Patented Medicine Prices Review Board

PMPRB NEWSletter

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April 2004

Inside...

Board Members

The Patented Medicine Prices Review Board is a quasi-judicial tribunal with the mandate to ensure that manufacturers' prices of patented medicines sold in Canada are not excessive.

Since our last issue...

Here are some of the key events which occurred since January 2004.

February 23:	The Board held its first quarterly meeting of 2004. A summary of the Minutes of the meeting are available on page 5.
March 5:	Martine Richard gave a presentation to the Canadian Forum on Pharmaceutical Marketing, *Assessing Regulatory Pricing Issues: An Update from the PMPRB*, in Toronto.
March 30:	Wayne Critchley gave a speech at the Insight Conference on Drug Patents, *Patented Medicines and Pricing Issues: Latest Trends and Developments*, in Toronto. His speech is available on our website under Publications; Speeches.
March 31:	In the Nicoderm case, the Federal Court of Canada dismissed a motion by Hoechst Marion Roussel Canada Inc. for the production of documents. More detailed information is available on page 2.
April 1:	The Standing Committee on Health tabled a report in the House of Commons entitled *Opening the Medicine Cabinet* in the context of its study on Prescription Drugs initiated last fall. This first report on the health aspects of prescription drugs dealt with surveillance of clinical trials, of adverse drug reactions, and of direct-to-consumer advertising.
April 13:	The PMPRB published a Notice and Comment on a proposed Advance Ruling Certificate for Viread. Additional information is available in the Message from the Chair.
April 29:	Réal Sureau gave a presentation on the role of the PMPRB at a conference organized by the Canadian Health Care Manager, Face to Face – An open dialogue on drug plan management, in Montréal.

Robert G. Elgie, Chairperson

Message from the Chair

The PMPRB published a Notice and Comment on Viread

On April 13, the Board published a Notice and Comment proposing to issue an Advance Ruling Certificate (ARC) with respect to the price of the patented medicine Viread, tenofovir disoproxil fumarate, sold by Gilead Sciences, Inc. Viread is indicated for the treatment of HIV-1 infection.

Pursuant to section 98(4) of the *Patent Act* (Act), an ARC is issued at the request of the patentee where the Board is satisfied that it would not have sufficient grounds to make an

All submissions shall be filed with the Secretary of the Board, at:

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

Or by e-mail at:
sdupont@pmprb-cepmb.gc.ca

Further information on the role and process of the Board may also be obtained from the Secretary of the Board by calling the PMPRB's toll-free line:

1 877 860-2150 or
613 954-8299.

order under section 83 of the Act. The ARC is issued when the patentee has clearly established that the proposed price of the medicine would not exceed the maximum non-excessive price as provided by the Board's Guidelines on Excessive Prices.

The Notice and Comment and the proposed Advance Ruling Certificate are available on our website or by contacting the Secretary of the Board. Persons who wish to make representations in this matter shall file a written submission with the Board **on or before May 7, 2004**. The Board will consider all submissions by the provincial and territorial Ministers of Health. All submissions by other persons shall include a clear statement of the person's interest in this matter, and shall state the reasons why the Board should consider the submission.

Board Staff and Gilead Sciences, Inc., will be given the opportunity to make written submissions in response to any written submissions received no later than May 25, 2004.

The PMPRB will publish its decision on its website at the earliest opportunity. ■

Robert G. Elgie
Chairperson

Nicoderm, Hoechst Marion Roussel Canada Inc.

On April 20, 1999, the Chairperson of the Board issued a Notice of Hearing to consider whether, under sections 83 and 85 of the *Patent Act* Nicoderm is being, or has been, sold by Hoechst Marion Roussel Canada Inc. (HMRC) in Canada at a price that, in the opinion of the Board, is excessive and if so, what order, if any, should be made. The matter was first reported on page 32 of the Annual Report for the year 2000 and updates have appeared in subsequent Annual Reports and issues of the NEWSletter.

Following the issuance of the Board's decisions, in 1999 and 2000 affirming its jurisdiction to conduct a hearing into the price of Nicoderm, HMRC commenced two judicial review applications in the Federal Court of Canada seeking to set aside the Board's decisions. These matters are currently under case management before the Federal Court.

Although the judicial review applications have not yet been heard on its merits, a number of interlocutory matters have been dealt with by the Federal Court and the Federal Court of Appeal.

On June 25, 2003, the Prothonotary of the Federal Court heard a motion filed by HMRC for production of documents seeking production of the Board Staff Report to the Chairperson. In a decision rendered on November 14, 2003, the Prothonotary denied HMRC's request. This decision was appealed to the Federal Court. On March 31, 2004, the Federal Court issued its decision denying HMRC's request for production of the Board Staff Report.

Although a hearing date for the judicial review applications has not yet been established, it is anticipated that the hearing may proceed in late fall. ■

Nicoderm is a transdermal nicotine patch, indicated as an aid for smoking cessation for the partial relief of nicotine withdrawal symptoms.

The Board's decisions are posted on the PMPRB website under Publications; Hearings.

CPI-Adjustment Factors for 2005

Consistent with section 85 of the *Patent Act*, the PMPRB's Price Guidelines limit price increases for patented drugs to increases in the Consumer Price Index (CPI). Since 1987, the average annual rate of increase in the prices of patented drugs has been below the average increase in the CPI.

In 2003, the Consumer Price Index increased by 2.8%. Finance Canada forecasts lower rates of increase of 1.4% in 2004 and 1.8% in 2005.

To facilitate continued compliance with the Guidelines, the PMPRB publishes, on an annual basis, CPI-Adjustment Factors for the following year. In this way, in the event a patentee intends to adjust its price, it can

Please refer to *Schedule 4* of the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a description of the CPI-Adjustment Methodology. The Compendium is available on our website under Legislation, Regulations and Guidelines.

calculate the new limit to ensure that the price will continue to be within the Guidelines. In recent years, the prices of most patented drugs have not increased by the full allowable increase based on the CPI. For those products that have gone up in price, increases are limited based on the CPI-Adjustment Factor.

The CPI-Adjustment Factors are based on the most current annual inflation projections by Finance Canada. This year, Finance Canada forecasts that the Consumer Price Index will increase by 1.4% in 2004 and 1.8% in 2005.

The methodology for monitoring compliance with the Guidelines on an annual basis is described in the *Compendium of Guidelines, Policies and Procedures*. It was developed in consultation with stakeholders, including representatives of the provincial ministries of health, consumer groups and the pharmaceutical industry. The Guidelines provide that the price of an existing patented drug product will be presumed to be excessive if it exceeds the benchmark price of the drug adjusted for changes in the CPI over the previous three years (or less for newer drugs). To prevent large one-time increases (for example, if a manufacturer seeks to "catch up" for increases not taken in a previous year) the Guidelines provide the further restriction that a one-year price increase may not exceed 1.5 times the projected increase in the CPI, even if the relevant CPI-Adjustment Factor for a multi-year period would have allowed for a larger increase. For 2005, the one-year limit is 2.7% in the event the CPI-Adjustment Factor would have allowed a larger increase.

The following table gives the CPI-Adjustment Factors for patented medicines for 2005 based on the benchmark year. The benchmark year is 2002 for all patented medicines introduced in 2002 or before and 2003 and 2004 for drugs introduced in those years.

2005 CPI-Adjustment Factors for Patented Drug Prices

	Benchmark Year		
	2002	2003	2004
2005 CPI-Adjustment Factor	1.061	1.032	1.018

If a patented drug product was first marketed in Canada in 2004, then 2004 is its benchmark year and its 2005 price may not exceed its 2004 price by more than 1.8%.

If a patented drug product was first marketed in Canada in 2003, then 2003 is its benchmark year and the price in 2005 may not exceed the lower of 3.2% over the price in 2003 and 2.7% over the price in 2004.

If a patented drug product was first marketed in Canada in 2002 or earlier, its benchmark year is 2002, and the price in 2005 may not exceed the lower of 6.1% over the price in 2002 and 2.7% over the price in 2004. ■

New Patented Medicines Reported to the PMPRB

Since the publication of the January 2004 NEWSletter, eight new DINs for human use (representing six medicines) were added to the list of New Patented Medicines Reported to the PMPRB for the period ending March 31, 2004. Two of these new medicines are new active substances, representing four DINs.

The following table presents the two new active substances reported to the PMPRB during the period January to March 2004. ■

Brand Name	Generic Name	Company
Cialis (10mg/tab; 20mg/tab)	tadalafil	Eli Lilly Canada Inc.
Bextra (10mg/tab; 20mg/tab)	valdecoxib	Pfizer Canada Inc.

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

Reports on New Patented Drugs – Bextra

Brand Name:	Bextra
Generic Name:	valdecoxib
DIN:	02246621 10 mg tablet 02246622 20 mg tablet
Patentee:	Pfizer Canada Inc.
Indication – as per product monograph:	For the acute and chronic treatment of the signs and symptoms of adult rheumatoid arthritis, acute and chronic treatment of the signs and symptoms of osteoarthritis, and for the relief of pain associated with primary dysmenorrhea.
Notice of Compliance:	December 11, 2002
Date of First Sale:	December 18, 2002
ATC Class:	M01AH03 *Anti-inflammatory and Antirheumatic, Non-Steroids, Coxibs, Valdecoxib*

Application of the Guidelines

Summary:

The introductory prices of the Bextra drug products were found to be within the PMPRB's Price Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison and the prices did not exceed the range of prices in other comparator countries where Bextra is sold.

Scientific Review:

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Bextra be reviewed as a category 3 new drug (provides moderate, little or no therapeutic advantage over comparable medicines).

The Therapeutic Class Comparison (TCC) test of the Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drugs that treat the same disease or condition. Comparators are generally selected from among existing drug products in the same 4th level of the Anatomical, Therapeutic, Chemical (ATC) System that are clinically equivalent in addressing the approved indication. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs.

Bextra is a COX-2 selective non-steroidal anti-inflammatory (NSAID). Two other similar agents are available on the Canadian market, Vioxx (rofecoxib) and Celebrex (celecoxib). Both of these drugs are indicated for the treatment of osteoarthritis; but only Vioxx is indicated for the treatment of primary dysmenorrhea and only Celebrex is indicated for rheumatoid arthritis. As a result of the improved toxicity profile of COX-2 selective NSAIDs on the gastrointestinal tract over traditional NSAIDs, the HDAP identified Vioxx and Celebrex as the most appropriate comparators.

The Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The recommended comparable dosage regimens for Bextra and the comparators are based on the respective product monographs and supported by clinical literature.

Price Review:

Under the Guidelines, the introductory price of a new category 3 drug product will be presumed to be excessive if it exceeds the prices of all comparable drug products, based on a TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations*. The price of Bextra was within the Guidelines as the daily cost of therapy did not exceed the cost of therapy with the comparator medicines.

Name	Dosage Regimen/day	Cost Per Day
Bextra (valdecoxib)	10 mg	$1.25[1]
Vioxx (rofecoxib)	12.5 mg	$1.25[2]
Celebrex (celecoxib)	200 mg	$1.25[2]

Name	Dosage Regimen/day	Cost Per Day
Bextra (valdecoxib)	20 mg	$1.25[1]
Vioxx (rofecoxib)	25 mg	$1.25[2]
Celebrex (celecoxib)	200 mg	$1.25[2]

1 PPS, January 2004;
2 Ontario Drug Benefit Formulary, 2003

In 2003, Bextra 10 mg and 20 mg tablets were also being sold in Germany, Sweden, the United Kingdom and the United States. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in those countries; the prices of Bextra 10 mg and 20 mg in Canada were the lowest of those countries. ■

Evidence/ References:

The references are available on the PMPRB website, under Publications; Patented Medicines; Reports on New Patented Drugs; Bextra.

PMPRB's Enhanced Website!

The PMPRB is completing a series of enhancements to its website. In order to better assist our users, we have added new features, such as a Frequently Asked Questions section. Consumers, patentees and other stakeholders will have ready access to information suited to their needs. Furthermore, you will be able to subscribe to the PMPRB's publications directly on-line.

We hope that these enhancements will facilitate your research on-line.

It is expected that the enhanced website will be accessible in a few weeks.

As always, we look forward to receiving your comments on the information available on our website and any suggestions you may have on our communications tools. ■

For more information on our website, please contact our Communications Officer, Anne-Marie Labelle, at alabelle@pmprb-cepmb.gc.ca. Subscriptions to the PMPRB e-mail or mailing lists, as well as requests for publications, should be forwarded to Elaine McGillivray at Elaine@pmprb-cepmb.gc.ca.

We look forward to hearing from you!

Patented Medicine Prices Review Board – February 23, 2004 Meeting

- At its meeting, the Board received briefings on:
  - The Strategic Plan 2004-2005;
  - New drug products reported to the PMPRB: Xigris and Crestor;
  - Comparisons of patented drug prices in Canada and other countries;
  - *Natural Health Products Regulations*;
  - Cross-border drug sales;
  - Ongoing activities under the National Prescription Drug Utilization Information System (NPDUIS);
  - Highlights of the report on the National Health Expenditure Trends, 1975-2003 released by the Canadian Institute for Health Information (CIHI) last December. ■

The next Board meeting is scheduled for May 18, 2004.

For any additional information, please contact the Secretary of the Board at

1 877 861-2350, or
(613) 954-8299, or
sdupont@pmprb-cepmb.gc.ca.

Upcoming Events

May 6
Harkness Fellows, Ottawa
Dr. Robert Elgie and
Wayne D. Critchley

May 13
Les Fonds d'investissement FMOQ (Fédération des médecins omnipraticiens du Québec), Québec City. The Role of the PMPRB
Réal Sureau

May 13-14
Cambridge Pharma Consultancy, *Opportunities in 2004 and Beyond*, Cambridge, U.K.
Wayne D. Critchley

May 18
Board Meeting, Ottawa

May 20
Les Fonds d'investissement FMOQ (Fédération des médecins omnipraticiens du Québec), Montréal. The Role of the PMPRB
Réal Sureau

May 25
Canadian-Australian Conference on Health Care Issues, Ottawa
Wayne D. Critchley

May 31
PMPRB 2003 Annual Report to the Minister of Health

May-June 31-1
HDAP meeting, Ottawa

June 14-15
Meeting of the NPDUIS Steering Committee

June 20-23
Council of Canadian Administrative Tribunals Third International Justice Conference, Toronto

September 23-24
Board Meeting, Ottawa

November 15-16
Pharmac 2004, Toronto

November
ATC/DDD Workshop, Ottawa
CIHI and the PMPRB

December 16-17
Board Meeting, Ottawa

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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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