



# PMPRB NEWSletter

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**Anthony Boardman**,  
B.A. (hons.), Ph.D.

**Ingrid S. Sketris**,  
BSc (Phm), Pharm.D.,  
MPA (HSA)

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 October 2001

- November 15: Wayne Critchley gave a presentation to Canada's Pharmaceutical Industry Congress, in Toronto.
- 
- December 3-4: Dr. Elgie gave the keynote address at the Insight Conference : Cutting Edge Strategies on Drug Cost Management, in Toronto. His speech, *A Delicate Balance: Can Governments Promote R&D and Control Drug Costs at the Same Time?*, is available on our website.
- At this same conference, Ron Corvari gave a presentation on the recent developments at the PMPRB.
- 
- December 10-11: The Board held its last meeting for 2001. A summary of the minutes of the meeting appears on page 10.
- 
- December 13-14: The Working Group on Price Review Issues met to continue its review of the PMPRB's Guidelines for category 3 drugs. A summary of the working notes of the meeting appears on page 11.
- 
- January 30, 2002: In the Nicoderm case, the Federal Court heard appeals by Board Staff and Board Hearing Panel of Prothonotary Aronovitch's July 13, 2001 decision limiting the PMPRB's right to participate in the judicial review. The Federal Court's decision is pending.

## Message from the Chair

### Wrap up of 2001!

This issue of the NEWSletter is the first of our 2002 series. In January 2002, we also begin to commemorate the PMPRB's 15<sup>th</sup> Anniversary.

In our October issue of the NEWSletter, we announced the implementation of a major transparency initiative with respect to drug price regulation. Following public consultation, we are acting on a recommendation of the Working Group on Price Review Issues to make publicly available the results of the reviews of new patented drugs by Board Staff, for purposes of applying our price guidelines. The first such report is available in this issue of the NEWSletter on page 4. This 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.



Robert G. Elgie

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



1-877-861-2350

[www.pmprb-cepmb.gc.ca](http://www.pmprb-cepmb.gc.ca)



## Senior Staff

Executive Director:  
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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**

## PMPRB Symposium - October 7-8, 2002

To commemorate its 15<sup>th</sup> Anniversary, the PMPRB will be hosting a symposium on Pharmaceutical Price Regulation in Canada next fall. **Mark this date in your agenda.** More information will be published in the April NEWSletter.

We are currently engaged in a major review of the price guidelines for new drugs. The Working Group is now looking at the Guidelines for new patented drugs in category 3 (drugs that offer moderate, little or no improvement over existing medicines). We have committed to further and broader public consultation prior to making any changes as a result of the Working Group's work.

In addition to regulating the prices of patented medicines, we have an important role in reporting on pharmaceutical price trends. For the past two and a half years, as a result of a Memorandum of Understanding (MOU) with the Minister of Health, we have been conducting detailed analyses and reporting on expenditure trends, price levels and cost drivers facing federal, provincial, territorial drug benefit plans.

In September, the Federal/Provincial/Territorial Ministers of Health announced agreement on a multi-faceted approach to better pharmaceutical management that consists of three initiatives: the establishment of a single, common review process for coverage of new drugs in Canada; an initiative to support best practices in drug prescribing and utilization; and the establishment of a

## Welcome to the PMPRB!

- On October 22, 2001, Dr. Marcin Szumski joined the Compliance and Enforcement Branch as Scientific Officer. Prior to joining the PMPRB, Marcin worked at the Bureau of Licensed Product Assessment at Health Canada.
- On January 21, 2002, Chris Skedgel joined the Policy and Economic Analysis Branch through the Interchange Canada Program for a period of 10 weeks. Chris comes to the PMPRB from the Population Health Research Unit at Dalhousie University. ■

National Prescription Drug Utilization Information System. The PMPRB, in partnership with the Canadian Institute for Health Information (CIHI), has been asked to take on responsibility for this information system. This new drug information system builds on the work that we have been doing under the MOU. It will bring together data from the major public drug plans in Canada and permit more in-depth analysis that can be used to facilitate continuous improvement in pharmaceuticals management.

Also, in the fall, we conducted an environmental scan and evaluation of our consultation and communications policies. Thank you to the individuals who agreed to take part in that survey. The results are reported in this issue of the NEWSletter on page 10. That survey contributed to the development of our Research Agenda for 2002-2005 which appears at page 6.

All in all, it appears that 2002, our 15<sup>th</sup> year, will be as busy and challenging as ever! ■



Robert G. Elgie,  
Chairperson

## Congratulations!

- Dr. Neil Shear, a member of the PMPRB's Human Drug Advisory Panel, was named Director of the Division of Dermatology, Faculty of Medicine, University of Toronto effective November 1, 2001. Dr. Shear holds an appointment as Professor in the Department of Medicine, with cross-appointments in the Departments of Pharmacology and Pediatrics and in the Faculty of Pharmacy. Since 1992, he has also served as Director, Division of Clinical Pharmacology. In addition, Dr. Shear is a Senior Scientist in the Sunnybrook and Women's College Health Sciences Centre. ■

## Euro – Coming into Force

The *Patented Medicines Regulations* require patentees to file the publicly available price at which a medicine is sold in each of the seven comparator countries, expressed in local currencies. As of the pricing period starting this January 1, all patentees are required to file prices in euros for those participating member countries, i.e. France, Germany and Italy. The 36-month exchange rate will be used to convert euros into Canadian dollars. If patentees have any questions on this matter, they should raise them with the compliance officer assigned to their company.

# Historical Perspective – Reflecting on the last 15 years!

December 7, 2002 will mark the fifteenth anniversary of the creation of the Patented Medicine Prices Review Board. In January 2002 we begin to commemorate this occasion, to turn back the pages of time and take a peek at how we have evolved as part of the federal programs and policies relating to pharmaceuticals.

We have experienced many changes over the years, changes to our legislation, our consultation process, to our Guidelines and to our daily business. Keeping pace with the dynamic pharmaceutical landscape has kept us busy and has made the past fifteen years full of challenges. As an organization we have grown, finding strength in the diversity and experiences of the Board and Staff, and have collectively worked towards a common goal of contributing to Canadian health care and protecting consumers by ensuring that the prices of patented medicines are not excessive.

We invite you to take a moment to step back in time with us and share a little piece of our past...

## The Evolution of Pharmaceutical Price Review in Canada and the PMPRB

The future of our health care system has governments, critics and Canadians busy. With health care taking centre stage in the headlines, we cannot overlook one of the fastest growing components of health care expenditures — pharmaceuticals. Despite policy differences that emerge from time to time, it has become increasingly evident in the ongoing health care analysis and debate that both federal and provincial governments have important roles to play in programs and policies affecting the prices of medicines in Canada.

The first Chairman of the PMPRB, the late Harry C. Eastman, summarized it best by saying: “The particular features of the intervention of these governments have varied over time, but the fundamental pattern is constant: the federal government regulates the prices of patented medicines by its use of the *Patent Act* for which it is responsible, while provinces affect the prices of medicines through their reimbursement programmes.”

While there are several approaches to the control of drug prices in the world, one of the most unique is embodied in the PMPRB. We felt it was important then to couch our journey back in time within the context of the evolution of the pharmaceutical provisions of the *Patent Act*.

Concern with the prices of medicines in Canada is hardly a novel issue. In fact, mounting concern over the prices of medicines in the 1960s led to several inquiries, all of which concluded that prices were too high. As a result, amendments to the *Patent Act* were made in 1969 to expand the policy of compulsory licensing of pharmaceutical patents.

By the time the 80's rolled around, concerns arose that the *Patent Act* discouraged pharmaceutical research and development and that Canada was out of step with its major trading partners. By 1987, a number of forces combined to help frame the major policy issues and principles related to the *Patent Act* as it concerns pharmaceuticals. These principles became known as the five pillars. They included: intellectual property; industrial benefits; Canada's multilateral relations; consumer protection; and health care. The PMPRB was created as the consumer protection component of the balance among these broad policy objectives.

## Addressing concerns in 1987 and 1993

Among other things, the 1987 amendments to the *Patent Act*, Bill C-22, restricted the use of pharmaceutical patent compulsory licenses. It also created the Patented Medicine Prices Review Board to ensure that pharmaceutical patentees did not abuse this increased patent protection by charging excessive prices.

In 1993, Bill C-91 extended the policy direction set out in the original Act. The key aspects of C-91 included: the elimination of compulsory licensing, a strengthening of the powers of the PMPRB and a shifting of ministerial responsibility to the Minister of Health.

The PMPRB has two fundamental roles in protecting consumers and contributing to

“To look backward for a while is to refresh the eye, to restore it, and to render it more fit for its prime function of looking forward.”

Margaret Fairless Barber

Canadian health care. The first is our regulatory mandate, to ensure that patented drug prices are not excessive; and the second is an analysis and reporting mandate, to provide information on pharmaceutical trends, including prices and research & development expenditures.

## What does the PMPRB do to control the prices of medicines in Canada?

The PMPRB regulates the prices charged by manufacturers for all drugs to which a Canadian patent pertains to ensure they are not excessive. Its jurisdiction applies to all patented drugs, both prescription and non-prescription. The manufacturer's price we refer to does not include wholesale or retail markups or dispensing fees. It has been estimated that on average this manufacturer's, or "factory gate" price accounts for 65% of the final retail price paid by consumers.

## Has the PMPRB really had an effect on prices of patented medicines since its inception in 1987?

The PMPRB does not set the manufacturer's prices; it sets limits on them in accordance with criteria set out in the legislation. These limits, along with provincial reimbursement policies and other factors have had an effect on controlling drug prices in Canada.

### Just the facts:

- ◆ Since 1987, the annual rate of increase in the prices of existing patented drugs has been below the Consumer Price Index (CPI).

- ◆ Internationally, Canadian prices were 23% higher than the median international prices in 1987, second only to the US. Since the mid-1990's, prices in Canada have remained consistent at about 10% below median international prices and in the mid-range of European countries.

## What happens if the price of a patented drug is excessive?

The PMPRB establishes Excessive Price Guidelines in consultation with its stakeholders — consumers, ministers of health and the pharmaceutical industry. They provide patentees with parameters and information that aid them in establishing, in advance, prices that may be presumed not to be excessive. The *Patent Act* ensures that patentees have the right to a fair hearing. To date, patentees have, for the most part, complied with the Guidelines without the Board holding many hearings. The PMPRB's policy of voluntary compliance and clear pricing guidelines are based on factors set out in the *Patent Act*, including:

- the prices of other medicines in the same therapeutic class;
- the prices of the medicine in other countries; and
- changes in the Consumer Price Index.

To continue our retrospection we invite you to read the upcoming issues of the NEWSletter. ■

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. This is the first such report. 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 – Prevnar

**Brand Name (generic):** Prevnar (pneumococcal 7- valent conjugate vaccine, diphtheria CRM<sub>197</sub> protein)

**DIN:** 02244081 - 1 na/vial

**Patentee:** Wyeth-Ayerst Canada Inc.

**Indication (as per the product monograph):** Prevnar is indicated for the active immunization of infants and children from 6 weeks until 9 years of age against invasive disease,<sup>1</sup> pneumonia and otitis media caused by *S. pneumoniae* due to the capsular serotypes included in the vaccine (4, 6B, 9V, 14, 18C, 19F, and 23F). The routine schedule is 2, 4, 6, and 12-15 months of age.

1. Invasive disease was defined as isolation and identification of *Streptococcus pneumoniae* from normally sterile body sites in children presenting with an acute illness consistent with pneumococcal disease.

**Notice of Compliance:** June 7, 2001  
**Date of first sale:** June 20, 2001  
**ATC Class:** JO7AL: Pneumococcal vaccines.

## Application of the Guidelines

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

- Prevnar is the only pneumococcal vaccine that has shown a good immune response in the age group of infants and toddlers from six weeks to two years of age against invasive disease, pneumonia and otitis media caused by *S. Pneumoniae* due to the seven capsular serotypes included in the vaccine.
- Based on the scientific evidence available, Prevnar is an effective product in the treatment of infections caused by *S. Pneumoniae* [see in particular Evidence/References 6 and 7].
- Although there are three other pneumococcal vaccines on the Canadian market (i.e., Pneumo 23, Pneumovax 23, Pnu-Imune 23), none of them are indicated for administration in children under two years of age. According to the Canadian Immunization Guide 1998, these three pneumococcal vaccines are only recommended in children two years of age or older with certain medical conditions (e.g., asplenia, splenic dysfunction, sickle-cell disease, chronic respiratory disease, cirrhosis, alcoholism, chronic renal disease, nephrotic syndrome, diabetes mellitus, HIV infection and other immunosuppression conditions). They are not recommended for younger children and infants because of poor antibody response. Although Prevnar is indicated for immunization until 9 years of age, the primary use will likely be in children less than two years of age. No direct alternatives are available for immunization of this group.

**Price Review:** An International Price Comparison (IPC) test was conducted. The Canadian price of Prevnar was found to be within the Guidelines as it did not exceed the median of the prices for the same drug sold in the countries listed in the *Patented Medicines Regulations*.

Country	Price per vial
Canada	76.0000
France	77.9246
Germany	75.1978
Italy	76.3192
Sweden	85.8240
United Kingdom	82.5962
United States	75.4510
International Median	77.1219

The comparators and dosage regimens referred to in the Summary Reports 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. ■

## Evidence/References considered by HDAP:

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

## Sources:

**France:** Sempex, August 2001\*

**Germany:** Rote Liste, July 2001\*

**Italy:** L'informatore Farmaceutico, September 2001\*

**Sweden:** Prislsta, September 2001\*

**US:** Average prices of Red Book, September 2001 and US Department of Veterans Affairs website

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

# PMPRB's Research Agenda 2002–2005

Issue	Description	Advisory Committee	Key Deliverables	Date
Guidelines: Category 3 Drug Prices	Review the methods to conduct therapeutic class comparisons and the guidelines for category 3 drugs, including use of pharmacoeconomics	PMPRB Working Group on Price Review Issues	1. Meeting of Working Group 2. Report – Part 1 3. Report – Part 2	Mar 27 & 28, 2002 July 2002 Oct 2002
Guidelines: Category 2 Drug Prices	Review of the appropriateness of the median price test for category 2 drugs, including use of pharmacoeconomics	Advisory Committee and schedule to be determined following review of the guidelines for category 3 drugs		
Guidelines: <sup>1</sup> International Price Comparison	<ol style="list-style-type: none"> <li>1. Review the appropriate test when fewer than 7 countries</li> <li>2. Review the appropriateness of the "Highest Price Rule"</li> <li>3. Review methodology for calculating the average price for a foreign country when conducting an International Price Comparison</li> </ol>	Advisory Committee and schedule to be determined following review of the guidelines for category 3	Report for Notice and Comment  Report	Jan 2003  2003-2004
Foreign Price Trends	An analysis of trends in prices of patented medicines in foreign countries		Report	2002-2003
International R&D Spending	An analysis of pharmaceutical R&D spending in foreign countries		Report	2002-2003
Price Review Timelines	Establish milestones and timelines for the price reviews of new patented medicines			2003-2004
Analysis of expenditures by publicly funded drug plans	Reports on drug prices and cost utilization trends produced as a result of the National Prescription Drug Utilization Information System		Reports	Commencing 2002-2003
Evaluation	<ol style="list-style-type: none"> <li>1. Evaluation of complaints-driven approach to regulating the price of veterinary drugs</li> <li>2. Evaluation of initiatives on transparency adopted by the PMPRB in 2001</li> </ol>		Report  Report	2002-2003  2003-2004

<sup>1</sup> In the 2001-2004 Research Agenda, these items were included under "Category 2 Drug Prices". These issues related to international price comparisons have now been separated as they have a broader application to all drugs reviewed by the PMPRB.

## Update on items which appeared on 2001–2004 Research Agenda

Issue	Description	Status	Reference
New Medicine Price Review Process	Price review process for new patented drugs	Following consultation through a Notice and Comment, the Board announced the implementation of a transparency initiative with respect to drug price regulation in October 2001.	NEWSletter October 2001
Analysis of expenditures by publicly funded drug plans	Reports on drug prices and cost drivers including: <ul style="list-style-type: none"> <li>• Pharmaceutical price trends by participating provincial and territorial drug plans</li> <li>• Overview of pharmaceutical trends</li> <li>• Comparison of Canadian and foreign prices of non-patented single source drugs</li> <li>• Interprovincial drug comparison analysis</li> </ul>	The Ministers of Health approved the release of six cost-driver reports at their meeting in September 2001.	NEWSletter October 2001
Evaluation	<ol style="list-style-type: none"> <li>1. Evaluation of the Consultation Policy published in 1998 (<i>Road Map for the Next Decade</i>) and of the Communications Policy</li> <li>2. Evaluation of the accuracy of the foreign patented drug price information filed by patentees</li> </ol>	<p>Survey of major stakeholders conducted August and September 2001.</p> <p>Complete</p>	<p>NEWSletter January 2002</p> <p>NEWSletter January 2002</p>

In our *Road Map for the Next Decade*, we committed to publishing the Research Agenda as part of our annual planning process. Among other things, the Research Agenda identifies initiatives that are currently, or may become, subject to public consultations.

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Box L40  
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Ottawa, Ontario  
K1A 1C1

This study is available on our website under Publications; Study Series.

## Questions and Comments

### We want to hear from you!

We would like to take a moment to remind you that your feedback is important to us. If you have any comments please contact us. You can e-mail us, call us or write to us.

We are continuing with the enhancement of our website to allow for easier communications with our stakeholders and the public (making it even easier for you to reach us). If you have any ideas on how to stay in touch we would be pleased to hear them! ■

## Verification of Foreign Patented Drug Prices (2000)

From time to time, the PMPRB conducts checks to verify the accuracy of price information submitted by patentees pursuant to the *Patented Medicines Regulations*. Among other things, patentees are required to file information showing the net ex-factory sales and prices of patented medicines in Canada and the publicly available prices in seven other countries: France, Germany, Italy, Sweden, Switzerland, the UK and the US. This information is used for purposes of applying the Excessive Price Guidelines and for studies comparing prices with those in other countries.

A recent study sought to verify the foreign prices filed by patentees with reference to publicly available sources of information. This study relied on the same methodology used for a similar study published as part of the *Road Map for the Next Decade* in 1998. Prices filed for the top selling 50 patented drug products for the year 2000 were compared to ex-factory prices derived from publicly available information for the other countries. The study found:

- There continues to be a high rate of compliance by patentees in filing foreign prices;
- For the six European countries, 90% of the filed prices were equal to or less than the derived publicly available prices;
- For the US, 83% of the filed prices were equal to or less than the published FSS prices; all but one of the filed prices were 8% to 29% below the Average Wholesale Price (AWP) reported in the Red Book. Prices in the US are not regulated, but some studies have estimated that the AWP includes, on average, a 20% mark up on manufacturers' selling prices.

While it is generally the case that discrepancies in the foreign price information will not affect the compliance status of the patented drug in Canada, Board Staff is in contact with the companies involved and will take appropriate action if necessary. ■

## DVA (U.S.) website address

Patentees are required to file U.S. DVA prices. Here is the DVA's latest website address: <http://www.vapbm.org>. ■



# National Health Expenditure Trends

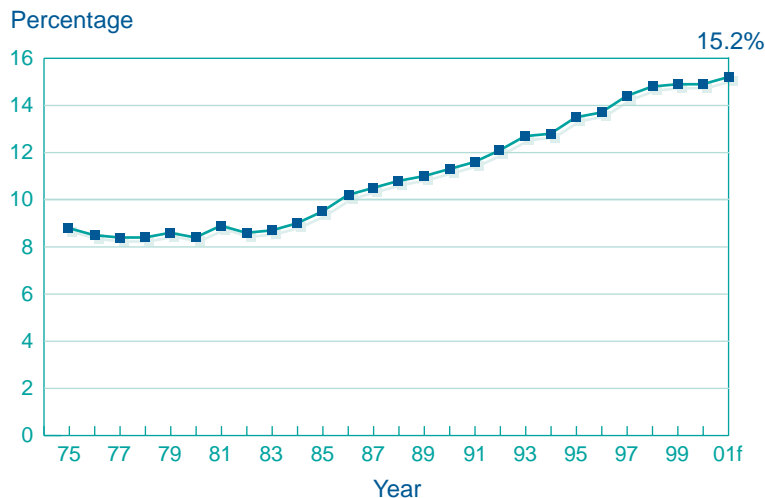
Spending on drugs in Canada is forecast to have risen by 8.6% in 2001 to \$15.5 billion, according to the *Canadian Institute for Health Information (CIHI)*. CIHI released its annual report, *National Health Expenditure Trends, 1975–2001*, in December 2001.

Canada's total health expenditure is forecast to have increased 6.9% to \$102.5 billion in 2001. Spending on drugs represented 15.2% of this total, up from 14.9% in 1999 and 2000. According to CIHI, drugs have ranked second to hospitals in share of total health expenditure since overtaking physician services in 1997. As seen in Figure 1, CIHI reports that total drug spending has increased steadily since 1985 from levels below 10%.

CIHI includes estimated expenditures on prescription and non-prescription drug products purchased at the retail level. Spending on drugs in hospitals and other institutions is reported in total expenditures for those categories. Non-prescription drugs include over-the-counter products and personal health supplies. Total spending on prescription drugs is forecast to have increased 10.6% in 2001 to \$12.3 billion. This figure represents 79.1% of total forecast drug expenditures or 12.0% of total health expenditures in 2001.

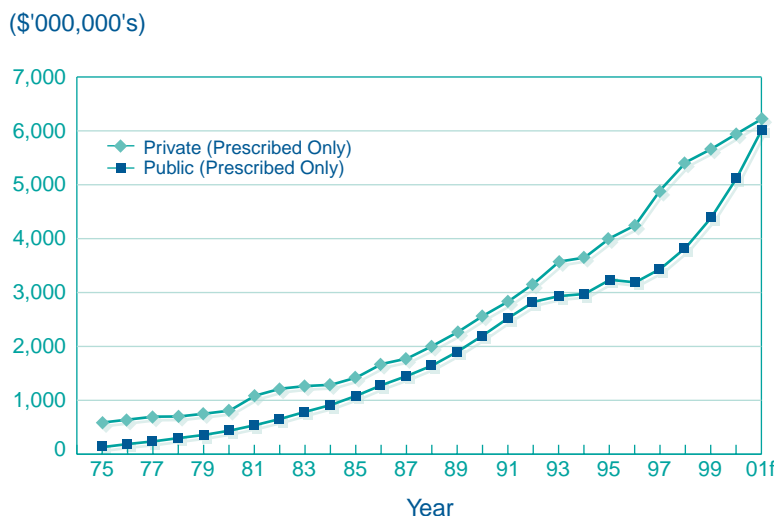
As shown in Figure 2, CIHI forecasts that public spending on prescription drugs has increased at a faster rate than private spending so that public spending would account for close to 50% of the total in 2001. Public expenditures on prescription drugs are forecast to have increased by annual amounts ranging between 14.4% and 17.6% from 1999 to 2001. Further breakdowns by province and territory appear in the report. ■

**Figure 1: Total Drug Expenditure as a % of Total Health Expenditures – Canada**



Note: Values for 2000–2001 are forecasted.

**Figure 2: Public and Private Sector Drug Expenditures – Canada**



Note: Values for 2000–2001 are forecasted.

To consult the National Health Expenditures Trends report go to [www.cihi.ca](http://www.cihi.ca).

# Patented Medicine Prices Review Board – December 10-11, 2001 Meeting

The next Board meeting is scheduled for February 4-5, 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](mailto:sdupont@pmprb-cepmb.gc.ca).

At its meeting, the Board:

◆ Approved proposals on:

- ◆ the 2001 Annual Report;
- ◆ the 15<sup>th</sup> PMPRB Anniversary Commemoration.

◆ Heard oral presentations by:

- ◆ Michael Decter, Chairman and Richard Alvarez, President and CEO of the Canadian Institute on Health Information (CIHI), on the role and future direction of CIHI.
- ◆ Karen Mosher, Executive Director of the Canadian Institutes of Health Research, on the role and future direction of CIHR.

- ◆ Ian Shugart, Assistant Deputy Minister, Health Policy and Communications, Health Canada, on Health Canada's work on pharmaceutical management.

◆ Received oral briefings on:

- ◆ the ongoing work of the PMPRB in the federal/provincial/territorial activities on drug prices under the PMPRB's Memorandum of Understanding with the Minister of Health;
- ◆ Compliance and Investigation Reports. ■

## Results of the Environmental Scan and Performance Evaluation for the Patented Medicine Prices Review Board

In the October 2001 issue of the NEWSletter, the PMPRB announced that it had contracted BDO Dunwoody & Associates Ltd. (BDO) to assist with an update of its Environmental Scan and to evaluate the effectiveness of its Consultation and Communications policies. The following is a summary of the more than twenty interviews with major stakeholders conducted by BDO.

### Environmental Scan

The objective of the environmental scan was to identify the major issues facing the pharmaceutical sector over the next three to five years. A number of issues and concerns were identified; however, the following four were the most prevalent and are listed in the order of importance based on the frequency of responses.

#### 1. Increasing prices of drugs in Canada

The majority of stakeholders, other than the pharmaceutical industry, feel that the issue of increasing prices of drugs will be

a continuous concern. They indicated that the rising price of drugs is increasing the overall cost of health care for Canadians. This increased health care cost impacts the availability of medications and treatments to those who really require it, especially with our aging population.

#### 2. Balancing drug prices and research and development spending

A major issue that the stakeholders felt existed is the need to balance price regulation of drugs and the need for research and development of new drugs and treatments in Canada.

#### 3. New technology associated with medication (genetics, biotechnology etc.)

The emergence of new gene therapy and biotechnological drugs will have an impact on the price review process. The concern is that the new costs for the research and development of these drugs and treatments will not be adequately considered when using the current price review structure.

#### 4. Transparency of the PMPRB pricing review process

Several of the stakeholder groups indicated that they felt the PMPRB needs to be more transparent during and after the price review process in order to increase consumers' confidence in the process.

### Review of Consultation and Communications Policies

The second component of the questionnaire was focused on obtaining feedback and recommendations on the PMPRB's efforts to consult and communicate with the various stakeholders. Some common themes emerged from the interviews of stakeholders.

The brand name industry representatives felt that they have not been well consulted and are not adequately consulted or repre-

sented on the Working Group on Price Review Issues. Conversely, most of the other stakeholders felt that the consultations are appropriate and that there is a good diversity of members on the Working Group. The majority of the stakeholders suggested that the PMPRB hold more public meetings and increase its face-to-face meetings with the various individual stakeholders. It was also suggested that the PMPRB involve more, and smaller, organizations in its consultations.

In general, the interviewees considered that communications from the PMPRB seems to have improved over the past few years. The PMPRB's website, NEWSletter and annual reports are very useful, but stakeholders feel there is still room for some improvement. ■

The BDO report is available on our website at [www.pmprb-cepmb.gc.ca](http://www.pmprb-cepmb.gc.ca) under Publications.

PMPRB

## Working Group on Price Review Issues – December 13–14, 2001 Meeting

The Working Group on Price Review Issues held its seventh meeting in Ottawa, December 13–14, 2001.

The Working Group continued its review of the items that it had previously identified for discussion on the current price Guidelines for category 3 drug products. The Working Group finalized its discussions on issues relating to the therapeutic class comparison

and began discussions on issues related to the price test.

The Working Group's review of the outstanding issues regarding the Guidelines for category 3 drug products will continue at its next meeting scheduled to take place in Ottawa on March 27–28, 2002. The Working Group expects to prepare a two-part report during 2002.

# February

## Upcoming Events

3	4	5	6	7	8	9
10	11	12				

February

**4-5**

Board Meeting

February

**11**

Strategy Institute's 4<sup>th</sup> *Maximizing Market Access* Conference, Toronto – Presentation by Wayne Critchley: *Price Regulatory Issues: Essential Information from the PMPRB*

March

**4-5**

Insight Conference, Drug Patents – New Developments, New Strategies, Toronto – Presentation by Wayne Critchley: *Drug Patents and Drug Prices: The Role of the Patented Medicine Prices Review Board*

March

**27-28**

Working Group on Price Review Issues, Ottawa

# April

21	22	23	24
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April

**22-23**

Human Drug Advisory Panel

# October

1	2	3	4	5	6	7	8	9
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October

**7-8**

PMPRB Symposium on Pharmaceutical Price Regulation in Canada, Ottawa



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## Comments

We want to hear from you. If you have any comments, ideas or suggestions on topics you wish to see covered in the NEWSletter, please let us know.



## Mailing List

To ensure that our mailing list is up to date and that we better serve our readers, please take a few moments to complete this form or fax us your business card.

Name: \_\_\_\_\_

Title/Organization: \_\_\_\_\_

Address: \_\_\_\_\_

Postal Code: \_\_\_\_\_

Telephone: \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_



**Please return the completed form to the PMPRB, at:**

Box L40  
Standard Life Centre  
333 Laurier Avenue West  
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Fax: (613) 952-7626  
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