

## Patented Medicine Prices Review Board

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# NEWSletter

Volume 5, Issue No. 4



October 2001



### Since our last issue ...

Here are some of the key events which occurred since July 2001

September 24-25: The Board held its third quarterly meeting for 2001. A summary of the

minutes of the meeting appears on page 9.

October: Dr. Elgie was appointed by the Board of Directors of the Institute for

Work & Health of Ontario to serve as Chair of its Five-Year Review panel.

If you wish to know more about the PMPRB, please contact us at our toll-free number: **1-877-861-2350** or consult our website at **www.pmprb-cepmb.gc.ca**.

### **News from the Chair**

#### Meeting of the Federal/Provincial/ Territorial Ministers of Health

Federal/Provincial/Territorial
Ministers of Health met in
St. John's, Newfoundland in
September and announced agreement and progress on a number of
initiatives which will improve
Canada's publicly funded health
system and ensure the system
continues to serve Canadians well
in the future.

Ministers took stock of the progress achieved since the First Ministers' meeting last year when they outlined their priorities and a vision for health – "Canadians will have publicly funded health services that provide quality health care and that promote the health and well-being of Canadians in a cost-effective and fair manner."



Robert G. Elgie

Of the several issues discussed, pharmaceuticals management is of particular interest to our stakeholders. You will recall that the September 2000 action plan of First Ministers directed Health Ministers to develop strategies to ensure Canadians continue to have access to appropriate and cost-effective drugs.

The Health Ministers announced agreement on a multi-faceted approach to better pharmaceuticals management.

 The establishment of a single, common review process for coverage of new drugs in Canada. While decisions on benefit coverage and formulary listing would be retained by individual provinces, territories

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.



#### F/P/T

For more information on the Health Ministers' September 2001 conference, please click on http://www.hc-sc.gc.ca/ english/fpt2001.

The cost driver reports are available www.hc-sc.gc.ca/english/fpt2001/reports.html.

#### **Peer-Reviewed Studies**

You can access Dr. Elgie's speech on our website under Publications, Speech Series, 1998.

## PMPRB Senior Staff

Executive Director: Wayne W. Critchley Secretary of the Board: Sylvie Dupont Director of Policy and Economic Analysis:

Economic Analysis: Ronald J. Corvari Director of Compliance

and Enforcement:
Ginette Tognet

Director of Corporate Services: Robert Sauvé

Senior Counsel: Martine Richard and the federal government, future cooperation in these areas is both possible and desirable. Ministers also agreed to increase collaboration and further enhance the assessment of cost effectiveness in the drug review process.

- An initiative to support best practices in drug prescribing and utilization. Doctors, pharmacists and patients all have a role in ensuring that the patient is receiving optimal drug therapy, and that the health system is getting as much value as possible from prescription drugs that are paid for through public funds.
- 3. The establishment of a National Prescription Drug Utilization Information System with the participation of the PMPRB and the Canadian Institute for Health Information (CIHI). This drug information system will provide critical analyses of price, utilization, and cost trends so that Canada's health system has comprehensive, accurate information on how prescription drugs are being used, and sources of cost increases. In addition, doctors and pharmacists will have better information from which to provide care to patients.

As well, the Health Ministers approved the release of several cost-driver reports prepared by the PMPRB on behalf of the federal/provincial/territorial Pharmaceutical Issues Committee (PIC) pursuant to a Memorandum of Understanding with the Minister of Health.

These studies support evidence-based decisions by publicly-funded drug plan managers. Among other things, they provide the foundation for work which feeds into F/P/T initiatives including Common Drug Review, Best Practices and post-marketing surveillance. They provide examples of the analysis that can be provided under the National Prescription Drug Information System.

## Peer-Reviewed Studies in the PMPRB's Price Review Process

Last September, leading medical journals introduced tougher ethical standards for the publication of peer-reviewed studies. We are taking the opportunity to remind our readers of the standards of evidence relied on by the PMPRB in reviewing the prices of new patented medicines (see page 8). I had also touched on these issues in a speech to the Canadian Institute of Law and Medicine in November 1998 – Ensuring the Appropriate Use of Health Technologies - Regulatory Models.

## Institute for Work and Health Review Panel

In October, I accepted the invitation of the Board of Directors of the Institute for Work and Health to serve as Chair of its Five-Year Review Panel. Now in its tenth year of active operation, the Institute's Board of Directors has commissioned this external review of its research and research transfer programs by a team of international experts.

The Institute for Work & Health is an independent, non-profit organization whose mission is to research and promote new ways to prevent workplace disability, improve treatment and optimize recovery and safe return-to-work. The Institute has been providing evidence-based research and practical tools for clinicians, policy-makers, employees and managers since 1990.

You can access the Institute website at www.iwh.on.ca. ■



## Transparency in the Price Review Process – Board's Decision

In the April 2001 issue of the NEWSletter, the Board announced that overall it agreed with the recommendations of its Working Group on Price Review Issues to increase the transparency of the price review process. Although some of the more specific recommendations could be implemented without further consultation, the Board decided to consult more broadly on the implementation of those recommendations that may have a wider effect. In the April NEWSletter the Board invited submissions from stakeholders and the public on the proposals to implement the following:

- publish summary reports of the reviews by Board Staff of new patented medicines for purposes of applying the Guidelines;
- implement this practice, at first, by publishing reports for new active substances;
- implement this practice effective for new patented medicines introduced as of January 1, 2001;
- report the relevant price test for all new patented medicines in lieu of reporting the category designation; and
- add a preamble section to the Compendium of Guidelines, Policies and Procedures (Compendium) to reflect the principle of transparency and a couple of paragraphs to the introduction section of the Compendium to clarify the Board's interpretation of information protected by virtue of section 87 of the Patent Act.

The Board received submissions from the following parties in response to the Notice and Comment:

Canada's Research-Based
Pharmaceutical Industries (Rx&D)
BIOTECanada
GlaxoSmithKline
Brogan Inc., Health Care Data, Research
and Consulting
Ken Brown, Pharmaceutical Consultant

## Analysis of Comments Publication of summary reports

All three submissions from the pharmaceutical industry supported the proposal to publish summary results as long as the reviews have

been completed. One of them recommended that summary reports should be published on a request basis only; two of them recommended that publication begin with new active substances introduced after January 1, 2002. Two of them recommended that patentees be provided an opportunity to review and comment on the summary report prior to its publication. One of the submissions from consultants advocated a yearly publication of the summary reports of results beginning after January 1, 2002, for those reviews of a more difficult nature, including some category 1 new drug products.

The Board's intention is that summary reports would only be published once Board Staff's review has been completed, the price found to be within the Guidelines and the patentee has been advised (see also Compendium section below). While some stakeholders had different views regarding the timing of the publication, the Board is of the view that from an operational and public interest perspective it makes the most sense to publish the summary reports on results as the reviews are completed. The Board is also of the view that it is appropriate to provide an advance copy of the summary report to the patentee.

The Board is of the view that starting with new active substances provides a more easily defined starting point. It is the new active substances that are likely to be more important from a therapeutic and cost perspective. The Board is however not prevented from publishing the results of other reviews if it so decides.

The Board agrees with the recommendation regarding the start date for publication of summary reports on results. Even though it was not expected that summary reports on results would have been published prior to the Board's decision, the January 1, 2002 date does not imply any retroactive application of the policy. Given the Board's current practice to publish the rationales for the categorization of breakthrough and substantial improvement new drugs, the Board has decided to prepare summary reports for those drugs introduced in 2001.

The Compendium is available on the website under Legislation, Regulations, Guidelines.

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#### Reporting relevant price test

The industry stakeholders supported the Board's proposal to report the price test in lieu of the category designation. In their view, the category designation is often wrongly perceived as an assessment of value - leading to an inaccurate interpretation of the benefits conferred by many new medicines. One of the consultants was of the view that the category designations provide for an assessment of the types of drugs that are introduced in the Canadian market and that this comparative information should continue to be made available. The other consultant did not express any view in terms of providing such information, but questioned whether simply reporting the price test for category 2 drug products would meet the transparency requirements.

The Board's proposal in the Notice and Comment was based on the consensus of the Working Group. The consensus is a strong indication that many stakeholders are not satisfied with the current system of reporting on categories. The Working Group's recommendations to report the price test used in lieu of the category designation is one way of changing that reporting, but there may be other ways to ensure that we report the most relevant information. The implementation of more relevant reporting may require further work. It is not clear whether simply changing the public reporting of the category while maintaining the current Guidelines would in fact be more transparent. The Board agrees that it is important to seek to determine if there are better ways to report information on new patented medicines. It has therefore decided not to implement the proposal to stop reporting category designation and to instruct Board Staff to do additional work in this area and to develop further options.

#### Compendium

Two industry stakeholders expressed concern that the language of the proposed amendments to the introduction section of the Compendium could imply that information on a particular review could be made publicly available prior to the completion of the price review. They recommended that the wording be revised to clarify that information would not be made publicly available prior to the completion of the review.

In terms of the publication of results, the Board's intention has always been to cover those drug products whose reviews have been completed, whose prices were found to be within the Guidelines and the patentee had been advised. The Board has therefore decided to replace the wording proposed in the Notice and Comment with the following:

- 4.3 Although section 87 of the Patent Act aims to protect commercially-sensitive information, as well as some publicly available information i.e. ex-factory foreign prices, the privilege does not extend to information and materials collected by the PMPRB itself including any analysis performed by Board Staff of that information.
- 4.4 Information on the status of the price review by the PMPRB, including the compliance status of patentees and applicants, is not information supplied by patentees and therefore may be made publicly available.
- 4.5 When the PMPRB has completed a review of a new patented medicine, and concluded that the price is within the Guidelines or does not warrant proceedings under the *Patent Act*, and the patentee has been notified, information concerning the outcome of the price review may be made publicly available through the publishing of a summary report, the content of which remains subject to the confidentiality provisions as outlined in paragraph 4.1 above.

#### **Board Decision**

- To publish summary reports on the results
  of the reviews by Board Staff for purposes
  of applying the Guidelines for all new active
  substances introduced after January 1,
  2002. These reports will be published as
  they become available. An advance copy
  of the summary report will be provided to
  the patentee as a courtesy.
- To publish summary reports on the price reviews by Board Staff for purposes of applying the Guidelines for those drug products introduced after January 1, 2001 that were categorized as "breakthroughs" or as "substantial improvements". The Board reserves the ability to publish additional reports if warranted.

- To instruct Board Staff to develop options for aggregate reports on new patented medicines.
- To modify the text proposed in the Notice and Comment for the Introduction section of the Compendium to reflect the Board's intention regarding the publication of the summary reports on the results of the price review.
- To make no change to the text proposed in the Notice and Comment for the Preamble section of the Compendium.

The Board wishes to take this opportunity to thank all of the parties who have provided comments. ■

All documents related to the activities and work of the Working Group on Price Review are accessible on our website under Working Group on Price Review Issues.

## **Voluntary Compliance Undertaking – Zanaflex**

Under the Compliance and Enforcement Policy, patentees are given an opportunity to make a Voluntary Compliance Undertaking (VCU) when Board Staff conclude, following an investigation, that a price appears to have exceeded the Board's Excessive Price Guidelines. Approval of a VCU by the Chairperson or Board is an alternative to the commencement of formal proceedings through the issuance of a Notice of Hearing.

On October 15, 2001, the Chairperson approved a VCU from Draxis Health Inc. for the patented medicine **Zanaflex** (tizanadine).

Zanaflex 4 mg/tablet is a patented medicine sold in Canada by Draxis Health and is approved for the management of spasticity. Health Canada issued a Notice of Compliance for Zanaflex on June 29, 1999. Draxis Health began selling Zanaflex on October 28, 1999 at approximately \$0.6808 per tablet.

Zanaflex was classified as a category 3 new medicine for purposes of the Board's Guidelines. A Therapeutic Class Comparison test was conducted by Board Staff using Lioresal (baclofen) and Valium (diazepam) as comparators. For purposes of the Guidelines, 24 mg per day of Zanaflex was compared to 80 mg of Lioresal and 40 mg per day of Valium.

Board Staff concluded that the price of Zanaflex of \$0.6808 per tablet exceeded the 1999 maximum non-excessive (MNE) price of \$0.6161 per tablet. In 2000, the price of Zanaflex continued to exceed the CPI-adjusted MNE price of \$0.6327 per tablet.

The terms and conditions of the VCU were agreed to between Board Staff and the patentee. Having considered the evidence

before it, the Chairperson approved the VCU submitted by Draxis Health. Under the terms of the VCU, Draxis Health has undertaken to:

- Reduce the average selling price of Zanaflex on or before November 19, 2001 so that the average price for 2001 does not exceed the 2001 MNE price.
- Offset excess revenues received by Draxis
  Health during the period October 28, 1999
  to December 31, 2000 by making a
  payment to the Government of Canada,
  on or before November 19, 2001, in the
  amount of \$62,599.
- To ensure that the price of Zanaflex remains within the Guidelines in all future periods in which it remains under the Board's jurisdiction.

Pursuant to section 103 of the *Patent Act*, the Minister of Health may enter into agreements with any province respecting the distribution of amounts collected as a result of orders made under the *Act*.

The Board's Guidelines provide that the introductory price of a category 3 new medicine is presumed to be excessive if it exceeds the prices of all comparable drug products in the same therapeutic class.

The Zanaflex VCU is available on our website under Publications; VCUs, ARCs, Hearings and Decisions of the Board.

### Publication of the New Patented Medicines List

The New Patented Medicines List is available on our website under Publications; Patented Medicines.

The website list of new patented medi-

cines now includes a new column which provides information on the status of the price review for each patented medicine on the list (i.e. under review, review complete, voluntary compliance undertaking, or notice of hearing). The website list is updated on a monthly basis.

As reported in the April 2001 issue of the NEWSletter, this change is part of the Board's Transparency Initiative; it implements a recommendation made by the Working Group on Price Review Issues and agreed to by the Board. ■

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## "Patent Pertaining" - What is a company to do?

The PMPRB has from time to time received inquiries pertaining to the issue of 'patent pertaining'. In light of the interest in the subject-matter and its importance, the PMPRB thought it may be useful to remind patentees of the various requirements to consider when faced with the question: Does my patent pertain to a medicine?

Pursuant to the *Patent Act*, the PMPRB is mandated to regulate the manufacturer's prices of patented medicines to ensure that they are not excessive and to take remedial action to correct any excessive pricing.

To ensure that the PMPRB may fulfill its statutory mandate, the *Act* requires a patentee of an invention pertaining to a medicine to comply with certain reporting requirements as set out in the *Patented Medicines Regulations*, 1994. In doing so, the patentee must address the issue of whether the 'patent pertains to a medicine'. Although the question is rather straight forward, the answer may not necessarily be so since it is one which goes to the jurisdiction of the PMPRB.

To answer this question, the patentee will be guided by a number of sources including ss 79(2) of the *Patent Act* as well as the definition of 'medicine' found in the *Compendium of Guidelines, Policies and Procedures* (Compendium) which provisions read as follows:

#### Patent Act

79(2) For the purposes of subsection (1) and sections 80 to 101, an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine.

#### Compendium

1.5 A medicine is defined as any substance or mixture of substances made by any means – whether produced biologically, chemically or otherwise – that is applied or administered in vivo in humans or in animals to aid in the diagnosis, treatment, mitigation or prevention of disease, symptoms, disorders, abnormal physical states, or modifying organic functions in humans or animals, however administered.

1.6 For greater certainty, this definition includes vaccines, topical preparations, anaesthetics and diagnostic products used *in vivo*, regardless of delivery mechanism (e.g. transdermally, capsule form, injectable, inhaler, etc.). This definition excludes medical devises, *in vitro* diagnostic products and disinfectants that are not used *in vivo*.

In addition to the above, a patentee should refer to the Federal Court of Appeal's decision in ICN Pharmaceuticals, Inc.v. Canada (Staff of the Patented Medicine Prices Review Board) (1997) 1 F.C. 32 (ICN) where the Court set out a three-fold test to determine whether the PMPRB has jurisdiction over patents pertaining to a medicine:

- the Board must determine that a party is a patentee of an invention;
- the patentee's invention must pertain to a medicine:
  - (a) the invention must be intended or capable of being used for medicine or for the preparation or production of medicine;
  - (b) there is no requirement that the patent actually be used in the production of the medicine:
  - (c) 'medicine' must be interpreted broadly not narrowly;
  - (d) there must be a rational connection between the invention and the medicine (the nexus test):
    - (i) to establish the required nexus, one does not have to go beyond the face of the patent;
    - (ii) the nexus can be one of the merest slender thread between the patent and the medicine; and
- the patentee must be selling the medicine in any market in Canada.

The application of the second criteria often times involves issues of interpretation as one can appreciate in reading the facts in the *ICN* case. What is perhaps less controversial but nonetheless noteworthy is the fact that the Federal Court of Appeal felt is was necessary to deal with what is referred to as an 'ancillary matter' being the patentee's failure to reveal to Board Staff the existence of a patent which

the patentee had unilaterally determined did not pertain to a medicine. In this regard, the Federal Court of Appeal underlines the importance for the pharmaceutical industry to be mindful of their reporting obligations under the Patent Act and its regulations and the possible consequences where a patentee unilaterally fails to disclose the existence of a patent on the basis that it does not pertain.

In the words of Justice Robertson: "It is one matter for a drug manufacturer to disclose the existence of a patent while refusing to provide sales determination on the ground that the Board lacks jurisdiction. It is quite another to make a unilateral determination as to the relevance of a patent and its effect on the Board's jurisdiction. Whatever the power of the Board be, it seems to me that at the very least pharmaceutical manufacturers run the risk of undermining their credibility, and that of their witnesses, before the Board, (not to mention running afoul of their statutory obligations under the Act and its regulations). To the extent that the task of determining whether prices charged or being charged for a medicine is regarded as a question of fact, it follows that adverse findings of credibility by the Board will not easily be displaced, either on judicial review or on appeal. In my view, minimum standards of cooperation, informed by common sense, must be observed by those in the pharmaceutical industry, otherwise, the Board will be unable to fulfil its

legislated mandate. In making these observations I do not wish to be regarded as having made a finding of a lack of bona fides on the part of ICN.....I take it for granted that, in future, it is also a matter deserving of due consideration by the pharmaceutical industry." [emphasis added]

From the PMPRB's perspective, where a patentee is confronted with a patent pertaining issue, as it relates to its reporting obligations, it should be guided by the above statement by the Federal Court of Appeal. Simply put, a patentee should avoid making unilateral decisions as to whether a patent pertains. Rather than failing to disclose the existence of a patent on the basis that it does not pertain, the patentee should advise Board Staff as to any decisions made in this regard

as well as the reasons supporting the decision.

This approach, as stated by the Federal Court of Appeal, will ensure minimum standards of cooperation between the pharmaceutical industry and the PMPRB which in the end allows the latter to fulfill part of its legislated mandate.

A patentee should avoid making unilateral decisions as to whether a patent pertains. Rather than failing to disclose the existence of a patent on the basis that it does not pertain, the patentee should advise Board Staff as to any decisions made in this regard as well as the reasons supporting the decision.

The Federal Court of Appeal's decision – ICN Pharmaceuticals, Inc.v. Canada (Staff of the Patented Medicine Prices Review Board) (1997) 1 F.C. 32 (ICN) – is available at www.fja.gc.ca/ fc/1997/pub/v1/1997fca0019.html.

### **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, questions, suggestions please let us know. You can send us an e-mail, call us or even write to us.

Over the next few months we will be enhancing our website to allow for easier communications with our stakeholders and the public (making it even easier for you to reach us). We will keep you abreast of the changes as they occur. If you have any ideas on how to stay in touch we'd love to hear them!

You can call us at: Toll free-line: 1-877-861-2350 General number: (613) 952-7360

or e-mail us at: pmprb@pmprb-cepmb.gc.ca

or write to us at: Box L40 Standard Life Centre 333 Laurier Avenue West 14th floor Ottawa, Ontario K1P 1C1



See, for example, "Sponsorship, Authorship, and Accountability," New England Journal of Medicine, 2001; Vol. 345, No. 11, pp. 825-827. www.nejm.org.

The Compendium is available on the website under Legislation, Regulations, Guidelines.

## Peer-Reviewed Studies in the PMPRB's Price Review Process

In September, the leading medical journals represented on the International Committee of Medical Journal Editors announced tougher ethical standards regarding the publication of peer-reviewed studies.

This development provides a good opportunity to remind patentees and others of the standards of evidence relied on by the PMPRB in reviewing the prices of new patented medicines.

As set out in the Compendium of Guidelines. Policies and Procedures, Board Staff and the Human Drug Advisory Panel (HDAP) rely on information provided by the patentee, publicly available scientific literature, and their own expertise in making recommendations for the categorization of new drug products and selection of comparable medicines, dosage forms and dosage regimens. The HDAP reviews and evaluates scientific information available, including submissions by patentees, and advice from other experts when deemed necessary. Its recommendations are significant in determining the appropriate price test to be applied for purposes of the Excessive Price Guidelines.

The Scientific Review Procedures (chapter 3 of the Compendium) request patentees to provide Board Staff with the product monograph for the new drug and references supporting any submissions they choose to make regarding the categorization of the new drug, its primary use, comparable drugs and

comparable dosage regimens. In addition, where the patentee is proposing that a drug be reviewed as a category 2 drug, i.e., breakthrough or substantial improvement, it should submit, among other things, up to five references (if available), including:

- a minimum of two well-controlled doubleblind statistically sound clinical trials which compare the new drug product to standard medicines whose value in the treatment of the disease is well recognized; generally, trials should be published in recognized peer-reviewed journals; and
- published reviews in recognized journals of the performance of the drug product or of the class of drug.

More details and examples are provided in sections 6 and 7 of the Scientific Review Procedures.

The Board considers that these provisions guide the HDAP to put the greatest weight on original reports in recognized journals, such as the journals represented on the International Committee; where the complete trial is not available, the HDAP and the Board have to rely on the highest level of evidence that is available and determine the appropriate weight to put on it.

Under the Board's Transparency Initiative reported elsewhere in this NEWSletter, the PMPRB will soon begin publishing reports on the review of new patented medicines for purposes of applying the Guidelines. These reports will ordinarily include the HDAP's assessment and references to the clinical studies and other evidence on which the HDAP relied to make recommendations.

The PMPRB expects patentees to submit the best scientific evidence available, such as studies that meet the "Uniform Requirements" of the International Committee of Medical Journal Editors. It also recognizes that where such evidence is limited or is not available, the PMPRB must rely on the best information available and will strive to ensure its reports reflect such limitations.

## PMPRB Rules of Practice and Procedure

In the July 2001 NEWSletter, the Board reported that it had pre-published its draft Rules of Practice and Procedure in the Canada Gazette Part I for public comment and that it had received one submission.

The Board has finalized the review of its Rules of Practice and Procedure and will be submitting them to the Governor-in-Council for promulgation. Upon promulgation, the Rules will be posted on our website under Legislation, Regulations, Guidelines. ■

### Nicoderm Hearing – Update

Initiated in 1999, the Nicoderm Hearing has been reported on regularly in the NEWSletter and Annual Report. In the July NEWSletter, we reported on the notices of appeal filed by both the Board and Board Staff of the decision issued by the Prothonotary on July 13, denying Board Staff the right to participate in the judicial review proceedings and allowing the Board to intervene in those proceedings on a limited basis. The Federal Court is scheduled to hear this case on January 30, 2002.

For more information on the Nicoderm hearing, please contact Sylvie Dupont, Secretary of the Board, at:

Toll-free number: 1-877-861-2350 Direct line: (613) 954-8299

Fax: (613) 952-7626

E-mail: sdupont@pmprb-cepmb.gc.ca ■

All Board's decisions and reasons are posted on our website: www.pmprb-cepmb.gc.ca, under Publications; Hearings and Decisions of the Board.

## **Environmental Scan and Performance Evaluation**

In 2001, the PMPRB undertook to update its Environmental Scan and to evaluate the effectiveness of its Consultation and Communications policies. BDO Dunwoody & Associates Ltd. assisted us in this project and conducted over twenty interviews with major stakeholders in August and September.

We wish to thank those who have accepted our invitation to participate. Your input will be taken into account and will help us in identifying the major trends and issues that may impact the PMPRB over the next three to five years. In addition, it will assist us in evaluating the effectiveness of our Consultation and Communications policies.

The results of the Environmental Scan and performance evaluation will be published in the January 2002 NEWSletter. ■

## Patented Medicine Prices Review Board – September 24-25, 2001 Meeting

At its meeting, the Board:

#### Approved:

- the recommendations of Board Staff on the results of the Notice and Comment on the Transparency in the PMPRB Price Review Process;
- the revised Rules of Practice and Procedure.

#### Received oral briefings on:

 Selected Public Policies & Practices Related to Drug Prices, Utilization, Expenditures, by Dr. Ingrid Sketris;

- Environmental Scan and Evaluation of Consultation and Communications Policies – Preliminary Results;
- ▶ Compliance Report.

The next Board meeting is scheduled for December 10 and 11, 2001.

For any additional information, please contact the Secretary of the Board at1-877-861-2350, or (613) 954-8299, or sdupont@pmprbcepmb.gc.ca.

## Working Group on Price Review Issues

The October 3-4 meeting of the Working Group on Price Review Issues has been postponed to December 13-14. A summary of the working notes of the Working Group will be published in the January 2002 NEWSletter. ■

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## **PMPRB Upcoming Events**



December December 10 - 11Board Meeting, Ottawa

Insight Conference, Toronto - Dr. Robert G. Elgie, Keynote Speaker – A Delicate Balance: Can Governments Promote R&D and Control Drug Costs at the Same Time?

December

Working Group on Price Review Issues, 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.



E-mail:

#### Mailing List

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## 

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