occurred since the end of January 2007.

February 16:	The Human Drug Advisory Panel held a quarterly meeting by teleconference.
February 22:	The Board heard a Motion for Adjournment by the Respondent in the matter of Eli Lilly Canada Inc. and its medicine Strattera.
February 27:	Ron Corvari briefed officials of the Department of Health of Russia on the role of the PMPRB.
February 28:	The Board resumed its public hearing in the matter of Janssen-Ortho Inc. and its medicine Risperdal Consta.
March 1:	The Board held its first quarterly meeting. A summary of the Minutes is available on page 9.
March 20:	Ron Corvari, Sylvie Dupont and Béatrice Mullington briefed the Inquiry Chair of the Pharmacy Market Inquiry of the Ministry of Health and Social Affairs of Sweden on the PMPRB's role and responsibilities.
March 21:	The Board resumed its public hearing in the matter of Janssen-Ortho Inc. and its medicine Concerta. Barbara Ouellet gave a presentation on the role of the PMPRB at the Canadian Pharma Industry Symposium, in Toronto.
March 26:	The Board issued a Notice of Hearing in the matter of sanofi-aventis Canada Inc. and its medicine Penlac Nail Lacquer.
March 27:	Barbara Ouellet gave a presentation on the role of the PMPRB at the Pharmaceutical and Biotech Regulatory Compliance Summit, in Toronto. Her presentation is available on our Web site under Publications; Speech Series (2007). The Board issued a Notice of Hearing in the matter of sanofi pasteur Limited and its medicines Quadracel and Pentacel.
March 28:	Dr. Benoit and Barbara Ouellet appeared before the Standing Committee on Health on Main Estimates. Dr. Benoit's Opening Remarks are available on our Web site under Publications; Speech Series (2007).
April 23:	Ron Corvari gave a presentation on the National Prescription Drug Utilization Information System (NPDUIS) at the Canadian Agency for Drugs and Technologies in Health (CADTH) 2007 Symposium – *Informing Policy, Influencing Practice, Improving Health.* The PMPRB did a poster presentation on monitoring and reporting on Non-Patented Prescription Drug Prices at the CADTH 2007 Symposium.

If you wish to know more about the PMPRB, please contact us at our toll-free number or consult our Web site.

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Senior Staff

Executive Director:
Barbara Ouellet

Secretary of the Board:
Sylvie Dupont

Director of Policy and Economic Analysis:
Ron Corvari

Director of Compliance and Enforcement:
Ginette Tognet

Director of Corporate Services:
Ravinder Dhillon

Senior Counsel:
Martine Richard

April 27:	Barbara Ouellet did a presentation on the role of the PMPRB and its price review process to the Board of Directors of Janssen-Ortho Inc.
April 30:	The Board resumed its public hearing in the matter of Shire BioChem Inc. and its medicine Adderall XR. ■

Comings and Goings

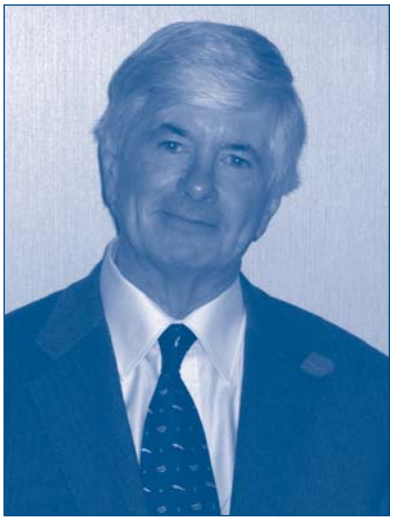
- Robert Squires, Senior Economist, formerly from Finance Canada, and Liam Cardill, Economist, formerly from Statistics Canada, have joined the Policy and Economic Analysis Branch.
- Lyse Ducharme has joined the Corporate Services Branch as Chief, Corporate Planning and Reporting.
- Jennifer Julien has joined the Secretariat and will assist the Secretary of the Board with the hearing activities.
- David Latour has returned to the PMPRB, Corporate Services Branch, following a secondment at Health Canada. Welcome back!
- Marie-Sophie Jobin, formerly from the *Unité de recherche en santé des populations* (URESP)-Centre hospitalier affilié universitaire de Québec, has joined the Compliance and Enforcement Branch as a Scientific Officer.
- Paul De Civita former acting Director, Policy and Economic Analysis Branch, joined the Canadian Food Inspection Agency.
- Brigitte Joly left the Compliance and Enforcement Branch to join the Competition Bureau.
- We also bid farewell to Steve Eyamie, Information Systems.

We offer them our best wishes in their new endeavours. ■

News from the Chairperson

Ms. La Forest's biographical notes are available on our Web site under About the PMPRB.

I am pleased to welcome Anne Warner La Forest as the newest Member of the Patented Medicine Prices Review Board. Ms. La Forest's appointment brings this Board to a full complement.



Brien G. Benoit, MD
Chairperson of the PMPRB

Ms. La Forest is currently a law professor at the University of New Brunswick. Member of the New Brunswick Securities Commission since 2004, she is also the Chair of the Commission's Human Resources Committee.

After working in private practice with the firm of Fraser & Beatty in Toronto for several years, Anne La Forest joined the Faculty of Law at Dalhousie University in 1991. In 1996, she was appointed Dean of its Faculty of Law, a position she held until 2004.

A member of the bars of New Brunswick, Nova Scotia and Ontario, Ms. La Forest has extensive experience as an arbitrator and has acted as a consultant on matters relating to human rights, employment, property and extradition law. She has been a member of the Nova Scotia Human Rights Tribunal and a member of the Social Sciences and Humanities Research Council and Chair of the Fellowships Committee. She has also served as Arbitrator in the province of Nova Scotia as well as Commissioner of the province's Human Rights Commission. She is a Fellow of the Cambridge Commonwealth Society and is currently a member of the Board of Governors of the National Judicial Institute.

Ms. La Forest was appointed to the PMPRB for a five-year term.

Welcome Anne! ■

Brien G. Benoit, MD

The Federal Court of Canada rules on the Board's decision in the matter of LEO Pharma Inc. and the price of the patented medicine Dovobet

On March 21, 2007, the Federal Court of Canada released its decision and reasons on the application for judicial review filed by LEO Pharma Inc. with regard to the Board's decision in the matter of the price of the patented medicine Dovobet.

The Board issued a Notice of Hearing on November 29, 2004 to hold a public hearing into the price of Dovobet, a dermatological drug administered for psoriasis. Following release of the Board's decision on the merits of this case in April 2006, LEO Pharma filed an application for judicial review with the Federal Court. In its application, LEO Pharma raised several issues, namely the Standard of Review of the Board's decision, its determination of the appropriate therapeutic class, the application of the International Price Comparison tests, the exclusion of free goods in the calculation of the average transaction price of Dovobet, and allegations of institutional bias with regard to the Board's structure.

As a result of the Federal Court decision, all reductions or benefits (as defined by the *Patented Medicine Regulations, 1994*) must now be included in the calculation of the average transaction price (ATP) of a patented medicine. That is, the Federal Court's decision supersedes the direction provided by the Board in its April 2000 NEWSletter and in its Excessive Price Guidelines (see Chapter 1, section 5 Average Price and Net Revenue Calculations, subsections 5.3 and 5.4). As a result, patentees will no longer be permitted to exclude from the ATP calculation any reductions or benefits of a like nature, whether or not they are supplied under a compassionate release program, trial prescription program or expenditure limitation agreements.

In his decision, Justice Blais upheld the Board's decision on all issues except in regards to the exclusion of free goods in the calculation of the average transaction price of Dovobet.

Standard of Review

In his decision, Justice Blais held that, given the nature of the questions raised which were of mixed fact and law, the appropriate standard of review was that of "reasonableness." In the words of Justice Blais: "Moreover, it is important to keep in mind that a decision of the Board on whether or not a medicine is excessively priced is highly discretionary, as the Act (*Patent Act*) and associated Regulations provide very limited guidance on the subject, and thus should be accorded greater deference."[1]

However, with respect to the allegations of institutional bias, Justice Blais, applying a standard of correctness, upheld the Board's structure. Justice Blais rejected the applicant's argument that the Board lacks sufficient institutional independence and impartiality to provide a patentee with a fair hearing in accordance with the principles of fundamental justice.

Board's Excessive Price Guidelines

In his decision, Justice Blais acknowledged that section 85 of the *Patent Act* is drafted in very general terms, thereby giving the Board broad discretion to determine excessive pricing issues. Justice Blais also acknowledged that it is appropriate for the Board to look to its Guidelines for rationale and methodology in considering the application of the factors in subsection 85(1), provided the Board does not consider itself bound by those Guidelines.

In considering the issue of the application of the appropriate price tests, Justice Blais upheld the Board's decision that the price of Dovobet ought to be no higher than the combined prices of its two constituent elements (Dovonex and Diprosone).

Free Dovobet

With respect to the exclusion of the free goods in the calculation of the average transaction price (ATP) of Dovobet, Justice Blais ruled that the distribution of free medicine must be included because the *Patented Medicines Regulations, 1994* (Regulations) require the patentee to report the price at which it has sold a patented medicine taking into consideration "any reduction [in price] given as a promotion or in the form of rebates, discounts, refunds, **free goods**, free services, gifts or any other benefits of a like nature." **[emphasis added]**.

Subsection 4(1)(e) of the *Patented Medicines Regulations, 1994* identifies the relevant reporting requirements used by Board Staff in the determination of the Average Transaction Price (ATP) of a patented medicine. Pursuant to the Regulations, patentees are required to report the quantity of the medicine sold and either the average price per package or the net revenue from sales of each dosage form, strength and package size in which the medicine was sold in final dosage form by the patentee to each class of customer in each province/territory during the relevant reporting periods.

In determining the ATP of a patented medicine, subsection 4(4) of the Regulations states that the actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefits of a like nature and after deduction of the federal sales tax **shall be used**. **[emphasis added]**.

Subsection 4(5) of the Regulations similarly states that, in calculating the net revenue from sales of each dosage form, strength and package size in which the medicine was sold in final dosage form, the actual revenue after any reduction in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefits of a like nature and after deduction of federal sales taxes **shall be used**. **[emphasis added]**.

1 Federal Court of Canada, http://decisions.fct-cf.gc.ca/en/2007/2007fc306/2007fc306.html, page 8, para 15.

Impact of the FCC decision on the application of the April 2000 NEWSletter

In the Board's April 2000 NEWSletter, an article was featured discussing various incentives and programs offered by patentees. These programs included manufacturers' compassionate release programs, trial prescription programs and expenditure limitation agreements between a manufacturer and a public drug plan. The NEWSletter article stated that products supplied under such programs could either be included or excluded by the patentees, as long as the inclusion or exclusion was consistent in all reporting periods.

Patentees are advised to continue reporting any and all information pertaining to reductions or benefits of a like nature. This includes, for example, any rebates or discounts required through provincial/territorial legislation, regulation, or negotiated agreement (e.g., resulting from Ontario's Bill 102, Quebec's Bill 130, or other agreements with payers/customers). Patentees are also advised that, beginning with the reporting period ending June 30, 2007, any reduction or like benefit will be included in the calculation of the ATP.

The Board is further assessing the implications of the Federal Court decision.

Patentees who wish to obtain further guidance on this matter are to contact the Compliance Officer responsible for their company. ■

Penlac is a new formulation of an existing compound (ciclopirox), indicated as part of a comprehensive nail management program in immunocompetent patients with mild to moderate onychomycosis (due to Trichophyton rubrum) of fingernails and toenails without lunula involvement

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.

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).

Hearings

The PMPRB's regulatory mandate is to ensure that patentees' prices of patented medicines are not excessive and hence protect consumer interests. 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.

In March, the Board issued two additional Notices of Hearing into the prices of Penlac Nail Lacquer and Quadracel & Pentacel, bringing the total of ongoing hearings to ten. The purpose of these hearings is to determine whether, under sections 83 and 85 of the *Patent Act*, the patentees are selling or have sold the said medicines in any market in Canada at a price that, in the Board's opinion, are or were excessive; and, if so, what orders, if any, should be made.

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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Penlac Nail Lacquer, sanofi-aventis Canada Inc.

The hearing in the matter of sanofi-aventis Canada Inc. and its medicine Penlac Nail Lacquer is scheduled to commence on July 23, 2007. A pre-hearing conference will be held on June 6, 2007.

Quadracel and Pentacel, sanofi pasteur Limited

The Hearing in the matter of sanofi pasteur Limited and its medicines Quadracel and Pentacel is scheduled to commence on August 20, 2007. ■

Amendments to the *Patented Medicines Regulations, 1994*

In our January NEWSletter, we reported that a revised regulatory package was in the final stages of moving forward to Treasury Board Cabinet Committee. As a next step, Board Staff met with Rx&D, the Canadian Generic Pharmaceutical Association and BIOTECanada in February and March to discuss the proposed amendments and how they would be implemented through changes to the various forms patentees are required to file as part of their regulatory reporting requirements. In the context of these various meetings, the industry raised concerns relating to a few specific proposed amendments implementation of which could have resulted in a significant increase in the regulatory burden of patentees. It also became clear that the amendments as drafted differed from the intention of the Board. As a result, the Board has further considered the matter and a revised regulatory package is being prepared for forwarding to Treasury Board Cabinet Committee for publication in the *Canada Gazette*, Part II. ■

Review of the Board's Excessive Price Guidelines

The Board is continuing its work to assess and consider potential modifications to its *Excessive Price Guidelines* (Guidelines) so that they remain effective both in facilitating Board Staff's review of patented drug prices and in promoting voluntary compliance on the part of patentees to ensure that prices of patented medicines sold in Canada are not excessive.

It is important to note that the purpose of the Guidelines is to provide transparency and predictability in the price review process for all stakeholders. The Board recognizes that the pharmaceutical environment has evolved since the last major revision to the Guidelines in 1994, and that it is essential to ensure that the Guidelines remain relevant and appropriate in the current context. At the same time, the Guidelines have been very effective in promoting voluntary compliance with non-excessive pricing. Currently, there are over 1100 patented drug products under the Board's jurisdiction. While there have been a number of recent Notices of Hearing, and several investigations into apparent excessive prices are ongoing, the overall rate of compliance with the Guidelines for all patented drugs being sold in Canada is extremely high – at over 90%.

In May 2006, the *Discussion Guide for the Consultations on the Board's Excessive Price Guidelines* (Discussion Guide) identified three main issues: 1) the current approach to categorization of new patented medicines; 2) the current approach to reviewing introductory prices; and 3) the reference in the *Patent Act* (Act) to consideration of prices in "any market." During the month of November, the face-to-face multi-stakeholder consultations probed further into the first and third issue in the Discussion Guide, and sought views on two other issues – potential Guiding Principles underpinning the approach to how the price factors in the Act are operationalized in the price review process; and the concept of "re-benching."

The Board will be continuing its analysis of all of the above issues. In addition, it has noted that the current Guidelines do not encompass all of the factors in the Act that the Board must consider in determining whether prices of patented medicines are excessive. That is, there is no guidance on the review of the second part of subsection 85(1)(c), "the prices at which …other medicines in the same therapeutic class have been sold in countries other than Canada."

Neither is there direction on subsection 85(2) – "Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors: (a) the costs of making and marketing the medicine; and (b) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances." The current Guidelines are silent on guidance as to when a determination of whether prices are excessive based on subsection 85(1) may not be possible, on how the costs of making and marketing the medicine may be assessed, and on other factors that may be relevant.

These gaps are being added to the Board's overall workplan on the review of the current Guidelines.

In order to further advance its work, the Board believes it would be useful to hold bilateral consultations with groups representing sectors of the pharmaceutical industry, federal/provincial/territorial governments and consumers. Organizations to be invited to these bilateral meetings will be identified in the coming weeks. In addition, the Board will be communicating the agenda for the meetings, including questions on which it will be seeking written and oral comments. Information on these meetings will be posted on our Web site as it becomes available, as will written submissions received by the Board during this next phase of consultation.

Recognizing that this first major review of the Guidelines since 1994 may create a certain degree of uncertainty for patentees and other stakeholders regarding the future price review process, the Board is committed to ongoing open communication through its NEWSletter, its Web site and other means, as appropriate. ■

The Discussion Guide and Summary Reports on each stakeholder meeting are available on the PMPRB's Web site under Consultations.

Upon publication, the BIA Guidelines and the New Drug Pipeline Monitor will be posted on our Web site under Reporting; National Prescription Drug Utilization Information System (NPDUIS).

NPDUIS - *Update*

The PMPRB is pleased to announce the upcoming release of the *Canadian Budget Impact Analysis Guidelines* (BIA) in May. The BIA Guidelines have been developed to provide clear guidance regarding the methodology and reporting methods to be used when submitting BIAs to the Common Drug Review (CDR), administered by the Canadian Agency for Drugs and Technology in Health (CADTH), or to federal, provincial or territorial drug plans that participate in CDR.

As well, the first edition of the *New Drug Pipeline Monitor* (NDPM) is scheduled for release in May. This inaugural edition outlines the methodology used to select drugs that are in the latter phases of research and that could have a significant impact in terms of therapeutic value. Twelve drugs are highlighted in this issue and information on their therapeutic potential is provided. Future editions of the NDPM will continue to track the clinical development of these drugs and will highlight potential new drugs in the pipeline. In addition, preliminary market analyses will be provided to inform decision-makers of potential cost impacts of the new drugs.

During 2007-2008, the PMPRB plans to produce two reports on pharmaceutical trends. The first report will provide an overview of expenditures and cost drivers, and the second will focus on the leading therapeutic groups. Aggregated DIN-level data, up to 2005-2006, has been provided by seven provincial drug plans (Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia and Prince Edward Island) and the Pharmacy Program of the Non-Insured Health Benefits, Health Canada.

The next meeting of the NPDUIS Steering Committee is scheduled to be held in Ottawa on May 11, 2007. ■

Monitoring and Reporting of Non-Patented Prescription Drug Prices

In October 2005, the federal/provincial and territorial (FPT) Ministers of Health announced the endorsement of the PMPRB to monitor and report on the prices of non-patented prescription drugs. In November 2005, the PMPRB received direction from the federal Minister of Health, on behalf of himself and his PT colleagues, to undertake this monitoring and reporting.

The third report on Non-Patented Prescription Drug Prices, *Market for New Off-Patented Drugs* is nearing completion. This report examines brand name drug products that have gone off-patent between the years 2001 and 2003.

Our fourth report, to be released this summer, will examine trends in prices of Non-Patented Single-Source Prescription Drugs sold in Canada and abroad. The analysis will cover issues such as recent developments in sales and prices, international price comparisons and an examination of factors determining market entry in Canada using a multivariate analysis.

To-date, two reports have been released — *Canadian and Foreign Price Trends*, in July 2006, which examined domestic and international price and sales trends of non-patented prescription drugs; and *Trends in Canadian Sales and Market Structure*, released in October 2006, which analyzed annual growth rates in sales, sources of growth, market shares, sales concentration, and international price comparisons by level of concentration. Both are available on our Web site under Reporting; Non-Patented Prescription Drug Prices. ■

Foreign Price Verification Factors

As per the *Patented Medicines Regulations, 1994*, the European countries included in the PMPRB's international price comparisons are France, Germany, Italy, Sweden, Switzerland and the United Kingdom.

Every year, the Policy and Economic Analysis Branch (P&EA) updates the backing-out formulas used by the Compliance and Enforcement Branch (C&E) to conduct foreign price verifications. These formulas remove legislated wholesale/retail mark-ups from the retail prices set by national drug plans in the European countries the PMPRB includes in its international price comparisons. By removing these mark-ups, the PMPRB obtains independent estimates of foreign ex-factory prices. C&E uses these estimates to check the accuracy of the foreign ex-factory prices submitted by manufacturers.

The backing-out formulas are based on information provided by officials of the foreign drug plans. It is expected that all information required for this year's update will have been received by the end of April, after which the 2007 formulas will be finalized and posted on the PMPRB's Web site, under Are you a Patentee? and Reference Documents for Patentees. ■

CPI Adjustment Factors for 2008

The *Patent Act* (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 PMPRB's CPI-Adjustment Methodology provides for the calculation of the CPI-Adjustment factors based on forecast changes in the CPI. The PMPRB informs patentees on an annual basis of the CPI-adjustment factors for the future pricing period.

The CPI-adjustment factors for 2008 are as follows:

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

	Benchmark Year		
	(1) 2005	(2) 2006	(3) 2007
Base-CPI	127.34	129.90	NA
2008 Forecast CPI	134.62	134.62	134.62
2008 CPI-Adjustment Factor	1.057	1.036	1.020

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

The 2008 Forecast CPI (134.62) is based on the actual CPI figures for 2006 (129.90), as published by Statistics Canada, and the latest available inflation projections (1.6% for 2007 and 2.0% for 2008) from the federal Department of Finance. ■

Calculations

Forecast for 2007 = 129.90 X 1.016 = 131.98
Forecast for 2008 = 131.98 X 1.02 = 134.62

Cap for 2008 = 3.0% (1.5 x 2.0%)

Report on New Patented Drug – Macugen, Pfizer Canada Inc.

Brand Name: Macugen

Generic Name: (pegaptanib sodium injection)

DIN: 02267225 (0.3 mg/90 ÌL syringe)

Patentee: Pfizer Canada Inc.

Indication – as per product monograph: For the treatment of subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration.

Date of Issuance of First Patent(s) Pertaining to the Medicine: February 14, 2006

Notice of Compliance: May 2, 2005

Date of First Sale: August 26, 2005

ATC Class: S01XA17
Sensory Organs; Ophthalmologicals; Other Ophthalmologicals

The PMPRB publishes the results of its reviews of new patented drugs for all new active substances introduced after January 1, 2002 on its Web site under Regulatory; Patented Medicines; Reports on New Patented Drugs for Human Use.

Application of the Guidelines

Summary

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

Scientific Review

Macugen is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that it be classified as a category 2 new medicine as it provides a substantial improvement in the treatment of subfoveal choroidal neovascularization (CNV) secondary to age-related macular degeneration, where current standard of care provides insufficient therapy options for patients who have minimally classic or occult lesions with no classic morphology. This recommendation is based on two randomized phase III clinical trials (VISION), by Gragoudas ES, Adamis AP, Cunningham ET, et al. (reference #7), in which patients treated with Macugen exhibited favourable results in all subtypes (classic or occult) of wet (CNV).

Loss of visual acuity is a major cause of incapacity and considerably reduces quality of life. The possibility to stop the progression of the disease while treating a greater spectrum of patients with Macugen, combined with the relative ease of administration and medically manageable side effects, remains very relevant in this patient population.

The HDAP did not identify any comparators for the conduct of a Therapeutic Class Comparison (TCC) test for Macugen as there are no comparators that can be considered clinically equivalent.

Price Review

Under the Excessive Price Guidelines (Guidelines), the introductory price of a new category 2 drug product will be presumed to be excessive if it exceeds the prices of all of the comparable drug products based on a TCC test, or the median of the international prices identified in an International Price Comparison (IPC) test. As no comparable drug products could be identified for purposes of conducting a TCC test, the introductory price of Macugen was considered within the Guidelines as it did not exceed the median of the international prices identified in the IPC test. Macugen was sold in only one other country (United States) of the seven countries listed in the Regulations at the time of introduction to the Canadian market.

Introduction Period (August to December 2005)

Country	Price per 0.3 mg/90 ÌL pre-filled syringe
Canada	$995.0000[1]
France	—
Germany	—
Italy	—
Sweden	—
Switzerland	—
UK	—
US	$1222.8725[2]

Source: 1. No publicly available price at introduction (2005) or in 2006. PPS Pharma January 2007.
2. Publicly available price as per the *Patented Medicines Regulations*.

The Guidelines provide that when a medicine is sold in fewer than five countries at the time of its introduction, the introductory price will be treated as the interim benchmark price. Board Staff will review the interim benchmark price at the end of three years or when the medicine is sold in at least five countries, whichever comes first.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by the PMPRB Staff and the HDAP for the purpose of carrying out the PMPRB's regulatory mandate, which is to review the prices of patented medicines sold in Canada to ensure that such prices are not excessive. The publication of these reports is also part of the PMPRB's commitment to make its price review process more transparent.

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

List of New Drugs introduced since the publication of the January 2007 NEWSletter

Since the publication of our January 2007 NEWSletter, 19 new DINs for human use (representing 10 medicines) were added to the list of New Patented Medicines reported to the PMPRB for the period ending March 31, 2007. Five of these new medicines are new active substances, representing nine DINS.

The following table presents the new active substances reported to the PMPRB during the period January to March 2007.

Brand Name	Generic Name	Company
Tysabri (20 mg/ml)	natalizumab	Biogen Idec Canada Inc.
Aptivus (250 mg/cap)	tipranavir	Boehringer Ingelheim (Canada) Ltd.
Exjade (125 mg/tab, 250 mg/tab, 500 mg/tab)	deferasirox	Novartis Pharma Canada Ltd.
Trileptal (20 mg/tab, 150 mg/tab, 300 mg/tab)	oxcarbazepine	Novartis Pharma Canada Ltd.
Tygacil (50 mg/vial)	tigecycline	Wyeth Pharmaceuticals

Patented Medicine Prices Review Board – March 1st, 2007 Meeting

At its meeting, the Board:

- Discussed:
  - The possible next steps in the Review of the Board's Excessive Price Guidelines
- Was briefed on:
  - The results of the compliance and investigation reports
  - The Work Plan for the 2006 Annual Report
  - Future PMPRB activities related to the National Prescription Drug Utilization Information System

The next Board meeting is scheduled for May 18, 2007.

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.

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 or/and mailing addresses 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 at pmprb@pmprb-cepmb.gc.ca.

Upcoming Events

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

May

8-9
APEX Symposium, Ottawa

11
NPDUIS Steering Committee

6-8
Canadian Council of Administrative Tribunals (CCAT), Vancouver

16-18
Board Meeting

23-24
National Pharmaceuticals Strategy Meeting, Toronto

31
PMPRB 2006 Annual Report to the Minister of Health

June

4-5
HDAP Face-to-Face Meeting, Ottawa Canadian Institute Conference – *Drug Pricing and Reimbursement in Canada*, Toronto

6
Pre-Hearing: Penlac Nail Lacquer

25
Pre-Hearing: Quadracel and Pentacel

July

23
Hearing: Penlac Nail Lacquer

31
Release of the July NEWSletter

August

20
Hearing: Quadracel and Pentacel

September

10
HDAP Teleconference

19-20
Board Meeting

October

31
Release of the October NEWSletter

December

5
HDAP Teleconference

12-13
Board Meeting

To be scheduled in June – Tabling of the PMPRB's 2006 Annual Report

To be scheduled in the fall – Board's Consultation on the Review of its Guidelines on Excessive Pricing

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