Patented Medicine Prices Review Board



**Inside…**



Canada

# NEWSletter

Volume 5, Issue No. 2 April 2001

## Since our last issue …

**Here are some of the key events which occurred since January 2001**

| | |
|---|---|
| March 5 & 6: | The Board held its first quarterly meeting for 2001. A summary of the minutes of the meeting appears on page 5. |
| March 6: | Presentation by Wayne D. Critchley, Executive Director of the PMPRB, *PMPRB - Pricing Regulatory Issues*, Maximizing Market Access Conference, in Toronto. |
| March 26: | Speech by Dr. Robert G. Elgie, Chairperson of the Board, *Enhancing Transparency in Drug Price Regulation*, to PHARMAC 2001, in Toronto. |

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

### Enhancing Transparency in Drug Price Regulation

On March 26th 2001, I addressed the PHARMAC 9th Annual Conference, where I reported on the current trends in drug prices and expenditures, recent decisions and initiatives of the PMPRB towards enhancing transparency in drug price regulation.

The significant growth in expenditures on pharmaceuticals has led to increased awareness on the part of policy makers and academics, making the PMPRB's role even more germane.

It is evident, given these trends, that making our work more transparent to Canadians is imperative. We have already introduced a number of initiatives to ensure that our work and processes are more transparent. In December 2000, the Working Group on Price Review Issues presented its report to the Board on various changes that would make the price review process even more open and transparent. A comprehensive report on the Board's decision and proposals for Notice and Comment to implement the Working Group's recommendations on the price review process is available on page 2 of this NEWSletter.

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.

"Increased transparency and openness in our processes can contribute to fostering an environment that facilitates evidence-based decision-making for stakeholders, researchers, policy-makers, and most importantly, the Canadian public."

Dr. Elgie's speech is available in its entirety on our website, under Publications, Speech Series 2001.

In addition, we continue to conduct extensive analyses of drug price trends for publicly-funded drug plans and to analyze the cost drivers in those plans under a Memorandum of Understanding with the Minister of Health. This year, that work is being expanded to include three more provinces and territories, and the federal drug plan for First Nations — the Non-Insured Health Benefits Plan. ■

*Robert G. Elgie*

Robert G. Elgie

## Congratulations!

On May 23, 2001, Dr. Robert G. Elgie, Chairperson of the Board, will be awarded an honorary degree by Dalhousie University: *Doctor of Laws, honoris causa*, in recognition of his outstanding personal achievements. ■

# Transparency in the Price Review Process

### Board's Decision on the Recommendations of the Working Group on Price Review Issues

In December, the Board received the second report of its Working Group on Price Review Issues, a report on the Board's price review process for new patented medicines. At its meeting on March 5, 2001, the Board considered the report in detail and reached a decision for further action. The Working Group report is available from the PMPRB website.

Overall, the Board agrees with the Working Group's recommendations. Although some of the more specific recommendations can be implemented without further consultation, the Board has decided that it wishes to consult more broadly on the implementation of those recommendations that may have a wider effect.

The Board is therefore publishing through this article, and through a separate Notice and Comment text, specific proposals to implement the Working Group's recommendations to make the price review process more open and transparent.

## Transparency - Guiding principles

The Working Group's report demonstrates its endorsement of the Board's commitment to ensure transparency in its work. To demonstrate its commitment, the Board proposes changes to the Compendium of Guidelines, Policies and Procedures to formally recognize the following principles:

- to be open and transparent in reviewing the prices of patented drugs;
- to respect the confidentiality of information; and
- to continue to promote voluntary compliance by patentees.

The proposed amendments to the Compendium can be found in the Notice and Comment text.

## Reporting on price reviews of new patented medicines

Board Staff apply the Excessive Price Guidelines in reviewing the prices of all new patented medicines. These reviews include, among other things, a comprehensive scientific analysis, often including the advice of the Human Drug Advisory Panel (HDAP), and comparisons of the price and cost of the drug relative to other therapies and other countries. The Board agrees with the Working Group that information concerning the outcome of the price review should be made publicly available when the review is completed.

In its report, the Working Group referred favourably to examples provided with the *Road Map for the Next Decade*. The Board agrees with the Working Group and proposes to begin publishing summary reports on the results of the price review for purposes of applying the Guidelines for all new active substances introduced after January 1, 2001.

Linked to this proposal is a recommendation of the Working Group that the Board cease publishing information on the category designation of new drugs. The Working Group concluded that the Board should provide information on the price test used and it would therefore no longer need to publish information on the category designation.

The Board has decided that it wishes to consult more broadly on these two proposals. More details on these proposals are provided in the Notice and Comment text.

The Board agrees with the Working Group that information on the status of the price review of individual drug products should be made publicly available. The website list of new patented medicines for 2001 will include a new column which will provide information on the status of the price review for each patented drug product. Watch for this change with the monthly update in September 2001.

The Board also agrees with the Working Group that it should, as much as possible, use "plain language" in all its publications. There will be ongoing efforts to make documentation more user friendly. To the extent possible, documentation will be made available directly from the website.

## Issues related to the scientific assessment of new drugs

The Working Group endorsed a number of the current measures governing the HDAP. It agreed that its members have a generalist base of expertise and that the conflict of interest measures currently in place for the HDAP are sufficient. No changes will be made in these areas.

There are currently three members of the HDAP, but there are circumstances where fewer than three may participate in a recommendation. The Board accepts the Working Group's recommendation that the HDAP should have a quorum of three members whenever it reviews a new drug product. The Board is considering how best to achieve this objective and has directed its staff to study this matter further.

The Working Group report is available from the PMPRB website www.pmprb-cepmb.gc.ca, under Working Group on Price Review Issues, Reports.

**The Board wishes to thank the members of the Working Group for their efforts in examining the price review process for new patented drug products.**

Comments on the proposed changes should be forwarded to the Secretary of the Board no later than June 30, 2001.

If you would like to send us your comments on these proposals, please include your e-mail address.

The Working Group did not reach consensus on the submission of many patentees that they be able to present additional scientific expertise directly to the HDAP. Under the Guidelines, the HDAP makes recommendations which are used by Board Staff for purposes of applying the Guidelines. Board Staff ensure that all scientific information relied on by the patentee, along with other information that may be identified, is made available to the HDAP.

The HDAP is not a decision-making body. Its recommendations and the Guidelines are not binding on patentees. If a dispute involving a scientific evaluation of a new drug resulted in the price being outside the Guidelines and therefore it became the subject of a hearing, the patentee would have the full opportunity to call evidence and defend its position before a panel of the Board. For its part, Board Staff would be required to provide evidence that the price was excessive for purposes of the *Patent Act* and would likely rely on the evidence of one or more members of the HDAP and other experts as may be required. To invite patentees to make oral submissions to the HDAP would risk turning the independent scientific advisory process into a preliminary hearing process. If patentees were permitted to make submissions in person to the HDAP, other stakeholders would expect the same opportunity. Under the current circumstances, the Board has decided that the current practice of no direct access to the HDAP remains appropriate.

## Input by non-industry stakeholders

In the *Road Map for the Next Decade*, the Board noted in the submissions of some stakeholders that they be provided a greater opportunity to input into the review of new drugs by Board Staff. The Working Group identified several options in this regard, including options whereby the Board would invite input in the course of individual drug reviews, but made no recommendations. All Working Group members could live with the option based on increased transparency through the measures described above.

On balance, the Board has concluded that it would not be necessary to propose going further at this time. The Board currently receives additional information or seeks it out if necessary in the course of a review. By publishing more comprehensive information on the drugs under review and their status, and by ultimately reporting the results of the review, the Board expects that persons who have additional information will not hesitate to communicate it.

The Board and all stakeholders will need some time to adapt to these changes and determine if they meet their needs. Therefore the Board proposes to evaluate all of these changes in two years time to determine if they adequately meet the objectives of transparency and openness of the price review process.

## Time lines

The Board agrees with the Working Group that it should establish milestones and time frames for the price reviews of new patented drugs. Work is ongoing to establish critical points to lay the groundwork for eventual milestones and time frames. Progress will be reported in future editions of the NEWSletter. Eventual proposals for milestones and time frames will be the subject of future consultation. ■

## Notice and Comment

A more complete text describing the proposed changes is being published for Notice and Comment which is circulated to the recipients of the NEWSletter along with the April 2001 issue. Copies of the Notice and Comment can also be obtained by contacting the Secretary of the Board at our toll-free number: 1-877-861-2350 or by accessing our website at: **www.pmprb-cepmb.gc.ca**, under Working Group on Price Review Issues, Notice and Comment. Comments on the proposed changes should be forwarded to the Secretary of the Board no later than June 30, 2001.

# Patented Medicine Prices Review Board - March 5 & 6, 2001 Meeting

At the March 5 & 6 meeting, the Members of the Board:

- Reviewed the report of the Working Group on Price Review Issues concerning the price review process of new patented medicines. A report on its detailed review and Notice and Comment to stakeholders appears in this NEWSletter, on page 2.
- Heard an oral briefing on:
  - the Fraser Institute Report on Prescription Drug Prices in Canada and the U.S., published in September 2000.
- Received the Compliance Report. ■

**The next Board meeting is scheduled for May 16, 2001.**

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.

# CPI-Adjustment Factors for 2002

The *Patent Act* specifies the factors to be used by the PMPRB 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.

To allow patentees to set prices in advance, the Board's CPI-Adjustment Methodology provides for the calculation of the CPI-Adjustment factors based on forecast changes in the CPI. The Board informs patentees on an annual basis of the CPI-adjustment factors for future pricing periods.

The CPI-adjustment factors for 2002 follow:

For additional information, consult the Compendium of Guidelines, Policies and Procedures, Chapter 1, EPG: 6 and Schedule 4. The Compendium is also available on our website at: http://www.pmprb-cepmb.gc.ca, under Legislation, Regulations, Guidelines.

**2002 CPI-Adjustment Factors for All Patented Drug Products (CPI 1992=100)**

| | Benchmark Year | | |
|---|---|---|---|
| | (1) 1999 | (2) 2000 | (3) 2001 |
| Base-CPI | 110.52 | 113.53 | n/a |
| 2002 Forecast CPI | 118.69 | 118.69 | 118.69 |
| 2002 CPI-Adjustment Factor | 1.074 | 1.045 | 1.021 |

**The 2002 Forecast CPI is 118.69**

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

For additional information, patentees can also contact the compliance officer assigned to their company.

The 2002 Forecast CPI is 118.69 (1992=100) and is based on the actual CPI figures for 2000 (113.53), as published by Statistics Canada, and the latest available inflation projections (2.4% for 2001 and 2.1% for 2002) from the federal Department of Finance.

# PMPRB Upcoming Events

May

**16**

Board Meeting, Ottawa

**29** **30**

Working Group on Price Review Issues

**31**

2000 PMPRB Annual Report to the Minister of Health

June

**30** Deadline to submit comments under the Notice and Comment on the proposals regarding the transparency in the price review process.

July

**31**

July 2001 NEWSletter

**To order our publications, call our toll-free number 1-877-861-2350**

## 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
Suite 1400
Ottawa, Ontario
K1P 1C1

Fax: (613) 952-7626

E-mail:
pmprb@pmprb-cepmb.gc.ca

Toll-free number:
1-877-861-2350
Tel: (613) 952-7360
TTY: (613) 957-4373