Patented Medicine Prices Review Board

NEWSletter

Volume 3, Issue No. 4 October 1999

Since our last issue, July 1999 …

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

August 3:	In the matter of Hoechst Marion Roussel Canada Inc. (HMRC) and the price of the nicotine patch NICODERM, the Hearing Panel released its decisions on jurisdictional issues raised by HMRC and on the disclosure of documents.
September 23:	At a ceremony attended by family members of the late Harry C. Eastman, colleagues and friends, the Honourable Allan Rock, Minister of Health unveiled a plaque dedicating the Harry C. Eastman Boardroom.
September 23 & 24:	The Board held its third quarterly meeting of the year. A summary of the meeting appears on page 5 of the NEWSletter. The Board will next meet on December 16 and 17.
October 16:	Wayne D. Critchley, Executive Director of the PMPRB, gave a presentation on the role and activities of the Board to students of the Faculty of Pharmacy, Laval University in Québec City, under the micro programme on the development of pharmaceutical products.
October 17 & 18:	The Working Group on Price Review Issues met to begin examining the second of three issues it has been tasked with reviewing - the PMPRB Price Review Process for New Patented Drug Products. The Working Group's objective is to review, analyze and report on improvements to the price review process for new patented drugs to make it more transparent and accountable. The minutes of the meeting will be available and posted on the PMPRB web site in mid-November.

Please contact us at our toll-free number: **1-877-861-2350** to obtain copies of any materials or consult our web site at: **http://www.pmprb-cepmb.gc.ca**.

PMPRB Web Site

If you want to know more about the PMPRB and you have access to the NET, look for our site at **http://www.pmprb-cepmb.gc.ca**

Inside…

Notice and Comment - Implementation of Use of U.S. FSS Prices in International Price Comparisons

Background

In the *Road Map for the Next Decade* (*Road Map*), released in September 1998, the Board reported on a number of issues raised by stakeholders, including international price comparisons (IPCs).

In its report, the Board stated that it:

> "believes it important to use the best information possible and that the public have confidence it is doing so."

The U.S. Federal Supply Schedule (FSS) sets out prices for drugs which are available to federal agencies and institutions in that country. The FSS prices are one of four prices negotiated and published in a formulary by the U.S. Department of Veteran Affairs (DVA). The three other drug prices negotiated by the U.S. DVA are the Big Four prices, the National Contract prices and the Blanket Purchase Agreement prices. These prices are only available to certain U.S. agencies and for a smaller subset of drug products.

The *Patented Medicines Regulations* require patentees to report information on the publicly

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.

The Report of the Working Group on Price Review Issues, *Appropriate Use of U.S. Department of Veteran Affairs Prices*, and background documents, are available on the PMPRB web site, under Working Group on Price Review Issues, Reports. Should you need any additional information on the activities of the Working Group, please contact the co-chairs of the Working Group, at our toll free line 1-877-861-2350 or directly:

Ron Corvari: (613) 952-3305 rcorvari@pmprb-cepmb.gc.ca
Laura Reinhard: (613) 952-7619 lreinhard@pmprb-cepmb.gc.ca

The Terms of Reference of the Working Group and all documents related to the *Road Map for the Next Decade* are available on our web site: **http://www.pmprb-cepmb.gc.ca**, under Working Group on Price Review Issues and Publications.

Comments on the implementation of the Working Group recommendations on the use of U.S. DVA prices should be forwarded to the Secretary of the Board no later than **November 30, 1999**, at the following address:

Box L40
Standard Life Centre
333 Laurier Avenue West
14th floor
Ottawa, Ontario
K1P 1C1
By fax: (613) 952-7626
By e-mail: sdupont@pmprb-cepmb.gc.ca

The Board will publish its decision on the use of U.S. DVA prices in its January 2000 NEWSletter.

available prices for drugs sold in other countries. In November 1997, the U.S. DVA began publishing its formulary prices. As a result, the Board announced in the *Road Map* that patentees would be required to report U.S. DVA formulary prices in their regular filings with the Board. The first such filings were due January 30, 1999 for the pricing period July 1 to December 31, 1998.

At the same time, the Board sought input from stakeholders on how that information should be used when conducting international price comparisons. Following comments raised by stakeholders, the Board referred this issue to the Working Group on Price Review Issues (Working Group) for its review.

The Working Group was created in February 1999 and is comprised of 12 representatives of the Board's major stakeholders. (See NEWSletter, April & July 1999) Its mandate is to review three issues relating to price review, of which the first was the appropriate use of prices in the DVA formulary (including the FSS price) in conducting IPCs. Two meetings were held in March and June 1999 to develop and evaluate options.

Information relating to U.S. DVA formulary prices, and U.S. prices in general, was provided to the Working Group in two documents and in presentations by Board staff.

Recommendation of the Working Group

The Working Group submitted its *Report to the Patented Medicine Prices Review Board on the Appropriate Use of U.S. Department of Veteran Affairs Prices*, in September 1999 and it was considered by the Board at its meeting on September 23-24, 1999. The Working Group proposed the following three recommendations to the Board for its consideration:

1. The U.S. Federal Supply Schedule (FSS) prices should be used along with the other U.S. prices currently reported by patentees to calculate the average U.S. price in conducting IPCs.
2. Patentees should be required to separately identify and report the U.S. FSS price in the "other"[1] class of customer.
3. Transitional measures should be developed for drug products with prices that exceed the Guidelines as a result of including U.S. FSS prices in conducting IPCs.

Given that the three other prices negotiated by the U.S. DVA are only available for a small subset of patented drug products sold in Canada, the Working Group concluded that it is not appropriate to use these prices in conducting an IPC.

Proposal

Upon consideration, the Board accepted the Working Group's recommendations and invites submissions from stakeholders and the public on the proposal to implement them in the following manner:

- Use of U.S. FSS prices in conducting IPCs will be effective the pricing period commencing January 1, 2000 for all new and existing medicines.
- Drug products whose prices would have exceeded the Guidelines in 1999, only as a result of including the U.S. FSS prices, will be provided a period of transition such that patentees will be required to ensure

1 Patentees are required to report publicly available ex-factory prices to four classes of customers: hospital, drugstore or pharmacy, wholesaler and other.

that the average Canadian transaction prices of these drug products do not exceed the Highest International Price Guideline by January 1, 2001.

It should be noted that U.S. FSS prices will be used in calculating U.S. drug prices for all international price comparisons conducted by the Board. This includes, for purposes of the Guidelines, calculating the median international price when conducting IPCs for category 2 new medicines as well as when conducting IPCs for the Highest International Price Guideline for new and existing medicines.

In addition, given the current regulations, patentees are required to continue to report all four prices listed on the U.S. DVA formulary although the Board will only be using the U.S. FSS price in calculating the average U.S. price.

Notice and Comment Period

Those wishing to comment on the Board's proposal are invited to provide their submissions to the Secretary to the Board by November 30, 1999. The Board will consider submissions received at its meeting in December 1999. Unless the Board publishes a decision to amend the proposal, the Board will implement this proposal effective the pricing period commencing January 1, 2000 by way of notice on its web site. ■

The Board dedicates its boardroom in memory of its first Chairperson Dr. Harry C. Eastman

On September 23, 1999, the Minister of Health, the Honourable Allan Rock, unveiled a plaque dedicating the PMPRB boardroom as the *Harry C. Eastman Boardroom*, in memory of its first Chairperson. Saddened by the sudden loss of Harry Eastman last April, the Board saw it fitting to gather family, friends and colleagues to honour his memory in a lasting way.

Dr. Eastman was member of the Board from 1987 to 1997 and its first Chairperson from 1987 to 1995. When he first became involved in the challenging public policy issues regarding pharmaceuticals, he had already had an outstanding career of considerable reputation; he had a happy and successful personal life and he was in the fortunate position of being able to choose the next stages in his career. It is a significant tribute to Dr. Eastman that he welcomed an opportunity for public service by heading up the Commission of Inquiry into the Pharmaceutical Industry in 1984 and then setting up the Patented Medicine Prices Review Board in 1987. He could have chosen easier jobs, but it was his sense of public responsibility and the knowledge that he could make a difference that led him to accept the challenge.

Dr. Eastman was able to introduce a large measure of reason and evidence-based policy analysis into an emotional and highly-charged matter of public debate. He demonstrated those same skills in setting up the PMPRB and in establishing its price guidelines and compliance policy. Dr. Eastman welcomed the challenges of setting up a new organization and he approached his responsibilities with good humour, common sense, a keen intellect and, above all, tremendous wisdom.

▲ Dr. Harry Claude MacColl Eastman, Ph.D., F.R.S.C., First Chairperson and Member of the Patented Medicine Prices Review Board

In his remarks, Dr. Robert Elgie, current Chairperson, said that dedicating the boardroom in Dr. Eastman's memory was a fitting tribute and expressed the wish that Dr. Eastman's memory will continue to inspire all to sound and wise actions. ■

The Honourable Allan Rock, Minister of Health, Dr. Robert G. Elgie, Chairperson of the Patented Medicine Prices Review Board, Julia Eastman and Harriet Eastman ▶

Nicoderm Hearing - Summary of the Hearing Panel's Decisions on jurisdictional issues and disclosure of documents

On August 3, 1999, the members of the Hearing Panel issued decisions following motions filed by Hoechst Marion Roussel Canada Inc. (HMRC) on the Board's jurisdiction in this case, and by Board Staff on disclosure of documents.

On the jurisdictional issues, the Board held that it had not lost jurisdiction due to institutional bias, nor had any actions on the part of the Board given rise to a reasonable apprehension of bias. With respect to documentary disclosure, the Board ordered HMRC to deliver the information and documents sought by Board Staff with some exceptions.

On September 2, 1999, HMRC brought an application in Federal Court for judicial review of the Board's decision on its jurisdiction. A hearing date has not yet been set.

The hearing will be held at the Standard Life Centre, 333 Laurier Avenue West, Ottawa. The date and time will be published on our web site.

The Board was scheduled to proceed with its hearing on the second part of the jurisdictional issues on October 25, 1999 but that has now been adjourned to a date yet to be determined. ■

For 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
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Once issued, the Board's decisions are posted on our web site: **http://www.pmprb-cepmb.gc.ca** under Publications, Hearings & Decisions of the Board.

To Patentees on Y2K

The PMPRB wishes to convey to patentees its expectations regarding the continued regulatory filing obligations under the *Patent Act* and the *Patented Medicines Regulations*.

The legislation requires the filing of data and information within specific time frames. Patentees who do not adhere with these filing requirements are considered to be in a failure to file situation which can attract serious penalties under the *Act*.

The onus is on patentees to ensure conformity with Y2K requirements.

Questions should be directed to the Compliance Officer responsible for your company. ■

The Planning Process

In the *Road Map for the Next Decade*, the Board undertook to publish its Research Agenda as part of its annual planning process. Among other things, the Research Agenda will identify initiatives that are currently, or may become, subject to public consultations.

The PMPRB's planning framework provides for the development of a strategic plan in late fall and the process is now underway. Input and comments received from the Working Group on Price Review Issues and other stakeholders during the year will be taken into consideration. The Board anticipates updating the Research Agenda and publishing it in the January 2000 issue of the NEWSletter. ■

Patented Medicine Prices Review Board - September 23 & 24 Meeting

At the September 23 & 24, 1999 meeting, the Members of the Board:

- Received the Report of the Working Group on Price Review Issues on the Appropriate Use of U.S. Department of Veteran Affairs Prices in international price comparisons and accepted its recommendations:
  - To use the U.S. Federal Supply Schedule (FSS) prices along with the other U.S. prices currently reported by patentees to calculate the average U.S. price in conducting international price comparisons;
  - To require patentees to separately identify and report the U.S. FSS price in the "other" class of customer; and
  - To develop transitional measures for drug products with prices that exceed the Guidelines as a result of including U.S. FSS prices in conducting international price comparisons.
- The Board decided to consult on specific proposals to implement these recommendations effective for pricing periods commencing January 1, 2000. These proposals are published for Notice and Comment in this NEWSletter.
- Received an oral briefing on the information released by the Council of Ministers of Health at their September 16, 1999 meeting. Among other things, the Federal/Provincial/Territorial Task Force on Pharmaceutical Issues was reconstituted as the F/P/T Working Group on Drug Prices. The Minister of Health has asked the PMPRB to continue to provide technical support in the analysis of drug price trends and cost drivers.
- Received an oral briefing from an official of the Department of Foreign Affairs and International Trade on the three challenges before the World Trade Organization involving Canada and the *Patent Act*.
- Received an oral briefing on Information Management and Security.
- Received a status report on the Board's follow-up activities to the September 1998 Report of the Auditor General on the PMPRB.
- Received the Compliance Report.

The next Board meeting is scheduled for December 16 & 17, 1999.

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 ■

PMPRB Upcoming Events

November 9:	Presentation by Wayne D. Critchley at the Brogan Seminars, on the activities of the Working Group on Price Review Issues, in Toronto.
November 30:	Speech by Dr. Robert G. Elgie, at the Canadian Pharmaceutical Industry Conference (CPIC) 1999, Status report on the *Road Map for the Next Decade*, in Toronto.

PMPRB List of Publications

Here are the latest additions to our Publications List:

- July 1999 NEWSletter
- Nicoderm Hearing - Hearing Panel's decisions: Jurisdiction - Part I; Disclosure of Documents, August 3, 1999
- Report of the Working Group on Price Review Issues to the Patented Medicine Prices Review Board on the *Appropriate Use of U.S. Department of Veteran Affairs Prices*, September 1999.

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: _____

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Please return the completed form to the PMPRB, at:

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