Patented Medicine Prices Review Board

PMPRB NEWSletter

Volume 10, Issue No. 1
January 2006

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 manufacturers 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...

The NEWSletter reaches a milestone!

Celebrating the 10th anniversary of the NEWSletter, the January issue is dedicated to all who have contributed to the success of the NEWSletter. Congratulations on reaching this milestone!

Previous issues of the NEWSletter are available on our Web site under Publications.

Here are some of the key events that occurred since October 2005.

November 17:	Barbara Ouellet gave a presentation on the *PMPRB Regulatory Process* at CCOHTA's F/P/T Advisory Committee on Pharmaceuticals, in Ottawa.
November 21:	Barbara Ouellet gave a presentation, *Drug Pricing: Current Trends and Future Directions*, at the PHARMAC Sales and Marketing Summit 2005, in Toronto.
November 29:	The Board resumed its hearing in the matter of LEO Pharma Inc. and the medicine Dovobet.
December 15:	The Board held its last meeting of the year. A summary of Minutes are available on page 11. ■

Comings and Goings

- Brigitte Joly has returned to the PMPRB, Compliance and Enforcement Branch, following a secondment at Health Canada. Welcome back!
- Greg McComb, from Environment Canada, and Carlo Rupnik, from Statistics Canada, have joined the Policy and Economic Analysis Branch as Senior Economists.
- James Gauthier and Jeff Marchand, of the Policy and Economic Analysis Branch, left the PMPRB to meet new challenges at Finance Canada and Health Canada respectively.
- Best wishes to Lisa Charbonneau in her new endavours. Lisa is leaving our Compliance and Enforcement Branch to join Health Canada. ■

News from the Vice-Chairperson

Pharmaceuticals management remains front and centre in health care policy discussions, and the PMPRB is proud of the role it plays in protecting Canadians from excessive prices for patented medicines, and its contribution to informed decisions and policy making.

After being appointed to the Board last May, briefing sessions were held to assist me in my new role – this, of course, came with *compulsory* reading materials. I recall reading Dr. Robert Elgie's last *Chairperson's Message*, in which he provided a brief history of his ten-year tenure at the PMPRB and the many challenges the organization faced during his tenure. I was struck by the constant change the PMPRB experienced. I am pleased to report that the PMPRB has in no way slowed down its activities, and it continues to remain responsive to the needs of Canadians.

Under the *Patent Act*, if the Chairperson is absent or incapacitated or if the office of Chairperson is vacant, the Vice-Chairperson has all the powers and functions of the Chairperson during the absence, incapacity or vacancy.

Senior Staff

Executive Director:
Barbara Ouellet

Secretary of the Board:
Sylvie Dupont

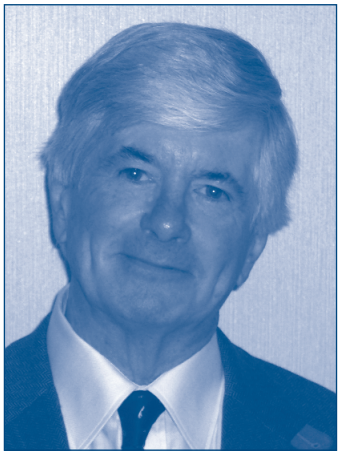
Acting Director of Policy and Economic Analysis:
Paul De Civita

Director of Compliance and Enforcement:
Ginette Tognet

Director of Corporate Services:
Robert Sauvé

Senior Counsel:
Martine Richard

In my short time at the Board, I have so far witnessed improvements to the price review process with the Time Lines initiative, which will ultimately lead to more efficient and effective procedures. There have been discussions and decisions in the context of two important consultations initiated in the first quarter of 2005: on the proposed amendments to the *Patented Medicines Regulations, 1994*, and on the Discussion Paper on Price Increases for Patented Medicines. In addition, new responsibilities were handed to us by the Federal/Provincial/Territorial Ministers of Health in October to monitor and report on non-patented prescription drug prices – with a first report due out this spring. Preparations are also underway for potential new regulations, which, if approved, will provide a faster review of patented drug prices, to the benefit of Canadians, and a more streamlined reporting process for patentees. There will also be increased enforcement activities. All this activity underscores both the dynamic environment of pharmaceuticals management in Canada, and the unique and important role played by the PMPRB.



Dr. Brien G. Benoit,
Vice-Chairperson of the PMPRB

Additional activity under our reporting function have in no way diminished our efforts to fulfil our core mandate. The expertise and professionalism of our Staff, along with the valuable contribution of our Board Members, have facilitated coordination with other organizations and stakeholders, so as to continue yielding benefits for Canadians.

I take this opportunity to offer our best wishes to all our readers for the New Year along with our commitment of service to our fellow Canadians. ■

Brien G. Benoit
Vice-Chairperson

The PMPRB and the Government of Canada Workplace Charitable Campaign 2005

Congratulations to All!

The PMPRB is happy and proud to announce, once again, that it has exceeded its goal by 68.41%. Staff's participation was registered at 96%. Our Staff is diligent and demonstrates tremendous support towards the community by continually contributing generously to the Campaign.

Elaine McGillivray, our Campaign Leader, and team members have once again managed to lead us in a successful campaign. Their dedication and hard work are always appreciated. Special thanks to Elaine, Gail Kohlmeyer and Catherine Jesty (missing from the photo) from all of us and particularly from those who will benefit from your efforts! ■

The Board will hold a Public Hearing into the price of Adderall XR

The Board has scheduled a hearing in the matter of Shire BioChem Inc. and the price of Adderall XR to start on April 24, 2006. A pre-hearing conference will be held on March 8, 2006.

The purpose of this hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, Shire is selling or has sold the medicine known as Adderall XR in any market in Canada at a price that, in the Board's opinion, is or was excessive; and, if so, what order, if any, should be made.

Persons wishing to intervene in this proceeding are required to apply to the Board for leave to intervene on or before February 10, 2006. ■

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

The Public Record is available on the PMPRB Web site under Publications, Hearings, Adderall XR.

All requests for information should be addressed to the Secretary of the Board:
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Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario K1P 1C1
Toll-free number:
1 877 861-2350
Direct line: (613) 954-8299
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sdupont@pmprb-cepmb.gc.ca

Federal Court Decision on HMRC Judicial Review Applications

Hoechst Marion Roussel Canada Inc. v. Attorney General of Canada 2005 FC 1552

On November 17, 2005, the Federal Court issued a decision with respect to two judicial review applications filed by Hoechst Marion Roussel Canada Inc. ("HMRC"). HMRC was seeking to set aside the decisions of the Patented Medicine Prices Review Board ("PMPRB") on the basis that the PMPRB was without jurisdiction to inquire into the pricing of the Nicoderm patch because:

(1) The overlapping functions of the PMPRB as investigator, prosecutor and adjudicator creates a reasonable apprehension of bias;

(2) The manner in which the PMPRB proceeded by making determinations prior to the issuance of the Notice of Hearing denied the Respondent a reasonable opportunity to be heard and gives rise to a reasonable apprehension of bias;

(3) Nicoderm is not a medicine for the purposes of section 83 of the *Patent Act*;

(4) Patent No 1,331,340 (" '340 Patent") and Patent No 1,338,700 ("'700 Patent") do not pertain to the medicine;

(5) The PMPRB cannot assert jurisdiction on the basis of Canadian Patent Applications.

On the issues dealing with the structure and manner of proceeding of the PMPRB, the Federal Court found that the PMPRB, as an administrative tribunal with economic regulatory functions, must be accorded a degree of flexibility and as such may perform multiple overlapping functions without creating a reasonable apprehension of bias. Furthermore, the Federal Court was of the view that the Board ought to be granted "a considerable degree of flexibility" in respect of its procedural requirements and as such found that natural justice and procedural fairness had been respected.

With respect to the issue of whether Nicoderm is a medicine, the Federal Court, relying on the Federal Court of Appeal in *ICN Pharmaceuticals, Inc.* v. *Canada (Staff of the Patented Medicine Prices Review Board)*, [1997] 1 F.C. 32 (F.C.A.) ("ICN"), found that, as the word "medicine" was to be interpreted broadly and in its ordinary meaning, Nicoderm fell within the definition of "medicine". The Federal Court, again relying on ICN, found that both Patents '700 and'340 did pertain to the medicine when applying the "merest slender thread" interpretation as articulated by the Federal Court of Appeal, and that a patent may pertain to the medicine even though it is not being used.

The Federal Court, however, dealing with the issue of patent applications found that, as a patent application gives rise only to a potential grant of patent, the PMRPB was not authorized to assert jurisdiction until the patent issued.

No appeal having been filed in the Federal Court of Appeal, this matter will be remitted to the Board. The Federal Court decision is available on our Web site under Publications; Hearings; Nicoderm.

Patentees will be interested to know that the HMRC decision does not affect the Board's present policy on patent pending, which is to assert jurisdiction retroactively to review the price at which the medicine was sold during the pre-grant infringement period, **once the patent issues**. ■

The Board issued a Notice of Hearing in April 1999 in the matter of Hoechst Marion Roussel Canada and its medicine Nicoderm. HMRC brought a motion for an order that the Board rescind the Notice of Hearing on the grounds that the Board was without jurisdiction to inquire into the matter raised in the Notice. The Board issued its decisions on the matters raised on August 3, 1999 and August 8, 2000 respectively. HMRC brought two judicial review applications seeking to set aside both of the Board's decisions.

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

Update on Dovobet Hearing

On November 29, 2004, the Board issued a Notice of Hearing in the matter of LEO Pharma Inc. and the price of its medicine Dovobet.

Dovobet 0.55 mcg/mg (DIN 02244126) has been sold in Canada since December 17, 2001. A dermatological drug, Dovobet is administered for bringing psoriasis under control.

The Hearing Panel heard closing arguments at the beginning of December. It is expected that the Panel will release its decision on the merits of this case in the near future.

For more information on this matter, visit our Web site under Publications; Hearings; Dovobet. You can also contact the Secretary of the Board:

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Ottawa, Ontario K1P 1C1
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Direct line: (613) 954-8299
Fax: (613) 952-7626
E-mail: sdupont@pmprb-cepmb.gc.ca

Voluntary Compliance Undertakings accepted during the last quarter

Dukoral™ is indicated for the protection against travellers' diarrhea and/or cholera in adults and children 2 years of age and older who will be visiting areas where there is a risk of contracting travellers' diarrhea caused by enterotoxigenic E. coli or cholera caused by *V. cholerea*.

The VCUs are public documents and as such are posted on our Web site, under Publications; Voluntary Compliance Undertakings.

Dukoral™

On December 15, 2005, the Vice-Chairperson of the Board accepted a VCU for Dukoral™, submitted by Sanofi Pasteur Limited (sanofi pasteur).

The terms of the VCU require that sanofi pasteur agree that the maximum non-excessive (MNE) price of Dukoral™ was $25.1842 in 2004, $25.9901 in 2005, and, based on the CPI methodology, $26.6449 in 2006; and reduce the average transaction price of Dukoral™ by the end of the January 1 to June 30, 2006 regulatory filing period to the lower of the 2006 MNE price of $26.6449 or the highest international price.

Sanofi pasteur offset excess revenues received during the period April 23, 2003 to June 30, 2005, in the amount of $481,198.49, by making a payment to Government of Canada.

Furthermore, any excess revenues received during the period July 1, 2005 to December 31, 2005 will be offset by making another payment to the Government of Canada within 30 days of the filing of semi annual price and sales data as required by the *Patented Medicines Regulations* in the amount of the excess revenues, as calculated by the PMPRB, received as a result of selling Dukoral™ at prices higher than the MNE price of $25.9901 during that period.

Finally, sanofi pasteur will ensure that the price remains within the Guidelines while Dukoral™ is under the PMPRB's jurisdiction until the expiry of its patent in June 2016 or such time as Dukoral™ is no longer sold by sanofi pasteur in Canada.

Risperdal (*risperidone*) is an anti-psychotic drug indicated for the management of schizophrenia and related psychotic disorders.

Risperdal

On December 21, 2005, the Vice-Chairperson of the Board accepted a VCU for Risperdal tablets, submitted by Janssen-Ortho Inc.

Under the terms of the VCU, Janssen-Ortho agrees that the 2004 MNE prices of Risperdal 1 mg, 2 mg, 3 mg, 4 mg, 0.25 mg, and 0.5 mg tablets were respectively, $1.0223, $2.0410, $3.0507, $4.0643, $0.4426, and $0.7410. It will ensure that the average transaction prices of Risperdal 1 mg, 2 mg, 3 mg, 4 mg, 0.25 mg, and 0.5 mg tablets do not exceed their respective 2005 MNE prices of $1.0421, $2.0806, $3.1144, $4.1481, $0.4527, and $0.7568 based on forecast CPI for 2005. In the event that the actual CPI differs from the forecast CPI for 2005, an adjustment may need to be made to the 2005 MNE prices or the amount of excess revenues received for 2005.

Janssen-Ortho will offset excess revenues of $669,426.81, and undertook to further reduce the average transaction prices of Risperdal tablets such that all excess revenues are offset no later than December 31, 2005. In the event that the aforementioned measures do not result in an offset of all cumulative excess revenues, Janssen-Ortho is to make a payment for any excess remaining at December 31, 2005 to the Government of Canada no later than January 31, 2006.

Finally, Janssen-Ortho will ensure that the prices of Risperdal 1 mg, 2 mg, 3 mg, 4 mg, 0.25 mg, and 0.5 mg tablets remain within the Guidelines in all future periods in which they remain under the PMPRB's jurisdiction. ■

2005 Public Consultations on Drug Price Issues

Last spring we received a number of stakeholder submissions in response to our Discussion Paper on Drug Price Increases, released in March. Among others, stakeholders raised a number of complex issues concerning the continued appropriateness and relevance of the current Excessive Price Guidelines.

The Board decided, at its December meeting, that certain issues raised by stakeholders require both further analysis and consultation with them. The April NEWSletter will lay out details regarding the work plan relating to this issue for the coming year. ■

The Discussion Paper and stakeholder comments are available on our Web site under Publications; Notice and Comments.

Regulatory Amendments – The Canada Gazette, Part 1

On December 31, 2005, proposed regulatory amendments to the *Patented Medicines Regulations, 1994*, were pre-published in the Canada Gazette, Part I. Pre-publication gives stakeholders a final opportunity to review and comment on a regulatory proposal at the last stages of the regulation-making process. Interested parties had 30 days, until January 30, 2006, to submit comments. Numerous stakeholders provided input at earlier stages of the PMPRB consultation process, all of which are available on our Web site.

Next steps, as outlined in the *Government of Canada Regulatory Policy*, consist in a summary of all comments received, which will be reflected in a revised Regulatory Impact Analysis Statement (RIAS), to be included in a package for approval by the Department of Justice and the Minister of Health. Subsequently, the Treasury Board Cabinet Committee will review all submitted information and determine final publication, in the Canada Gazette, Part II. We anticipate that approval of the proposed Regulations might occur by spring of 2006.

The proposed amendments will come into force on the day after the date on which they are registered, i.e. approved by Cabinet, and then published in the Canada Gazette, Part II. ■

Non-Patented Prescription Drug Price Monitoring and Reporting

In October 2005, the Health Ministers agreed to give the PMPRB the responsibility to monitor and report on non-patented drug prices. The price monitoring and reporting function is aimed at providing a centralized credible source of information on non-patented drug prices.

As per section 90 of the *Patent Act*, in a letter dated November 17, 2005, the federal Minister of Health, on behalf of himself and his Provincial/Territorial colleagues, directed the PMPRB to report on the prices of non-patented prescription drugs. In November, representatives of British Columbia, Health Canada and the PMPRB met with the Canadian Generic Pharmaceuticals Association (CGPA), Rx&D and BIOTECanada to communicate and discuss the intent of this new reporting.

In context of the monitoring and reporting function, the PMPRB will publish quarterly reports according to the Terms of Reference agreed to by Federal/Provincial/Territorial governments. The first report is to be published in late spring of 2006. Health Canada contracted with IMS HEALTH to obtain the MIDAS dataset, which will be the primary data source for the non-patented prescription drug price monitoring and reporting.

In keeping with the PMPRB's overall focus on transparency, this initiative will involve information dissemination, and opportunity for the pharmaceutical industry and stakeholders to provide feedback at appropriate points as work proceeds.

This initiative does not in any way affect the mandate of the PMPRB under the *Patent Act*. It does, however, continue the evolving work of the PMPRB in contributing to Canadian health care and informed policy decisions, by reporting on pharmaceutical trends of all medicines. ■

As part of the September 2004 *10-year Plan to Strengthen Health Care*, First Ministers committed to develop and implement a National Pharmaceuticals Strategy (NPS). In establishing the NPS, the First Ministers agreed that "no Canadian should suffer undue financial hardship in accessing needed drug therapies". One of the nine elements of the NPS involves achieving international parity on the prices of non-patented drugs.

The Terms of Reference for Monitoring and Reporting on Non-Patented Prescription Drug Prices are available on our Web site under National Pharmaceuticals Strategy.

NPDUIS – Update and Looking Ahead

Pursuant to the findings of the *Budget Impact Analysis (BIA) Guidelines: Needs Assessment*, we are moving forward under the guidance of an Advisory Committee to develop BIA guidelines. Members of the Advisory Committee have been selected from the NPDUIS Steering Committee and the Canadian Coordinating Office of Health Technology Assessment (CCOHTA).

We are close to bringing two more studies to completion: the *Pharmaceutical Trends Overview Report* and the *Program Expenditure Forecasting Methodology*.

A new project, *New Drug Pipeline Monitoring*, has been approved. The project deliverable is a report that will summarize information concerning new drug products expected to be introduced in Canada within the next five years.

We continue to work with the NPDUIS Steering Committee to better align NPDUIS analysis with the needs of public policy decision-makers, and to address the challenges and opportunities that will be faced in the coming years. ■

An Update of the PMPI Figures Published in the 2004 Annual Report

The PMPI measures annual trends in manufacturers' prices of patented drugs. This index is reported in the PMPRB's Annual Report and assists stakeholders in tracking the evolution of prices of patented medicines in Canada. This index was developed in the context of the PMPRB's reporting mandate which includes, among others, reporting on price trends of patented medicines. The PMPI is reported in the context of changes in the consumer price index (CPI) – prices of patented medicines may not increase by more than the changes in the CPI. The PMPI is based on price and sales information filed by pharmaceutical patentees pursuant to their filing obligations under the *Patented Medicines Regulations*.

Pursuant to section 7 of the Regulations, any information provided shall be accompanied by a certificate signed by a duly authorized person certifying that the information is true and correct.

Following a further review of the Patented Medicine Price Index (PMPI) published in our most recent Annual Report, we are now reporting that the manufacturers' prices of patented drugs increased by 0.9% in 2004. This replaces the price decrease of 0.2% that had originally been reported.

During the review of the data for the 2004 Annual Report, variability in price changes by therapeutic class was noticed. In the spirit of transparency, this variability was noted in the Annual Report, and the Board undertook to do further analysis. As part of this effort, we found that there had been new filings by patentees since the cut-off date for production of the Annual Report. The information filed consisted of data additions and corrections by patentees. The impact was a significant change in the PMPI for 2004 from -0.2% to +0.9%.

In light of this finding and in the interest of due diligence, we widened our review to include all past PMPI calculations to evaluate the possible impact such data amendments may have had on the figures previously reported. It was found that similar increases to the PMPI occurred for 2002 and 2003, from -1.2 to +0.4 and from -1.1 to -0.1 respectively. During the period from 1987 to 2001, any corrections and additions that occurred had little effect on the PMPI. The PMPI results to be published in the 2005 Annual Report will include these and any other changes to the PMPI for previous years, as of the cut-off date for the Report.

The changes are not reflective of an inherent problem with the PMPI methodology, but rather a function of data correction or newly filed data. It is important that the information filed by patentees be accurate. Patentees are reminded of their obligations under the *Patent Act* and that the accuracy of their reporting plays an important role in the efficient administration of the price review process, and the information available to stakeholders on pharmaceutical trends in Canada. ■

Table – Updated PMPI Figures for 2002 – 2004

Year	PMPI Reported in the Annual Report (% Change)	Revised PMPI (% Change)	% Point Change
2002	-1.2	0.4	1.6
2003	-1.1	-0.1	1.0
2004	-0.2	0.9	1.1

Source: PMPI Program

2005 CPI-Adjustment Factors

CPI-Adjustment Factors Based on Inflation Forecasts

The 2005 CPI-Adjustment Factors included in Table1 were published in the April 2004 NEWSletter. The 2005 CPI-adjustment factors are based on forecasts of annual CPI-inflation rates for 2004 and 2005. The Base CPI is the average of the monthly CPI figures, as published by Statistics Canada, for the benchmark year.

Table 1 – 2005 CPI-Adjustment Factors for All Patented Drug Products (CPI 1992=100)

	Benchmark Year		
	(1) 2002	(2) 2003	(3) 2004
Base-CPI	119.03	122.32	n/a
2005 Forecast CPI	126.26	126.26	126.26
2005 CPI-Adjustment Factor	1.061	1.032	1.018

The 2005 Forecast CPI was 126.26 (1992=100) and was based on the actual CPI figures for 2003 (122.32), as published by Statistics Canada, and the latest available inflation projections (1.4% for 2004, and 1.8% for 2005) from the federal Department of Finance.

Cap for 2005 = 2.7% (1.5 x 1.8)

CPI-Adjustment Factors Based on Actuals

As of January 2006, Statistics Canada reports annual average CPI values of 124.56 and 127.34 for 2004 and 2005, respectively. Table 2 gives revised CPI-adjustment factors incorporating these actuals.

Table 2 – 2005 CPI-Adjustment Factors for All Patented Drug Products (CPI 1992=100)

	Benchmark Year		
	(1) 2002	(2) 2003	(3) 2004
Base-CPI	119.03	122.32	124.56
2005 Actual CPI	127.34	127.34	127.34
2005 CPI-Adjustment Factor	1.070	1.041	1.022

The actual 2005-over-2004 CPI-inflation rate was 2.2% compared to the 2005 forecast rate of 1.8%. This gives a 2005-over-2004 price increase cap of 3.3% (= 1.5% x 2.2%) rather than the 2.7% cap calculated on the basis of the 2005 forecast inflation rate. ■

HDAP Process

The HDAP is composed of three members who hold qualifications as physicians, pharmacists or other professional designation with recognized expertise in drug therapy and who have experience in clinical research methodology, statistical analysis and the evaluation of new drugs.

The role of the Human Drug Advisory Panel (HDAP) is to provide recommendations for the categorization and the selection of comparable drug products and dosage regimens for all new active substances. The HDAP may also recommend that a new drug product be considered a breakthrough or substantial improvement (i.e. category 2) which may or may not be a new active substance. Recommendations of the HDAP will be based on the criteria set out in the PMPRB's *Compendium of Guidelines, Policies and Procedures*. The approach is evidence based and the recommendations reflect medical and scientific knowledge, and current clinical practice.

The HDAP meets four times a year. The dates of the meetings for **2006** are **February 15, May 29, August 21 and November 20**.

The HDAP reviews and evaluates scientific information available to the PMPRB including submissions by patentees. Each member of the HDAP conducts an independent review of the drug product which will be discussed during the HDAP meetings or conference calls. Such recommendations of the HDAP are based on a majority vote.

In order to provide for fairness to the patentee, assurance that a drug will in fact be scheduled for discussion at a meeting and to expedite the process, a patentee must provide Board Staff with a product monograph or draft product monograph (if product not yet approved for sale in Canada) at least three months prior to a meeting.

If a patentee wishes to make a submission with respect to category and comparable drugs and dosage regimens, the submission must be made two months prior to a meeting. For more details on what should be included in a company submission, please refer to the *Compendium of Guidelines, Policies and Procedures, Scientific Review Procedures, Sections 6 and 7*. Board Staff will refer any submission as well as any information collected by Board Staff to the HDAP, at the latest, one month before an HDAP meeting.

Recommendations of the HDAP are made available to the patentee. Comments or recommendations of individual HDAP members are not disclosed.

HDAP's recommendations on the new active substances and all category 2 drug products are published in a summary report on the results of the price review in the NEWSletter and/or on our Web site.

Summary reports are available on our Web site under Patented Medicines.

Summary of Meetings for 2006 and Information to be Submitted

Date of HDAP Meeting	Information	Deadline
February 15, 2006	1 copy of product monograph or draft product monograph	November 15, 2005
	7 copies of company submission	December 15, 2005
May 29, 2006	1 copy of product monograph or draft product monograph	February 28, 2006
	7 copies of company submission	March 29, 2006
August 21, 2006	1 copy of product monograph or draft product monograph	May 21, 2006
	7 copies of company submission	June 21, 2006
November 20, 2006	1 copy of product monograph or draft product monograph	August 20, 2006
	7 copies of company submission	September 20, 2006

New Patented Medicines Reported to the PMPRB

Since the publication of the October 2005 NEWSletter, 26 new DINs for human use (representing 15 medicines) were added to the list of New Patented Medicines Reported to the PMPRB for the period ending December 31, 2005. Six of these new medicines are new active substances, representing 13 DINs.

The following table presents the six new active substances reported to the PMPRB during the period September to December 2005.

As of December 31, 2005

Brand Name	Generic Name	Company
Sensipar (30mg/tablet; 60mg/tablet; 90mg/tablet)	*Cinacalet hydrochloride*	Amgen Canada Inc.
Abreva (100mg/gm)	*docosanol*	GlaxoSmithKline, Consumer Healthcare Inc.
Tarceva (100mg/tablet; 150mg/tablet)	*erlotinib*	Hoffmann-La Roche Ltd.
Avastin (25mg/ml)	*bevacizumab*	Hoffmann-La Roche Ltd.
Tramacet (37.5/325/tablet)	*Tramadol hydrochloride/acetaminophen*	Janssen-Ortho Inc.
Lyrica (25mg/capsule; 50mg/capsule; 75mg/capsule; 150mg/capsule; 300mg/capsule)	*pregabalin*	Pfizer Canada Inc.

Report on New Patented Drug – Sensipar

Brand Name: Sensipar

Generic Name: *(cinacalcet hydrochloride)*

DIN:
02257130 30 mg tablet
02257149 60 mg tablet
02257157 90 mg tablet

Patentee: Amgen Canada Inc.

Indication - as per product monograph: For the treatment of secondary hyperparathyroidism in patients with Chronic Kidney Disease (CKD)

Notice of Compliance: August 9, 2004

Date of First Sale: September 29, 2004
The first patent pertaining to Sensipar was issued on August 30, 2005 and it came under the PMPRB's jurisdiction at that time.

ATC Class: H05BX01
Systemic Hormonal Preparations Excluding Sex Hormones and Insulins, Calcium Homeostasis, Anti-parathyroid Hormones

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.

Application of the Guidelines

Summary

The introductory prices of Sensipar 30 mg and 60 mg tablets were 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 they were sold or did not do so by an amount sufficient to trigger any of the investigation criteria under the *Compliance & Enforcement Policy*. The introductory price of Sensipar 90 mg tablet exceeded the median of the prices of the same drug in those countries listed in the Regulations in which it was sold in the introductory period. However, its price was considered within the Guidelines in the subsequent reporting period.

Scientific Review

Sensipar is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Sensipar be reviewed as a category 2 new medicine (breakthrough or substantial improvement) as it provides a substantial improvement in the treatment of secondary hyperparathyroidism in patients with Chronic Kidney Disease (CKD) where the current standard of care is insufficient to control parathyroid hormone (PTH) levels because there is currently a lack of effective therapy for patients who do not meet the National Kidney Foundation Disease Outcome Quality Indicators; failure to meet these indicators has been shown to result in morbidity and mortality.

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 prices of all comparable drug products, based on a TCC Test, and the median of the international prices identified in an International Price Comparison (IPC) Test.

As no comparable drug products were identified for purposes of conducting a TCC Test, the introductory prices were reviewed based on the median of the IPC Test. When Sensipar was first sold in 2004, the price of the 30 mg tablet was within the Guidelines; the price of the 60 mg was considered within the Guidelines as its price did not exceed the MNE price by a margin which would trigger the investigation criteria; and the price of the 90 mg tablet exceeded the MNE price by a margin which would have triggered the criteria for commencing an investigation. The price of the 90 mg tablet was considered within the Guidelines in the following reporting period.

Introductory Period (September to December 2004)

Country	Price for 30 mg tablet	Price for 60 mg tablet	Price for 90 mg tablet
Canada	$10.7070	$21.4140	$32.1210
France			
Germany			
Italy			
Sweden			
Switzerland	$11.0665	$20.1005	$27.1384
U.K.			
U.S.	$11.3456	$22.6912	$34.0369
Median	$11.2060	$21.3959	$30.5877

Source: Publicly available prices 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. The interim benchmark price may be reviewed 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. ■

Evidence/ References:

The references are available on the PMPRB Web site, under Publications, Patented Medicines; Reports on New Patented Drugs; Sensipar.

Research Agenda

As part of our 1999 *Road Map for the Next Decade*, we established the PMPRB's Research Agenda. Each year since, we have developed the agenda as part of our annual planning process, outlining current and upcoming projects that are or may become subject to public consultations.

Over the past year, new projects and initiatives have been added to our regular activities, for example, the proposed regulatory amendments, the Discussion Paper on Price Increases, NPDUIS projects and, most recently, the non-patented prescription drug price reporting. It has been thought that stakeholders will be better served if these projects and initiatives are reported on separately in our NEWSletter and on our Web site.

We remain committed to consulting our stakeholders, as we have in the past year, and will continue to do so in order to ensure that their input is reflected. ■

Patented Medicine Prices Review Board – December 15, 2005 Meeting

At its meeting, the Board

- was briefed on the:
  - National Pharmaceuticals Strategy
  - Monitoring and Reporting on Non-Patented Prescription Drug Prices
  - NPDUIS
- discussed the next steps on the PMPRB's consultations on proposed amendments to the *Patented Medicines Regulations, 1994*, and on Drug Price Issues, initiated in 2005.
- approved the meeting schedule for 2006. ■

The next Board meeting is scheduled for February 22-23, 2006. 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.

Questions and Comments

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

February
9-10
Centre for Health Services and Policy Research – 18th Annual Health Policy Conference, *Towards a National Pharmaceuticals Strategy* – Lessons from Abroad, Vancouver.

February
15
HDAP Meeting, Ottawa

March
8
Adderall XR Pre-Hearing Conference, Ottawa

March
30-31
Canadian Pharma Summit, Toronto

May
4
McGill University Health Care – 37th Annual Course in Drug Therapy, Montréal

May
17-18
Board Meeting, Ottawa

August
21
HDAP Conference

June
12-13
National Healthcare Leadership Conference, Victoria

December
13-14
Board Meeting, Ottawa

February
20-22
Drug Safety Summit 2006, Toronto

February
22-23
Board Meeting, Ottawa

February
27-28
Insight Conference - Drug Patents, Toronto

April
24
Adderall XR Hearing, Ottawa

April
27-28
Canadian Institute – Fundamentals of Administrative Law and Practice, Toronto

May
29
HDAP Conference

September
20-21
Board Meeting, Ottawa

November
20
HDAP Conference

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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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