Patented
Medicine Prices
Review Board

PMPRB NEWSletter

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April 2002

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 2002

February 4-5:	The Board held its first meeting for 2002. A summary of the minutes of the meeting appears on page 9.
February 11:	Wayne Critchley gave a presentation to the Strategy Institute's 4th Maximizing Market Access Conference — *Price Regulatory Issues: Essential Information from the PMPRB*.
March 4:	Wayne Critchley gave a speech at the Insight Conference on Drug Patents — *Drug Patents and Drug Prices: The Role of the Patented Medicine Prices Review Board*. A summary of his speech appears on page 9.
March 25-26:	The Working Group on Price Review Issues met and a summary of its working notes is available on page 9.
April 22-23:	The Human Drug Advisory Panel (HDAP) met and welcomed a new member. Details are available on page 2.

Message from the Chair


Robert G. Elgie

As one of the major events to mark our 15th anniversary, the PMPRB will be holding its first conference, PMPRB Symposium 2002, on October 7 and 8 in Ottawa. The topic for the symposium is "Current Issues in Pharmaceutical Price Regulation in Canada." It is intended to provide a forum to share information and views on current issues in drug price regulation to the benefit of our stakeholders, the general public and ourselves. We are hoping that many of our stakeholders, including ministries of health, consumers, patient advocacy groups, health care and professionals groups, and the pharmaceutical industry, will be able to attend.

We are assembling a group of experts from within and outside Canada, including Professor Sir Michael Rawlins, Chairman of the National Institute for Clinical Excellence (NICE), United Kingdom; Lloyd Sansom, Chairman of the Pharmaceutical Benefits Advisory Committee, Australia; and Michael Decter, Chairman of the Canadian Institute for Health Information (CIHI). Together with stakeholders, we hope to gain more information on the latest developments, trends and issues in pharmaceutical price regulation in Canada and abroad.

To act as a sounding board for the PMPRB in the development of the Symposium program, we created an Advisory Group. Members of this group provided advice and suggestions on the overall theme, topics, speakers and panelists.

Senior Staff

Executive Director:
Wayne Critchley

Secretary of the Board:
Sylvie Dupont

Director of Policy and Economic Analysis:
Ronald Corvari

Director of Compliance and Enforcement:
Ginette Tognet

Director of Corporate Services:
Robert Sauvé

Senior Counsel:
Martine Richard

We identified persons recognized for their knowledge and contribution in fields related to pharmaceutical price regulation in Canada to be part of the Advisory Group. Some considerations included expert knowledge, experience, interest and representation of major stakeholder groups.

I wish to take this opportunity to thank the members of the Advisory Group for their time and effort in assisting us in developing what we hope will be an exciting and timely program.

The future of our health care system occupies centre stage in the domestic policy agenda. It is widely recognized that pharmaceuticals represent the fastest growing component of health care expenditures. All developed countries are grappling with significant growth in drug expenditures. Approaches to drug price and cost controls are continually evolving; many countries are relying on international drug price comparisons. Some countries are placing greater reliance on cost-effectiveness analysis to assist in the decisions on coverage of new drugs. The promise of major breakthroughs in drug therapy offers Canadians great hope, while the cost of such treatments are a cause for concern for individuals and governments.

We hope that you will join us at the PMPRB Symposium 2002 for exciting and timely discussions on *Current Issues in Pharmaceutical Price Regulation in Canada*. ■

Robert G. Elgie,
Chairperson

For more information on the Symposium and to register on-line, visit our website at www.pmprb-cepmb.gc.ca — click on PMPRB/CEPMB Symposium 2002.

Human Drug Advisory Panel: Goodbye and Welcome!

On April 23, the PMPRB bid farewell to Dr. Peter Jewesson who completed his term as member of the Human Drug Advisory Panel (HDAP). We want to take this opportunity to thank Dr. Jewesson for his expert advice and invaluable contribution to the scientific review of new patented drugs over the last six years. Our very best wishes for success accompany him in his future endeavours.

We are pleased to welcome Dr. James P. McCormack as member of the HDAP. Dr. McCormack is Professor at the Faculty of Pharmaceutical Services at the University of British Columbia. He has extensive experience in drug evaluation and therapeutic assessment. We look forward to Dr. McCormack's input in the scientific review process of new patented medicines.

The mandate of the Human Drug Advisory Panel is to provide credible, independent and expert scientific advice to the PMPRB respecting the development and application of the PMPRB Guidelines related to the scientific evaluation of new patented medicines. A panel of three members, the HDAP's main functions are to:

- review and evaluate scientific information available to the PMPRB respecting new patented drug products regarding the proposed category, comparable medicines and comparable dosage regimens;
- assist the PMPRB in identifying and seeking out other experts as necessary;
- make recommendations respecting the category, primary use and the selection of comparable drug products and dosage regimens for new patented drug products submitted for review; and
- provide advice to support the development of PMPRB policies and procedures respecting the scientific evaluation of new patented drug products. ■

National Prescription Drug Utilization Information System

In September 2001, Federal/Provincial/Territorial Ministers of Health announced a multi-faceted approach to better pharmaceuticals management. Among other things, they agreed to establish a National Prescription Drug Utilization Information System (NPDUIS) to "provide critical analyses of price, utilization and cost trends so that Canada's health system has more comprehensive, accurate information on how prescription drugs are being used, and sources of cost increases. In addition, doctors and pharmacists would have better information from which to provide care to patients."

The NPDUIS is being established as a partnership between the Canadian Institute for Health Information (CIHI) and the PMPRB. For the PMPRB, the NPDUIS represents a natural evolution of the work that was previously conducted under a Memorandum of Understanding between the Minister of Health and the PMPRB.

The PMPRB's expected work under the NPDUIS, reports on drug prices and utilization trends, is included in our Research Agenda. More information on the NPDUIS will be reported in future issues of the NEWSletter. ■

CPI-Adjustment Factors for 2003

The *Patent Act* specifies the factors to be used by the Board 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 as described in the Compendium.

To allow patentees to set prices in advance, the 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 future pricing periods.

The CPI-Adjustment factors for 2003 follow.

Readers will want to consult the Compendium of Guidelines, Policies and Procedures, EPG: 6, schedule 4 available on our website under Legislation, Regulations, Guidelines.

2003 CPI-Adjustment Factors for All Patented Drug Products (CPI 1992=100)

	Benchmark Year		
	(1) 2000	(2) 2001	(3) 2002
Base-CPI	**113.53**	**116.41**	**n/a**
2003 Forecast CPI	**120.99**	**120.99**	**120.99**
2003 CPI-Adjustment Factor	**1.066**	**1.039**	**1.020**

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

The 2003 Forecast CPI is 120.99 (1992=100) and is based on the actual CPI figures for 2001 (116.41), as published by Statistics Canada, and the latest available inflation projections (1.9% for 2002 and 2.0% for 2003) from the federal Department of Finance.

Under its transparency initiative, the Board is to make publicly available the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's price Guidelines. It is an important initiative which we hope will provide another valuable source of information about new patented drugs. The Board looks forward to feedback on this initiative.

Report on New Patented Drugs – Cerezyme

Brand Name (generic): Cerezyme (imiglucerase)

DIN: 02230694 - 200 unit/vial
02241751 - 400 unit/vial

Patentee: Genzyme Canada Inc.

Indication (as per the product monograph): Cerezyme is indicated for long-term enzyme replacement therapy for patients with a confirmed diagnosis of Type 1 Gaucher disease that results in one or more of the following conditions: anaemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly.

Notice of Compliance: February 12, 1997 - 200 unit/vial
February 23, 2000 - 400 unit/vial

Date of first sale: 1997 - 200 unit/vial
2000 - 400 unit/vial

The first patent pertaining to Cerezyme was issued on May 22, 2001 and it came under the PMPRB's jurisdiction at that time.

ATC Class: A16ABO2: *Other Alimentary Tract and Metabolism Products, Enzymes*.

Application of the Guidelines

Scientific Review: The PMPRB's Human Drug Advisory Panel recommended that Cerezyme be reviewed as a category 2 new drug (breakthrough or substantial improvement) based on the following information:

- Cerezyme is the first drug product to be approved and sold in Canada which has been demonstrated to be effective as a long-term enzyme replacement therapy for patients with confirmed diagnosis of Type 1 Gaucher disease.
- Ceredase (alglucerase), another medicine supplied by the same manufacturer, had been identified as a possible comparator for Cerezyme. Ceredase was supplied in Canada under the Special Access Program (SAP) until it was phased out as patients were switched to Cerezyme. Ceredase is no longer available and consequently, Cerezyme is the only drug approved and sold in Canada for this indication.

Price Review: Under the Guidelines, the price of a new drug in category 2 should not exceed the higher of the prices of other drugs that treat the same disease (therapeutic class comparison, or TCC test) and the median of the prices of the same drug in the seven countries listed in the *Patented Medicines Regulations*. It was not possible to conduct a TCC test for Cerezyme as the HDAP did not identify any comparable medicines.

	200 unit/vial	400 unit/vial
Canada	**$1,160.0000**	**$2,320.0000**
Germany	$1,352.1802	$2,781.5752
France	—	—
Italy	$965.5091	—
Sweden	$1,427.2996	$2,854.5304
Switzerland	—	—
UK	—	—
US	$1,098.8034	$2,197.6068
Median	$1,225.4918	$2,781.5752

An International Price Comparison (IPC) test was conducted on each strength of Cerezyme. The Canadian price of each strength was found to be within the Guidelines as it did not exceed the median of the prices for the same drug in those countries in which it is being sold.

The *Patented Medicines Regulations* require that patentees file publicly available prices in the seven countries listed therein (see ss. 4(1)(g)).

Evidence/ Reference considered by HDAP:

Available on the PMPRB website, under Publications; Patented Medicines; Reports on New Patented Drugs; Cerezyme.

Sources:

Germany: Rote Liste, November 2001*

Italy: L'Informatore Farmaceutico, June 2001*

Sweden: Prislista, June 2001*

US: "Direct Prices," Drug Topics Red Book, 2001

* Derived from publicly available formulary price using regulated wholesale mark-ups set out in PMPRB Study Series S-0215

Schedule 3 of the Compendium of Guidelines, Policies and Procedures sets out the methodology to conduct an IPC test. The Regulations and the Compendium are both available on our website under Legislation, Regulations, Guidelines.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by 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. ■

New Patented Medicines Reported to the PMPRB

The list of new patented medicines reported to the PMPRB in a given year is published and updated monthly on our website.

On March 31, 2002, the list of **New Patented Medicines Reported to the PMPRB – 2001** indicates that there were 82 new DINs for human use (representing 53 medicines) reported to the PMPRB in 2001. Of these, 18 medicines (34 DINs) are new active substances.

The following table presents the 18 new active substances reported to the PMPRB in 2001.

The lists of New Patented Medicines Reported to the PMPRB are posted on our website under Publications; Patented Medicines.

New Active Substances – 2001

Cerezyme (200 400 units/vial)	imiglucerase	Genzyme Canada Inc.
Comtan (200 mg/tab)	entacapone	Novartis Pharmaceuticals Canada Inc.
Coversyl (2 & 4 mg/tab)	perindopril erbumine	Servier Canada
Definity (150 mcg/mL)	perflutren	Bristol-Myers Squibb Pharmaceutical Group
Kaletra (133.3/33.3 & 80/20)	lopinavir/ritonavir	Abbott Laboratories, Limited
Melacine (1.25 mL)	melanoma theraccine	Schering Canada Inc.
Meridia (10 & 15 mg/cap)	sibutramine hydrochloride	Knoll Pharma Inc.
Nexium (20 mg/tab & 40 mg/tab)	esomeprazole magnesium	AstraZeneca Canada Inc.
Peg-Intron (74, 118.4, 177.6 & 222 ug/vial)	peginterferon alpha-2b	Schering Canada Inc.
Prevnar (0.5 mL/vial)	pneumococcal 7-valent conjugate vaccine	Wyeth-Ayerst Canada Inc.
Rapamune (1 mg/mL)	sirolimus	Wyeth-Ayerst Canada Inc.
Remicade (100 mg/vial)	infliximab	Schering Canada Inc.
Reminyl (4, 8 & 12 mg/tab)	galantamine hydrobromide	Janssen-Ortho Inc.
Rescriptor (100 mg/tab)	delavirdine mesylate	Agouron Pharmaceuticals Canada Inc.
Sustiva (50, 100 & 200 mg/cap)	efavirenz	Bristol-Myers Squibb Pharmaceutical Group
Tequin (400 mg/tab & 10 mg/mL)	gatifloxacin	Bristol-Myers Squibb Pharmaceutical Group
Teveten (300, 400 & 600 mg/tab)	eprosartan	SolvayPharma Inc.
Zyvoxam (600 mg/tab & 2 mg/mL)	linezolid	Pharmacia Canada Inc.

Total: 34 DINs

The list of **New Patented Medicines Reported to the PMPRB – 2002** was added to our website at the end of April. There are 19 new DINs for human use (representing 12 medicines) reported for the current year to date. Three of these new medicines are new active substances, representing 4 DINs.

The following table presents the three new active substances reported to the PMPRB to date for 2002.

New Active Substances – 2002

Aerius (5 mg/tab)	desloratadine	Schering Canada Inc.
Pulmozyme (1 mg/mL)	dornase alfa	Hoffman-LaRoche Canada Ltd.
Tracleer (62.5 & 125 mg/tab)	bosentan	Actelion Pharmaceuticals Canada Inc.

Total: 4 DINs

Filing Requirements: A Reminder

The Compendium of Guidelines, Policies and Procedures is available on our website under Legislation, Regulations, Guidelines. As for the Patentees' Guide to Reporting, copies can be ordered by calling our toll-free number 1 877 861-2350.

The PMPRB is an economic regulatory body whose mandate is to protect consumer interests and contribute to Canadian health care by ensuring that the prices of patented medicines sold in Canada are not excessive.

In order to fulfill its mandate, the PMPRB relies, in part, upon the patentees' full and timely disclosure of any and all medicines being sold in Canada to which a patent pertains. In fact, the Federal Court of Appeal in *ICN Pharmaceuticals, Inc.* v. *Canada (Staff of the Patented Medicine Prices Review Board)*[1] has reminded the pharmaceutical industry that a certain standard of cooperation must be observed as it relates to disclosure of information to the PMPRB and that, apart from running afoul of the statutory obligations, withholding of information by a patentee may ultimately affect its credibility before the Board.

Pursuant to the statutory scheme put in place by Parliament, a patentee is required to comply with various reporting requirements which fall into three categories: medicine and patentee identification information, prices and sales information, and revenues and scientific research and experimental development expenditures (R&D).

In this regard, the *Patent Act* and *Patented Medicines Regulations, 1994 (the 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.

For those patentees who need to be reminded of the necessity to report in a timely manner or for those who may soon be selling a patented medicine in Canada and thus subject to the jurisdiction of the PMPRB, we thought it would be useful to provide a summary of the main statutory reporting requirements. They are fully described in the *Patent Act*, the *Regulations*, the *Compliance and Enforcement Policy Guidelines* and the *Patentees Guide to Reporting*.

Patentee & Medicine Information

Information	Timing	Patent Act	Regulations	Form
Identity of medicine, patentee and patent(s)	Earliest of: **Thirty (30) days** after the date the first Notice of Compliance issued **Thirty (30) days** after the date the medicine is first offered for sale in Canada	80(1)(a) 80(2)(a)	3(1) 3(2) 3(3)	1
Updating information on identity of medicine/patentee	Within **thirty (30) days** after any modification of information		3(4)	1

Price and Sales Data

Information	Timing	Patent Act	Regulations	Form
Price & sales data for the medicine sold	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)	2
Publicly available ex-factory price for the medicine sold to each class of customers	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 Germany, France, Italy, Sweden, Switzerland, United Kingdom and United States	On or before **January 30** (July 1 to December 31 reporting period)		4(1)(g)	

1. *ICN Pharmaceuticals, Inc.* v. *Canada (Staff of the Patented Medicine Prices Review Board), [1997]*1F.C.32

Revenue and R&D Expenditures

Information	Timing	Patent Act	Regulations	Form
Revenues from sales and expenditures on R&D	On or before **March 1** of each year	88(1) 88(2)	5, 6	3

Notwithstanding that the above reporting requirements are very clear, some patentees have fallen into a "failure to file" situation by refusing and/or failing to: (i) report the identity of a patented medicine, (ii) submit a Form 1, Form 2 and/or Form 3 within the required time frame, (iii) submit a duly completed Form 1, Form 2, and/or Form 3, or (iv) update the Form 1 following any modification of the information contained therein.

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, 2002, 48% of reporting patentees had not filed their semi-annual report on price and sales information (Form 2); and
- As of March 2, 2002, 56% of reporting patentees had not filed their annual R&D report (Form 3).

Late filing by patentees is an important issue because it may delay the price review and it requires time consuming follow-up by Board Staff. While 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, patentees are reminded that it is their responsibility to ensure that their data is filed **within** the statutory time frame. The PMPRB will continue to monitor very closely any non-compliance by patentees with respect to the timeliness of their filings and will take the appropriate steps, including seeking sanctions if necessary, in the event of a "failure to file." In the past, the PMPRB has indeed reported in its Annual Report the names of patentees who failed to file a Form 3 on a timely basis.

Patentees should also note that the PMPRB's Research Agenda 2002–2005 includes the "Price Review Timelines" project which will establish milestones and timelines for the price reviews of new patented medicines. This project will also require tracking of patentees' performance with respect to the filing requirements.

Patentees are further reminded that Parliament considered the reporting requirements of a patentee as a very serious matter. Firstly, section 96 of the *Patent Act* specifically grants to the Board (as it relates to the production and inspection of documents and the enforcement of the Board's orders) all such powers, rights and privileges as are vested in a superior court. Secondly, section 76.1 of the *Patent Act* allows for criminal proceedings to be brought against a patentee who contravenes or fails to comply with its filing requirements or any order made by the Board. For example, a corporation failing to comply with the filing requirements under the *Regulations* or an order by the Board to file information may be found guilty of an offence punishable on summary conviction and liable to pay a fine up to $25,000 dollars per day.

In recent months, the PMPRB has received a number of inquiries pertaining to filing issues. We thought it may be useful to share with our patentees some of these inquiries:

Where a patentee alleges that a medicine does not fall under the PMPRB's jurisdiction, what should a patentee do?

The PMPRB strongly encourages patentees to report first and argue later as has been suggested by the Federal Court of Appeal in *ICN*.[1]

Does a patentee have to report the foreign ex-factory prices for the countries listed in the Regulations even if that patentee does not sell the product in those countries?

Yes. Both the *Patent Act* and the *Regulations* provide that the patentee **shall** report the publicly-available ex-factory price for the medicine sold to each class of customer in each country where it is being sold for each six month reporting period. Therefore the patentee should report the foreign price information even if the product is being sold in another country by a different company.

For purposes of "publicly-available ex-factory prices" (Form 2, Block 5), what should the patentee report if there was more than one price during the six-month period?

The patentee should report the most recent publicly-available ex-factory price for the said reporting period, which would be the price as on June 30 and December 31 of each calendar year. [Note: This advice refers only to "publicly-available ex-factory prices," not the actual net factory sales price, Form 2, Block 4]

Does a patentee whose patent will expire need to report the expiry of the patent to the PMPRB?

Yes. The patentee should advise the PMPRB, no later than 30 days following the expiry of the patent, that it will no longer be filing data beyond the expiry of the patent and also certify that there are no other patents or patent applications pertaining to the medicine.

When a patentee files its price and sales information for a given reporting period and where there are reductions (i.e. promotions, discounts, refunds, returns etc.) to be taken into account, is it sufficient for a patentee to ensure that these reductions are reflected in the net revenues reported?

The average manufacturer's selling price is calculated on the basis of the total net revenues from all packages/sizes of a drug product sold during a pricing period divided by the number of units sold. It is therefore mandatory for a patentee not only to report net revenues but also **net quantities of products sold** for any given period. For example, if there are returns for refund or credit, both the dollar value of the refund or credit and the quantities returned should be included in the calculations of net revenues and quantities.

While the overall purpose of this article is to remind patentees of their legal obligation to file accurate and timely information, the PMPRB also wishes to remind and encourage patentees who have any questions pertaining to filing issues to obtain advice from the PMPRB by contacting the compliance officer assigned to their company. ■

Questions and Comments

Communicating just got a whole lot easier!

We made a commitment to continue enhancing our website to facilitate two-way communications and information exchange with our stakeholders and the public. You can now reach us on-line through our new electronic feedback form at **www.pmprb-cepmb.gc.ca** under Contact.

The feedback form is another way that you can communicate with us. If you have any questions, comments or ideas we would love to hear from you. Your feedback is important to us and there are a variety of ways you can reach us: e-mail, telephone, fax or mail and now through our on-line feedback form — try it out and let us know what you think! ■

PMPRB

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Patented Medicine Prices Review Board – February 4-5, 2002 Meeting

At its meeting, the Board:

- Reviewed:
  - the 2002–03 to 2004–05 Strategic Plan and Research Agenda.
- Heard oral presentations by:
  - Catherine Dickson, Director, Information and Technology Trade Policy Division, Department of Foreign Affairs and International Trade, on the WTO and DOHA Agreements;
  - Doug Clark, Patent Policy Directorate, Industry Canada, on patent issues.
- Received oral briefings on:
  - Board Staff's review of Prevnar, as published in the January 2002 NEWSletter;
  - the ongoing work of the PMPRB in the federal/provincial/territorial activities;
  - the planning for the PMPRB Symposium 2002 to be held October 7–8, 2002;
  - the Compliance and Investigations reports;
  - Highlights of the report — *National Health Expenditure Trends*, 1975–2001 — released by the Canadian Institute for Health Information (CIHI) in December 2001. ■

The next Board meeting is scheduled for May 16-17, 2002.

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.

Working Group on Price Review Issues

The Working Group on Price Review Issues held its eighth meeting in Ottawa March 25–26, 2002.

The Working Group finished its review of the items that it had previously identified for discussion during its review of the current price Guidelines for category 3 drug products. It finalized Part I of its report, *Price Guidelines for Category 3 Drugs*, which deals with the first three of the four groupings of issues:

- Therapeutic Class Comparison (TCC)
- Components of a TCC
- Other Factors
- Price Test

Part I of the Working Group's report will be submitted to the Board at its May 16–17, 2002 meeting.

Part II of the report, to be submitted later in the year, will deal with issues related to the price test under the Guidelines for category 3 drugs.

The submission of that report will represent the completion of the work of the Working Group on Price Review Issues as set out in its Terms of Reference. ■

Drug Patents and Drug Prices

In a speech on March 4, 2002, PMPRB Executive Director Wayne Critchley reported on the evolving jurisprudence under the *Patent Act* and the policies of the PMPRB on issues related to its jurisdiction. Among other things, he discussed the Board's policies concerning patent applications and patent dedication and stated that it watches for evidence of strategies to attempt to avoid its jurisdiction.

The *Patent Act* creates rights and obligations and "drug manufacturers who seek to obtain the benefits of patent protection in Canada should accept the responsibilities and obligations with respect to the pricing of the drug. The safest route is to file and report with the PMPRB, to establish prices that are within the Guidelines, and, when in doubt, to seek advice and assistance from the PMPRB." ■

The full text of the remarks, *Drug Patents and Drug Prices: The Role of the Patented Medicine Prices Review Board*, is available on our website under Publications; Speech Series; 2002.

Upcoming Events

May
31
2001 Annual Report to the Minister of Health

May
16-17
Board Meeting

June
2-4
Council of Canadian Administrative Tribunals Annual Conference

August
12
Deadline for the Early Bird registration for the PMPRB Symposium 2002

August
2
July 2002 NEWSletter

October
7-8
PMPRB Symposium 2002 – *Current Issues on Pharmaceutical Price Regulation in Canada*, Ottawa

November
8
October 2002 NEWSletter

December
12-13
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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