Patented Medicine Prices Review Board

NEWSletter

Volume 4, Issue No. 2 April 2000

Since our last issue, January 2000 …

Following are some of the key events which occurred over the last quarter:

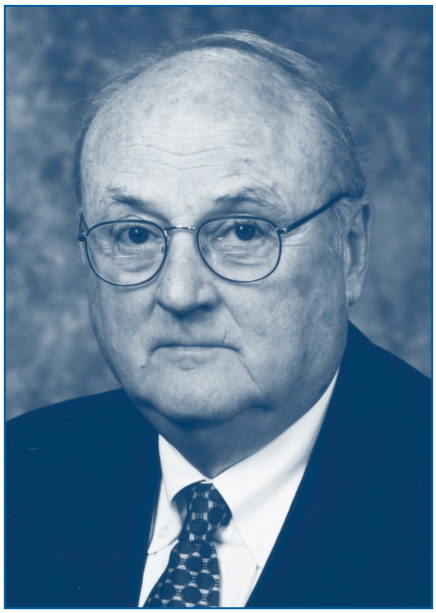
February 24:	The Board held its first quarterly meeting for 2000. A summary of the minutes of that meeting are available on page 6.
March 13:	The Hearing Panel in the HMRC/Nicoderm case issued an Interim Order. A summary of the Order appears on page 2.
March 29:	The Board held a hearing in the ICN/Virazole case and issued a Variation Order. A summary of the Board's decision is published in this issue of the NEWSletter on page 2.

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

Noteworthy

- On March 8, 2000, Dr. Robert G. Elgie was re-appointed Chairperson of the Patented Medicine Prices Review Board for a five year term. Dr. Elgie said he was very pleased to have the opportunity to continue his work with the PMPRB and, in particular, to oversee the gradual implementation of the Action Plan set out in the Board's 1998 *Road Map for the Next Decade*.

- Elaine McGillivray, Assistant to the Secretary of the Board, and Gerry Taylor, Chief of Management Services, celebrated 25 years with the federal Public Service in December 1999 and March 2000 respectively. Elaine joined the Department of Consumer and Corporate Affairs on December 16, 1974, where she worked until she joined the PMPRB upon its creation on December 7, 1987. Gerry joined the Public Service Commission on March 4, 1975. He came to the PMPRB on August 18, 1997 from Health Canada. ■



Dr. Robert G. Elgie, Chairperson of the Patented Medicine Prices Review Board

The Patented Medicine Prices Review Board is an independant quasi-judicial tribunal with the mandate to ensure that manufacturers' prices of patented medicines sold in Canada are not excessive.

Board Members

Chairperson:
Robert G. Elgie,
LL.B., M.D., F.R.C.S. (C)

Vice-Chairperson:
Réal Sureau, FCA

Members:
Anthony Boardman,
B.A. (hons.), Ph.D.

Ysolde Gendreau,
B.C.L., LL.B., LL.M., Ph.D.

Ingrid S. Sketris,
Bsc (Phm), Pharm.D.,
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Inside…

Canada

Nicoderm Hearing - Update Part II on jurisdictional issues

On March 13, 2000, the Hearing Panel issued an Interim Order offering the parties the opportunity to present additional evidence and argument on two points. The Hearing Panel will hear the additional evidence on June 28 and 29, 2000.

As reported in previous issues of the NEWSletter, the Chairperson of the Board issued a Notice of Hearing on April 20, 1999, to consider whether, under sections 83 and 85 of the *Patent Act*, the patented medicine Nicoderm is being, or has been, sold by Hoechst Marion Roussel Canada Inc. (HMRC) in Canada at a price that, in the opinion of the Board, is excessive and if so, what order, if any, should be made. This matter was first referred to on page 32 of the 1998 Annual Report.

Nicoderm is a transdermal nicotine patch. It is indicated as an aid for smoking cessation for the partial relief of nicotine withdrawal symptoms.

By Notice of Motion dated May 25, 1999, HMRC challenged the jurisdiction of the Board to proceed with the matters described in the Notice of Hearing. For procedural purposes, the jurisdiction motion was divided into two parts, the first concerning allegations of institutional bias and the second challenging the Board's jurisdiction on statutory and constitutional grounds. The Board heard argument on the first part of the motion on July 5, 1999, and issued its decision affirming its jurisdiction on August 3. HMRC has filed an application for judicial review of this decision in the Federal Court of Canada.

On December 13 to 16, the Hearing Panel heard evidence and argument on the second part of HMRC's motion, and in particular on its submissions that:

- Nicoderm is not a medicine for the purpose of section 83 of the *Patent Act*;
- HMRC is not a patentee of the patents in question and/or the patents in question do not pertain to Nicoderm;
- Any interpretation of the *Patent Act* that would extend the Board's jurisdiction in the manner alleged by Board Staff would exceed the jurisdiction of Parliament.

For information on this hearing, please contact the Secretary of the Board, at:

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The Board's decisions and reasons are posted on our web site: **www.pmprb-cepmb.gc.ca** under Publications, Hearings & Decisions of the Board.

Virazole, ICN Canada Ltd. and ICN Pharmaceuticals, Inc.

In 1996, following a hearing under section 83 of the *Patent Act*, the Board issued an order regarding the price of the medicine Virazole. This case was first reported on in the PMPRB's 1995 Annual Report.

Virazole is sold in Canada by ICN Canada Ltd., a wholly-owned subsidiary of ICN Pharmaceuticals, Inc. of the U.S. (hereinafter collectively called "ICN"). Virazole is the brand name for the generic medicine ribavirin, which is a drug used in the treatment of hospitalized infants and children who suffer from lower respiratory tract infection due to respiratory syncytial virus.

On July 26, 1996, the Board concluded that ICN had been selling Virazole at an excessive price and that it had engaged in a policy of excessive pricing. It ordered ICN to lower the price of Virazole to a non-excessive level. ICN was also ordered to offset twice the excess revenues it had received by making an immediate payment

of $1.2 million to Her Majesty in right of Canada and by reducing the price of Virazole from $1540 to approximately $200 per 6 gram vial (which would be $200 below the maximum non-excessive price of approximately $400). This additional price reduction was to remain in effect until the earlier of December 31, 1999, or the date on which an amount equal to twice the cumulative excess revenues, for a total of $3.5 million, had been offset by the sum of the amount paid and the cumulative price reductions. In the event that the cumulative excess revenues were not offset by December 31, 1999, ICN was to make a payment or payments to Her Majesty in right of Canada equal to the balance of excess revenues outstanding.

In January 2000, Board Staff asserted that the amount of $1,711,957 remained to be paid while ICN was of the view that no further payments were required to satisfy the Board's Order. On March 10, 2000, Board Staff filed a motion for directions from the Board.

On March 28, following discussions with ICN, Board Staff filed a proposed Variation Order. The Board heard the parties on the proposed Order on March 29. The Board agreed that the Variation Order was in the public interest and was superior to an immediate one-time payment to the Crown. The Board issued the Variation Order on the terms to which the parties had consented.

In summary, the Variation Order provides that ICN has a continuing obligation to offset over $1.7 million and that it will continue the combination of cash payments and reduced prices for Virazole for a further four years. ICN made an initial cash payment of $350,000 on April 27, 2000, and has reduced the price of Virazole by at least $200 per vial below the maximum non-excessive price until ICN's full obligation of $1,711,957 has been satisfied. If in any calendar year, starting with the year 2000, there are not sufficient sales of Virazole to result in a reduction of the obligation by at least $350,000, ICN is required to make a cash payment to ensure that the obligation is reduced by at least $350,000 for that year. In the event that sales of Virazole generate net revenues of less than $27,500, or if Virazole is removed from the market, the balance of ICN's obligation, then owing, becomes payable. ■

Notice and Comment - Voluntary Compliance Undertaking - Plavix

A. Purpose of this Notice

1. The purpose of this notice is to provide Ministers of Health in the provinces and territories and other interested persons with an opportunity to make submissions on the appropriateness of the VCU made by Bristol Myers Squibb Pharmaceutical Group (BMS) and Sanofi-Synthélabo Canada Inc. (Sanofi) regarding the patented medicine Plavix.

B. Background

2. The Board received a VCU from BMS and Sanofi on April 12, 2000, in respect of the price of the medicine Plavix (clopidogrel bisulfate).
3. Plavix 75 mg/tablet is a patented medicine sold in Canada by BMS. Plavix is approved for the secondary prevention of vascular ischemic events (myocardial infarction, stroke, vascular death) in patients with a history of symptomatic atherosclerotic disease.
4. Health Canada issued a Notice of Compliance to Sanofi for Plavix 75 mg/tablet (DIN 02238682) on October 7, 1998. Pursuant to agreements between BMS and Sanofi, Plavix has been sold in Canada since October 7, 1998 at a daily dosage cost of approximately $2.47 per tablet.
5. The Board's Human Drug Advisory Panel (HDAP) classified this product as a category 3 new medicine. 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.
6. On the basis of its review, Board Staff concluded that the introductory price of Plavix exceeded the Guidelines as it was higher

Voluntary Compliance Undertakings

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 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.

than the price of Ticlid (which, at $2.19 per day, was the most expensive comparator recommended by the HDAP) and commenced an investigation into the price of Plavix on April 23, 1999.

7. These prices are considerably higher than the price of ASA, which is often referred to as the "drug of choice" for this indication. On the other hand, the price of Plavix in Canada is lower than the price in all six countries, in which it is sold, that the Board is required to use for purposes of international price comparisons. The Canadian price of Plavix is also lower than the Federal Supply Schedule price in the U.S. of Cdn$2.64.
8. BMS and Sanofi provided additional scientific and economic evidence in support of the price of Plavix. After careful analysis of the evidence provided, Board Staff and the patentees engaged in discussions and agreed to the terms of a VCU, as set out below, that would be referred to the Board. BMS and Sanofi have undertaken:
   1) To agree that the maximum non-excessive (MNE) price for Plavix at the time of introduction is considered as $2.3316 per tablet, 5.6% below the price that was actually charged of $2.4700.
   2) To reduce the current price of Plavix to the MNE price for the year 2000 of $2.4015 per tablet, effective April 10, 2000, using the Board's CPI adjustment methodology.
   3) To offset all of the excess revenues received from the sale of Plavix at prices higher than the MNE prices from October 1998 to April 9, 2000 as calculated by the Board in the following manner:
      a) For sales prior to March 1, 2000 by making a payment to Her Majesty in right of Canada no later than 30 days following the acceptance of the undertaking by the Board to offset excess revenues from October 1998 to February 29, 2000; and
      b) By issuing credit notes, no later than 30 days following acceptance of the undertaking by the Board, to pharmacies, wholesalers, hospitals and other customers for the difference between actual prices paid and the MNE price of $2.4015 with respect to sales between March 1, 2000 and April 9, 2000.
9. BMS and Sanofi have reduced the price of Plavix as of April 10, 2000 as per the terms of their VCU and have commenced issuing credit notes.

C. Additional Information

10. Subsequent to the VCU from the patentees, a study by Bennett et al, which is pending publication, was released by the New England Journal of Medicine (NEJM) on April 21, 2000 regarding thrombotic thrombocytopenic purpura (TTP) associated with clopidogrel. On April 27, 2000, the patentees were requested to provide input with respect to the significance of this information and the impact that it may have on any of their submissions made to date. In a response dated May 1, 2000, the patentees stated that cases of suspected TTP have been reported to a number of regulatory agencies, including Health Canada, and that this information does not, in the patentees' view, impact on the VCU.

D. Proposal

11. The Board will consider submissions in this matter in determining whether to accept the VCU.

E. Process for Submissions

12. All persons who wish to make representations in this matter shall file a written submission with the Board on or before June 9, 2000.
13. All submissions by the Ministers of Health will be considered by the Board.
14. All submissions by other persons shall include a clear statement of the person's interest in this matter, and shall state the reasons why the Board should consider the submission.
15. Board Staff and BMS/Sanofi will be given the opportunity to make written submissions in response to any written submission received within 15 days thereafter.
16. Copies of the VCU, the Board Staff memorandum, the April 21, 2000 NEJM article and Sanofi's letter of May 1, 2000 can be obtained from the Secretary of the Board.
17. All submissions shall be filed with the Secretary of the Board. ■

Secretary of the Board
The Patented Medicine Prices Review Board
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All submissions shall be placed on the public record.

Calculation of the average transaction price in the event of special programs and incentives offered by patentees - Clarification of the Board's Guidelines

Over the years, we have received several inquiries regarding the effect of the various incentives and programs offered by patentees in calculating the average transaction price of a patented medicine for price review purposes. These programs include manufacturers' compassionate release programs, trial prescription programs and expenditure limitation agreements between a manufacturer and a public drug plan.

Under the *Patent Act*, we review the average manufacturer's selling price (i.e., the factory-gate price) of a patented medicine. Pursuant to ss. 4(5) of the *Patented Medicines Regulations, 1994*, patentees report net revenues to the PMPRB taking into account reductions given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts and other such benefits. The Board's Compendium of Guidelines, Policies and Procedures describes the manner in which the average price and net revenues are calculated. Generally, the average price is calculated on the basis of the total net revenues for all package sizes of the drug product sold during the pricing period, divided by the number of units sold.[1]

The Compendium also provides further clarification in the case of products supplied by a manufacturer at no charge by stating that adjustments for free goods will only include products provided to customers in a saleable form, i.e. in the same strength and package sizes as those being offered for sale. Samples provided to physicians in a non-saleable form are not considered free goods and patentees should not report those with the sales and price data submitted under the Regulations.[2]

If it is unclear how the Regulations should be applied in special cases, it has been our practice to advise manufacturers to report all the information and to clearly identify what is to be included or excluded from the calculation of the average price in all reporting periods. For instance, products supplied under a compassionate release program can either be included or excluded by the patentees; however, the inclusion or exclusion thereof must be consistent in all reporting periods.

In summary, it is the Board's intention in these circumstances that its policies and procedures not discourage a patentee from offering an incentive program or entering into an agreement which would benefit patients. However, the patentee must be consistent in reporting such programs from one reporting period to the next so as to avoid artificial fluctuations in the price calculated for price review purposes. ■

1 See Compendium: EPG:3, paragraph 5.4
2 See the Compendium: EPG:3, paragraph 5.2

If you have any comments or submissions you would care to make on this matter, please direct them to the Secretary of the Board.

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Patentees seeking clarification should contact the compliance officer assigned to their company.

Working Group on Price Review Issues

The Working Group on Price Review Issues held its fourth meeting in Ottawa March 16 & 17, 2000.

The Working Group continued its review of issues concerning the price review process for new patented medicines. The discussions focused on issues relating to input by stakeholders into the price review process (e.g. its appropriateness, when should it take place, etc.) and the communication of information including the results of price reviews. Several options were identified reflecting the full range of views of Working Group members on the issue of stakeholder input into the price review process.

PMPRB Legal Counsel gave a background presentation on the principles of accountability, transparency and fairness as they relate to the price review process. He also provided information on the existing legislative framework for dispute resolution.

Dr. Chris Turner of the Bureau of Licensed Product Assessment (Therapeutic Products Programme, Health Protection Branch, Health Canada) provided an overview of the work that is underway in terms of post-approval assessment activities.

The Working Group expects to finalize its report on the price review process at its next meeting scheduled for the Fall of 2000 and to begin its review of the final issue of its mandate, which is to review the methods to conduct therapeutic class comparisons and the guidelines for category 3 drugs, including the use of pharmacoeconomics. ■

Patented Medicine Prices Review Board - February 24, 2000 Meeting

The next Board meeting is scheduled for May 25 & 26, 2000.

At the February 24, 2000 meeting, the Members of the Board received:

- an oral briefing on R&D incentives in Canada and in major industrialized countries from Jacek Warda, Principal Research Associate and Manager, Innovation Council, Conference Board of Canada.
- an oral briefing on the Strategic Plan for 2000-2003.
- an oral briefing on the work performed by Board Staff in the context of the activities of the Federal/Provincial/Territorial Working Group on Drug Prices.
- a detailed status report on the PMPRB's follow-up activities to the September 1998 Report of the Auditor General.
- an oral briefing on the December 1999 Report of the Canadian Institute for Health Information on *National Health Expenditure Trends*.
- the outline and work plan for the 1999 Annual Report.
- the Compliance Report.

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 2001

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.[1]

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 2001 follow:

2001 CPI-Adjustment Factors for **All Patented Drug Products**
(CPI 1992 = 100)

	Benchmark Year		
	(1) 1998	(2) 1999	(3) 2000
Base-CPI	108.63	110.52	n/a
2001 Forecast CPI	115.43	115.43	115.43
2001 CPI-Adjustment Factor	1.063	1.044	1.021

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

The 2001 Forecast CPI is 115.43 (1992 = 100) and is based on the actual CPI figures for 1999 (110.52) as published by Statistics Canada and the latest available inflation projections (2.3% for 2000 and 2.1% for 2001) from the February 2000 Federal Budget. ■

A description of the CPI-Adjustment Methodology can be found in Schedule 4 of the Compendium of Guidelines, Policies and Procedures, available on our web site at **www.pmprb-cepmb.gc.ca,** under Frequently Requested Items, CPI-Adjustment Factors.

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

1 See the Compendium of Guidelines, Policies and Procedures, EPG: 6 and Schedule 4.

Canadian International Trade Tribunal inquiry into certain iodinated contrast media - update

In the January 2000 issue of the NEWSletter, we reported on the Notice of Commencement of Inquiry issued on January 4, 2000, by the Canadian International Trade Tribunal (CITT), pursuant to section 42 of the *Special Import Measures Act*, respecting the dumping in Canada of certain iodinated contrast media used for radiographic imaging, in solutions of osmolality less than 900mOsm/kg H_2O, originating in or exported from the United States of America (including the Commonwealth of Puerto Rico).

The CITT held its public inquiry on March 28th to March 31st, 2000, into the preliminary determination of dumping and whether there has been injury to the Canadian producer. The Tribunal issued its decision on May 1, 2000, and found that the dumping in Canada of the aforementioned goods has caused material injury to the domestic industry. The Tribunal is scheduled to issue its statement of reasons on May 16. Information on this inquiry is available on the CITT web site at **www.citt.gc.ca**. ■

PMPRB Upcoming Events

May 25 & 26:	Board meeting
May 31:	1999 PMPRB Annual Report to the Minister of Health

PMPRB List of Publications

Here are the latest addition to our Publications List:

- HMRC / Nicoderm Hearing: Hearing Panel's Interim Order, March 13, 2000
- ICN / Virazole case: Board's Variation Order, March 29, 2000 and Board's Reasons, March 31, 2000

TO ORDER, 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:

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