Patented Medicine Prices Review Board

PMPRB NEWSletter

Volume 9, Issue No. 2
April 2005

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 that occurred since January 2005.

February 18:	Barbara Ouellet addressed the Board of Directors of the Canadian Healthcare Association (CHA) on the role of the PMPRB, as part of the CHA's information program on pharmaceutical issues, in Ottawa.
February 21:	The Board accepted a Voluntary Compliance Undertaking (VCU) in regard to the medicine Evra submitted by Janssen-Ortho Inc. It concluded the proceedings initiated with the issuance of the December 23, 2004 Notice of Hearing. (More information is provided on page 6.)
March 7:	The Chairperson approved two VCUs in regard to Paxil CR, submitted by GlaxoSmithKline Inc., and to Tamiflu, submitted by Hoffmann-La Roche Limited. (More information on both VCUs is available on page 6.)
March 8:	A farewell reception was held to honour Dr. Elgie. He left the PMPRB after ten years at its helm as Chairperson. (See News from the Vice-Chairperson, on page 2).
March 9-11:	The Board's hearing in the matter of LEO Pharma Inc. and the medicine Dovobet is ongoing. The Board will resume sitting in September.
March 30:	Maria Gutschi, Scientific Officer, gave a presentation at the National Cancer Institute of Canada – Clinical Trials Group Spring meeting, on the PMPRB process and perspective on global drug pricing and mandate of the Board.
March 30:	Barbara Ouellet participated at the Canadian Biotechnology Advisory Committee (CBAC) Multisectoral Roundtable panel, in Toronto.
April 15:	Martine Richard gave a presentation on the role and the activities of the PMPRB, to MBA students enrolled in the Pharmaceutical Management Program, *Université Laval*, in Québec City.
April 18:	Réal Sureau and Barbara Ouellet appeared before the Standing Committee on Health. Mr. Sureau's introductory remarks are available on our Web site under Publications; Speech Series; 2005.
April 25-26:	Barbara Ouellet participated at the Canadian Coordinating Office on Health Technology Assessment's International Symposium — *Relevance, Quality, Capacity: Current Issues for Health Technology Assessment*, in Ottawa. ■

Comings and Goings

- Dr. Anthony Boardman was appointed Member of the PMPRB for a second term. Welcome back! Dr. Boardman's biographical notes are available on our Web site under About the PMPRB; Membership.
- Paul De Civita, from Healthy Environments and Consumer Safety Branch, Health Canada, has joined the PMPRB as Acting Director, Policy and Economic Analysis.
- Andrew MacDonald, from the Canadian Food Inspection Agency, has joined the Policy and Economic Analysis Branch.
- Best wishes to Brigitte Joly who has accepted a position with the Health Policy Branch at Health Canada.
- We also wish best of luck to Stéphanie Patenaude who has accepted a position with the RCMP. ■

Congratulations to Dr. Jean Gray, C.M.

Dr. Jean Gray, C.M., Chair of the Canadian Institutes of Health Research (CIHR) Advisory Board for the Institute of Gender and Health, and member of the Human Drug Advisory Panel, was named member of the Order of Canada in January.

Dr. Gray is one of Canada's outstanding medical educators. As Professor Emeritus of medical education, medicine and pharmacology at Dalhousie University, she has developed tools to better evaluate residents in training and has championed mentoring programs for women medical students.

On behalf of the Members and Staff of the Patented Medicine Prices Review Board, we wish to congratulate Dr. Gray on this well-deserved honor. ■

Notice and Comment on the proposed amendments to the *Patented Medicines Regulations*

The Board wishes to thank all who have participated in the Notice and Comment process on the proposed amendments to the *Patented Medicines Regulations*. After having considered the submissions received, the Board will report on next steps in an upcoming issue of the NEWSletter. ■

News from the Vice-Chairperson

PMPRB

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.

It is my distinct honour to thank Dr. Robert Elgie for his invaluable contribution to the Patented Medicine Prices Review Board as its Chairperson from March 1995 to 2005. Dr. Elgie showed leadership and dedication, whether it be in conducting public hearings, leading the 1998 public consultation on the PMPRB's role, function and methods, overseeing the implementation of our *Road Map for the Next Decade* or presiding over the 2002 PMPRB International Symposium on drug prices, to name a few.

From left to right: Réal Sureau, Vice-Chairperson; Wayne Critchley, former Executive Director, 1990-2005; Robert G. Elgie, Chairperson, 1995-2005; Barbara Ouellet, Executive Director.

Dr. Elgie has had a tremendous career – by training, a lawyer and a medical doctor, he is by profession a neurosurgeon, a teacher; and by calling, a dedicated public servant – in elected office as Minister of Labour and of Consumer and Commercial Relations in Ontario, and then as head of the Workers Compensation Board in Ontario and in Nova Scotia.

His career illustrates his personal commitment to lifelong learning, which was acknowledged when he was awarded an honourary degree in 2001 by Dalhousie University, where he had established the Health Law Institute 10 years earlier.

Dr. Elgie brought his passion for learning to his work with the PMPRB as well as his curiosity and desire to get to the bottom of a question. He genuinely cares for people and believes that we all have a duty to leave our world a better place – and he has demonstrated that passion in every action he has taken as Chair of the PMPRB. His lifelong contributions to public service were appropriately recognized when he was awarded the Order of Canada two years ago.

He achieved a lot during his term. Most importantly, the PMPRB has continually met its objectives of protecting Canadian consumers from excessive drug prices. In the last six months as Chair, he issued two

Notices of Hearing; approved a settlement with a 45% price reduction and multimillion dollar offset; approved our "Looking Ahead" project to further integrate the National Prescription Drug Utilization Information System (NPDUIS) into the National Pharmaceutical Strategy; and launched the most important review of the drug price guidelines in a decade.

Always looking ahead, Dr. Elgie has challenged us all to continue to study and debate our policies and to be ready to modify them as necessary.

Thank you for your contribution and your support over the past decade and best wishes to you and Nancy in the years ahead. ■

Réal Sureau, Vice-Chairperson

Dr. Robert Elgie and his wife Nancy at the farewell reception, accompanied by their son Stewart and their grandson Kenny.

May 9 deadline!
Discussion Paper on Price Increases for Patented Medicines

The Board issued a Discussion Paper on Price Increases for Patented Medicines in March seeking stakeholders' comments. The Discussion Paper is available on our Web site under Publications; Notice and Comments; Price Increases for Patented Medicines. The Board is looking forward to receiving your submissions on this important issue.

Please direct your comments to the Secretary of the Board, **no later than May 9, 2005**. ■

National Drug Expenditure Trends, 1985-2004

On April 5, 2005, the Canadian Institute for Health Information (CIHI) released the latest edition of *Drug Expenditure in Canada, 1985-2004*. This annual publication is recognized as the reference for retail spending on drugs in Canada.

Providing annual estimates of drug spending made by Canadians between 1985 and 2004, this report includes updated information on national drug expenditure; provincial and territorial drug expenditure; international comparisons and factors affecting drug expenditure in Canada. New for this year, the report includes analysis of drug expenditure in hospitals based on CIHI's Canadian MIS Database.

According to CIHI's estimates, the total spending on drugs in Canada, including prescription and non-prescription medicines, is expected to have risen to $21.8 billion in 2004, representing an 8.8% increase over the forecast $20 billion spent the previous year and approximately a five fold increase over the $3.8 billion spent by Canadians in 1985. As a share of the total health care expenditure, the amount spent on drugs has risen from 9.5% in 1985 to an expected 16.7% in 2004. Once again, as they have since 1997, drug expenditures have surpassed physician spending as the second largest category of health care spending after hospitals.

This report is available in the National Health Expenditure (NHEX) database. Data available are estimates of the consumption of pharmaceuticals by Canadians, outside of the institutional setting and represent the final price paid by Canadians, including retail and wholesale mark-ups, dispensing fees and taxes.

Of the total drug expenditure, prescription drugs account for an increasing amount of total spending, rising from 67.5% in 1985 to an estimated 82.5% in 2004. It is anticipated that the public sector will have paid for 47.3% of these expenditures. By province, CIHI estimates the proportion of prescription drugs financed by the public sector ranged from a low of 33.5% in New Brunswick to a high of 50.6% in British Columbia. Provincial drug expenditures in hospitals are separate from these figures and amount to $1.3 billion in 2002, the last year with available data.

When looking at individual spending, CIHI has forecast that the average Canadian will have spent approximately $632 in 2003 and $681 in 2004 for medications, representing an annual increase of 7.7% and 7.8% each year. Across provinces in 2004, the per capita expenditure is expected to range from a high of $732 in Ontario to a low of $542 in British Columbia.

According to CIHI's research, when compared to 11 other member countries of the Organization for Economic Cooperation and Development (OECD), in 2002, Canada had the third highest level of total drug spending per capita after the U.S. and France. On the basis of drug expenditure as a percentage of total health care spending, Canada ranked fifth highest behind Hungary, Korea, France and Japan.

The PMPRB is partnered with CIHI on the assessment of public sector drug utilization and expenditures as part of the National Prescription Drug Utilization Information System (NPDUIS). The information published in *Drug Expenditure in Canada* is a valuable complement to this collaboration. ■

CPI-Adjustment Factors for 2006

PMPRB

Following reports of price increases last Fall, the Board launched a public consultation on price increases for patented medicines and released a Discussion Paper, seeking input from stakeholders by May 9, 2005. Once the Board has considered submissions by stakeholders, it will determine next steps.

The Discussion Paper on Price Increases for Patented Medicines is available on our Web site under Publications; Notice and Comment; Price Increases for Patented Medicines.

The *Patent Act* specifies the factors to be considered by the PMPRB in determining whether the price of a patented drug product sold in Canada is excessive. One of these factors is changes in 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 next year's pricing period.

The CPI-adjustment factors for 2006 are as follows:

2006 CPI-Adjustment Factors for All Patented Drug Products (CPI 1992=100)

	Benchmark Year		
	(1) 2003	(2) 2004	(3) 2005
Base-CPI	122.32	124.56	NA
2006 Forecast CPI	129.47	129.47	129.47
2006 CPI-Adjustment Factor	1.058	1.039	1.020

PMPRB

For more details on the CPI-Adjustment Methodology, readers will want to consult Schedule 4 of the *Compendium of Guidelines, Policies and Procedures*, accessible on our Web site under Legislation, Regulations and Guidelines.

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

The 2006 Forecast CPI is 129.47 (1992=100) and is based on the actual CPI figures for 2004 (124.56), as published by Statistics Canada, and the latest available inflation projections (1.9% for 2005 and 2.0% for 2006) from the federal Department of Finance.

Cap for 2006 = 3.0% (1.5 x 2.0). ■

Filing Requirements – Timeliness of Filing

In our April 2002 NEWSletter, we published an article reminding patentees of their obligations to comply with the reporting requirements under the *Patent Act* (Act) and the *Patented Medicines Regulations, 1994* (Regulations).

The Act and Regulations clearly set out the reporting obligations of patentees, the time frame within which patentees are to submit their information to the PMPRB and the penalties for failure to do so.

The tables below summarize these obligations and the time frame to submit the information.

Price and Sales Data – Form 2

Information	Timing	Patent Act	Regulation
Price & sales data for the medicine sold by province and by class of customers	When a drug is first offered for sale in Canada, no later than **sixty (60) days** after the first sale date covering the thirty (30) day period following the first sale;	80(1)(b) 80(2)(b)	4(1)(e) 4(2) & (3)
Publicly available ex-factory price for the medicine sold by province and by class of customers	Thereafter: On or before **July 30** (January 1 to June 30 reporting period);		4(1)(f)
Publicly available ex-factory price sold to each class of customer in France, Germany, Italy, Sweden, Switzerland, United Kingdom and United States	On or before **January 30** (July 1 to December 31 reporting period)		4(1)(g)

Revenue and R&D Expenditures – Form 3

Information	Timing	Patent Act	Regulation
Revenues from sales and expenditures on R&D	On or before **March 1** of each year	88(1) 88(2)	5, 6

In terms of the Form 2 information consisting of the price and sales data for the medicine(s) sold, the information for the July to December 2004 period was due on January 30, 2005. As January 30, 2005 fell on a Sunday, patentees had until Monday, January 31, 2005 to file their Form 2 information. Although ordinarily most patentees ultimately comply with the filing requirements, there is an issue regarding a number of patentees' failure to file complete information within the time frames specified in the Regulations.

- As of January 31, 2005, 64% of reporting patentees had not filed their semi-annual report on price and sales information.

In the April 2002 NEWSletter, we reported information on filing for the corresponding period.

- As of January 31, 2002, 48% of reporting patentees had not filed their semi-annual report on price and sales information.

Late filing by patentees is an important issue as it may delay the price review and it requires time consuming follow-up of the information by Board Staff. It is a patentee's responsibility to ensure that its information is filed within the statutory time frame.

The current practice of the PMPRB has been to either contact the patentee directly and/or send a reminder letter to deal with this issue. There are cases where additional reminder letters and/or phone calls have been necessary.

Beginning with the filing period of January to June 2005, we are changing our practice regarding patentees who have failed to file

Existing Patented Drugs

Prices of patented drugs may appear to exceed the PRMRB's Price Guidelines if a price increase exceeds the allowable increase calculated in accordance with the CPI or if the price exceeds the prices of the same medicine in all countries listed in the *Patented Medicines Regulations*. In order to ensure timely price reviews, the PMPRB is streamlining its process. When a reported price appears to be outside the Guidelines, Board Staff will immediately inform the patentee. The patentee will be given 30 days to provide clarification or justification for the price, which is to be accompanied by supporting evidence. In the absence of such a response, Board Staff will, without further delay, initiate an investigation.

For additional information on filing requirements under the *Patented Medicines Regulations*, patentees are encouraged to contact the Compliance Officer assigned to their company.

the Form 2. Similarly, this new practice will apply to Form 3 information, starting with the 2005 filing. Where the required information is not filed by the date required, a patentee will be advised in writing that the information required to be filed has not been received by the PMPRB and will be given a further seven (7) days to provide the information. In the event that a patentee does not file within the further period, Board Staff shall request that the Board issue an order pursuant to sections 81 and/or 88 of the Act requiring that the patentee file the specified information. ■

A VCU is a written undertaking by the patentee to adjust its price to conform with the PMPRB's Excessive Price Guidelines. A VCU can also be submitted following the issuance of a Notice of Hearing. The PMPRB reports publicly on all VCUs. Please consult the *Compendium of Guidelines, Policies and Procedures* for more information on VCUs.

VCUs accepted during the last quarter

Evra, Janssen-Ortho Inc.

On February 21, 2005, the Board concluded proceedings commenced on December 23, 2004, in regard to the patented medicine Evra by accepting a Voluntary Compliance Undertaking (VCU) by Janssen-Ortho Inc. Under the terms of the VCU, Janssen-Ortho lowered the price of Evra by approximately 45% to $4.47 per patch.

To offset excess revenues from past sales of Evra accrued from the date of first sale to June 30, 2004, Janssen-Ortho made a payment to the Government of Canada in the amount of $1,359,263.67. Finally, the balance of excess revenues remaining, totalling $1,496,019.02, for the period July 1, 2004 to December 31, 2004, will be offset by reducing the price of one of Janssen-Ortho's patented medicines, Levaquin 5mg/mL (DIN 02236839) and 25mg/mL (DIN 02236840) as of March 1, 2005.

Evra (norelgestromine/ethinyl estradiol) is a contraceptive transdermal system.

In the event that the full amount of the excess revenues is not offset by December 31, 2005, Janssen-Ortho Inc. will offset any remaining excess revenues by making a further payment to the Government of Canada no later than January 31, 2006.

The price of Evra will remain under the PMPRB's jurisdiction until the expiry of the patent in June 2016.

Paxil CR, GlaxoSmithKline Inc.

In order to comply with the PMPRB's Price Guidelines, GlaxoSmithKline (GSK) undertook to reduce the average transaction price of Paxil CR by the end of the January 1 to June 30, 2005 regulatory filing period such that the average transaction price for 2005 does not exceed the 2005 maximum non-excessive price of $1.5861 for Paxil CR 12.5 mg and $1.7019 for Paxil CR 25 mg.

Paxil CR (paroxetine hydrochloride) provides a controlled-release to the alternative range of presentations of Paxil, an anti-depressant.

GSK also offset excess revenues it received during the period of January 5, 2004 to December 31, 2004 by making a payment to the Government of Canada in the amount of $310,403.64.

The price of Paxil CR will remain under the PMPRB's jurisdiction until the expiry of the patent in July 2016.

Tamiflu, Hoffmann-La Roche Limited

In order to comply with the PMPRB's Price Guidelines, Hoffmann-La Roche Limited (Roche) agreed that the maximum non-excessive (MNE) price of Tamiflu 75 mg capsule was $3.7695 for the period January to December 2003, $3.8383 for the period January to December 2004, and is $3.8917 for the period January to December 2005. Roche undertook to ensure that the average transaction price of Tamiflu 75 mg capsule does not exceed the MNE price of $3.8917 per capsule for 2005.

Tamiflu (oseltamivir) is a direct acting antiviral neuraminidase inhibitor.

Also, to offset excess revenues received for the reporting periods January 1, 2003 to December 31, 2004 Roche made a payment to the Government of Canada in the amount of $442,973.47.

The price of Tamiflu will remain under the PMPRB's jurisdiction until the expiry of the patent in May 2019. ■

Publication of Voluntary Compliance Undertakings

It has been the practice of the Board to publish VCUs upon their approval by the Chairperson. Once a patentee has been informed that the terms of a VCU have been approved, the document becomes public. In the context of the PMPRB's policy on compliance and enforcement, VCUs are posted on our Web site, reported in our NEWSletter and in our Annual Report.

The Board wishes to remind patentees that in the spirit of transparency, the Board issues a press release announcing the acceptance of a VCU along with the main terms of the undertaking.

For additional information on this process, please contact the Secretary of the Board at 1 877 861-2350 or (613) 954-8299, or sdupont@pmprb-cepmb.gc.ca. ■

New Patented Medicines Reported to the PMPRB

Since the publication of the January 2005 NEWSletter, 15 new DINs for human use (representing 9 medicines) were added to the list of New Patented Medicines Reported to the PMPRB for the period ending March 31, 2005. Four of these new medicines are new active substances, representing 7 DINs.

The following table presents the four new active substances reported to the PMPRB during the period January to March 2005.

As of March 31, 2005

Brand Name	Generic Name	Company
Lantus (100units/ml)	Insulin glargine	Aventis Pharma Inc.
Multihance (529mg/ml)	Gadobenate dimeglumine	Bracco Diagnostics Canada Inc.
Relpax (20mg/tablet) Relpax (40mg/tablet)	Eletriptan hydrobromide	Pfizer Canada Inc.
VFend (50mg/tablet) VFend (200mg/tablet) VFend (200mg/vial)	Voriconazole	Pfizer Canada Inc.

Status Listing of New Drugs Introduced

In September 2001, the PMPRB began providing information on the status of the price review for each drug product. The Board had agreed with one of the recommendations of the Working Group on Price Review Issues to make information on the status of the price review of individual drug products publicly available.

Starting with the new patented medicines introduced in 2005, the status column will report information as follows: Under Review, Under Investigation, Within Guidelines, VCU (Voluntary Compliance Undertaking), NOH (Notice of Hearing).

A new patented medicine is under review when it first comes under the jurisdiction of the PMPRB, that is when it is patented and sold. When the review is complete, the price of the drug product is either within the Guidelines or under investigation. A drug product will come under investigation when it appears that the criteria for commencing an investigation have been triggered.

An investigation provides a further opportunity to the patentee to provide additional information. There are three possible results of this further review: the price is found to be within the Guidelines, the patentee submits a Voluntary Compliance Undertaking, the Chairperson issues a Notice of Hearing.

For more information on this matter, patentees may want to contact the Compliance Officer assigned to their company. ■

See Schedule 5 of the *Compendium of Guidelines, Policies and Procedures* for further information on the criteria for commencing an investigation.

The list of new patented drugs which come under the jurisdiction of the PMPRB in a given year is available on our Web site under Patented Medicines.

Report on New Patented Drugs – Bondronat

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.

Brand Name:	Bondronat
Generic Name:	ibandronate sodium
DIN:	02232770 1mg/ml 2ml ampoule for injection
Patentee:	Hoffmann-La Roche Limited
Indication - as per product monograph:	For the treatment of tumour-induced hypercalcemia with or without metastases.
Notice of Compliance:	June 8, 1998
Date of First Sale:	May 31, 2004
ATC Class:	M05BA06 *Drugs used for the treatment of bone diseases. Drugs affecting bone structure and mineralization; bisphosphonates*

Application of the Guidelines

Summary reports are available on our Web site under Patented Medicines; Reports on New Patented Drugs for Human Use.

Summary

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

Scientific Review

Bondronat is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Bondronat be reviewed as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable medicines).

The HDAP identified Pamidronate (pamidronate disodium), Zometa (zoledronic acid) and Ostac or Bonefos (clodronate) as the most appropriate comparators for Bondronat. All these drug products share the same 4th level WHO ATC class and are indicated for the treatment of tumour-induced hypercalcemia.

The PMPRB's 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 Bondronat and the comparators are based on their 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 price of all of the comparable drug products in the Therapeutic Class Comparison test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations*.

The price of Bondronat was within the Guidelines as the cost of therapy did not exceed the cost of therapy with the comparator medicines.

In 2004, Bondronat was also sold in France, Germany, Sweden, Switzerland and the United Kingdom. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in those countries. The price in Canada was the 3rd lowest, below the median international price.

Evidence/ References

The references are available on the PMPRB Web site, under Patented Medicines; Reports on New Patented Drugs for Human Use; Bondronat.

Name	Strength	Dosage Regimen	Cost of therapy
Bondronat	1mg/mL	4mL	$346.50[1]
Pamidronate	60mg/vial	2 vials	$569.90[2]
Zometa	4mg/vial	1 vial	$519.75[3]
Ostac	30mg/mL	100mL	$570.70[1]
Bonefos	60mg/mL	50mL	$590.00[1]

1. PPS, January 2005
2. Publicly available price as per the *Patented Medicines Regulations*
3. AQPP, October 2004

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. ■

Patented Medicine Prices Review Board – February 24-25, 2005 Meeting

At its meeting, the Board:

- approved:
  - the Discussion Paper on Price Increases for Patented Medicines.
- received briefings on:
  - the Internet Pharmacy review initiated by the Standing Committee on Health;
  - the status on the production of the 2004 Annual Report;
  - the monthly compliance and investigation activities; and
  - the NPDUIS projects. ■

The next Board meeting is scheduled for May 17-18, 2005.

For any 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.

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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

May
16-18
Federal Court of Canada — HMRC Case / Judicial Review Application

May
17-18
Board Meeting

May
18
HDAP Meeting

May
31
2004 Annual Report to the Minister of Health

June
Tabling of the 2004 Annual Report

June
19-21
Canadian Council of Administrative Tribunals (CCAT) Annual Conference: *Administrative Justice in the Modern Canadian Mosaic*

July
30
July NEWSletter

August
16
HDAP Meeting

August 29 - September 2
29-2
1er Congrès international sur le médicament, Montréal

September
22-23
Board Meeting

September
Dovobet Hearing (ongoing)

October
18-19
Canadian Institute's Fourth Annual Forum on Pharma Patents

October
20-21
The Canadian Institute's 5th Annual Advanced Administrative Law & Practice

October
31
October NEWSletter

November
17
HDAP Meeting

December
15-16
Board Meeting

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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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