Patented Medicine Prices Review Board

NEWSletter

Volume 4, Issue No. 4 October 2000

Since our last issue, July 2000 ...

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

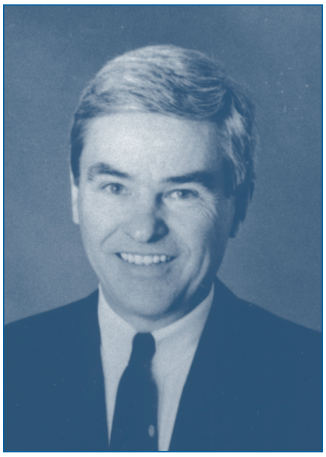
September 14 & 15:	The Board held its third quarterly meeting for 2000. A summary of the minutes of the Board meeting is available on page 5.
October 3 & 4:	The Working Group on Price Review Issues held its fifth meeting. A summary of the working notes of the meeting is available on page 4.

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**.

Congratulations!

Dr. Elgie, Chairperson

- In September, Dr. Elgie received the Award of Merit of the University of Ottawa Faculty of Medicine Alumni Association. This award recognizes distinguished graduates of the Faculty who have made outstanding contributions to the profession, their communities and to the Faculty.
- More recently, Dr. Elgie was appointed to the Ontario Press Council.
- On October 4, Réal Sureau was re-appointed to the Board as member and Vice-Chairperson.
- Monique Lesage, Assistant, Policy and Economic Analysis Branch, celebrated 15 years with the federal Public Service in March 2000. Monique joined the PMPRB in January 1996 after previous assignments with Health Canada and Citizenship and Immigration Canada. ■



Réal Sureau, Vice-Chairperson

Monique Lesage,
Assistant, Policy and
Economic Analysis Branch

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.

Board Members

Inside...

Canada

Nicoderm Hearing: Hoechst Marion Roussel Canada brings judicial review applications on the Board's decisions regarding its jurisdiction

On September 8, 2000, Hoechst Marion Roussel Canada (HMRC) filed an application for judicial review in the Federal Court of Canada with respect to the Board's decision of August 8, 2000 on Part II of HMRC's motion challenging the Board's jurisdiction to hear proceedings in the Nicoderm matter.

HMRC had filed an application on September 3, 1999 in regard to the Board's decision in Part I of the jurisdictional challenge last year. Proceedings on the first judicial review application had been held in abeyance until the Board's decision on the second part of the jurisdictional issues had been rendered.

On October 25, 2000, Board Staff filed a motion to intervene in the two applications for judicial review initiated by HMRC. ■

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

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

Euro currency filing requirements

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 currency.

On January 1, 1999, the euro became the official currency of 11 Member States of the European Union. Although euro notes and coins will not appear until January 1, 2002, the euro currency can be used by consumers, retailers, companies of all kinds and public administrations from January 1, 1999 in the form of "written money" - that is, by means of cheques, travellers' cheques, bank transfers, credit cards and electronic transactions. This means that during the transition period both the euro and national currency are legal.

Only three of the PMPRB's comparator countries have decided to adopt the euro at this point: France, Germany and Italy. The United Kingdom and Sweden have decided for the present not to join. Switzerland is not part of the European Union.

The conversion rates between the euro and the currencies of the Member States adopting the euro have been irrevocably fixed and will therefore be stable during the transition period.

Euro notes and coins will be issued as of January 1, 2002 and will become the only currency which has the status of legal tender in all Member States adopting the euro. Banknotes and coins in a national currency will remain legal tender within their territorial limits until six months after the end of the transition period at the latest, that is July 1, 2002.

1. **As of the pricing period starting January 1, 2002**, all patentees will be required to file prices in euro for those participating Member States (i.e. France, Germany and Italy).
2. **During the transition period from January 1, 1999 to January 1, 2002**, patentees may elect to file in euro, in national currency or in euro and national currency.
3. **During the transition period**, the irrevocably fixed conversion rates published in the Official Journal of the European Communities will be used as the basis to convert those euro prices filed by patentees into the respective national currency. The existing 36-month methodology will continue to apply to convert the national currency into Canadian dollars.
4. **Following the end of the transition period for the implementation of the euro**, January 1, 2002, the 36-month exchange rate will be used to convert euros into Canadian dollars.

The Bank of Canada began publishing exchange rates for the euro in 1999. The Bank of Canada is the source that the PMPRB uses for exchange rates for all of its international price comparisons.

The PMPRB's use of the European Community's fixed rates for the transition period provides a simple and transparent means to convert euro prices into national currencies.

These filing requirements are intended to reflect the steps governing conversion to the euro currency in the countries affected. If patentees have any questions with this approach, they should raise them with the compliance officer assigned to their company. ■

Guidance regarding the patentees' reporting requirement of U.S. DVA prices

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. In the October 1999 issue of the NEWSletter, the Board announced that it had accepted the recommendation of the Working Group on Price Review Issues that the U.S. FSS price along with the other U.S. price information currently reported by patentees be used to calculate the U.S. price for purposes of International Price Comparisons (IPC).

The Board decided to implement the inclusion of the U.S. FSS price in conducting IPCs effective the pricing period commencing January 1, 2000 for all new and existing medicines.

During the Notice and Comment period which preceded the implementation of the use of the U.S. FSS prices, industry stakeholders submitted that it was an unnecessary regulatory burden to require them to file all four prices on the U.S. DVA formulary given that only one price, the FSS price, will be used by the PMPRB.

Noting that the filing of publicly available prices is a regulatory requirement, the Board agreed to review the requirements regarding the other three prices listed in the U.S. DVA formulary given that the Working Group had recommended that only the U.S. FSS price be used in conducting IPCs. The other three prices represent a limited number of drug products. The Working Group did not make any recommendations regarding the reporting requirement relating to the three other prices listed on the U.S. DVA formulary.

The U.S. DVA negotiates four prices:

- the Federal Supply Schedule (FSS)
  The FSS lists the pharmaceutical products and their prices which are available to federal agencies and institutions and several other purchasers, such as the District of Columbia, U.S. territorial governments and many Indian tribal governments. The FSS price is equal to or better than the price manufacturers charge to their "most favoured" non-federal customers under comparable terms and conditions. The FSS price may not be the lowest price in the market as terms and conditions may vary by drug product.
- the Big Four
  The prices of drugs sold to the DVA, the Department of Defence, the Public Health/ Indian Health Service and the Coast Guard are negotiated and generally represent a lower price than the FSS price. In accordance with the Veterans Health Care Act, these prices may not exceed a ceiling price of 76% of the non-federal average manufacturers prices (non-FAMP), but in fact are often lower.
- the National Contract (NC)
  National contracts typically provide the lowest prices on the formulary. Manufacturers bid for national contracts on a competitive basis in order to provide the U.S. DVA with a specific drug. Prices for that drug can be offered by manufacturers at lower prices as

Since 1998, the PMPRB has required patentees to file all price information on the U.S. Department of Veterans Affairs (DVA) formulary as part of their filing of prices in the U.S. **Effective immediately, patentees will be required to only report the U.S. Federal Supply Schedule (FSS) price** and will no longer be required to report the three other prices negotiated by the U.S. DVA, that is the Big Four, the National Contract Price and the Blanket Purchase Agreement prices.

the contract ensures that all purchases for the therapeutic class of that particular drug will be made from the manufacturer. The applicability of such a contract is limited to those drug products whose therapeutic classes have several interchangeable drugs with sufficient sales volume.

- the Blanket Purchase Agreement (BPA) Prices for a very limited number of drugs have been negotiated under BPAs. BPAs are agreements with authorized suppliers of pharmaceutical products and offer a simple way of obtaining products where demand is repetitive.

Of the 878 patented drug products for human use which were sold in Canada in 1997 and subject to the PMPRB's jurisdiction, 685 were also sold in the U.S. Of those, 625 drug products had FSS prices, 218 also had Big Four prices, 22 had NC prices and 12 had BPA prices.

After careful examination of this issue, the Board has decided to specify the reporting requirement as those prices that are relevant and which can be used for conducting IPCs. Given that the three other prices on the U.S. DVA formulary are available for only a smaller subset of drug products and that these prices will not be used for the purpose of conducting IPCs, the Board has provided guidance regarding the reporting requirement of the U.S. DVA formulary prices such that patentees will be required only to report the U.S. FSS price and not the three other prices negotiated by the U.S. DVA.

If patentees have any questions on this matter, they should raise them with the compliance officer assigned to their company. ■

The implementation of this guidance regarding the reporting requirement does not preclude the Board from requiring such information from patentees if necessary, either pursuant to section 80 or through a Board order under section 81. Additionally, the Board would not be precluded from revising its guidance of the reporting requirement if necessary as a result of changes to the current practice regarding the use of DVA formulary prices.

Working Group on Price Review Issues - October 3 & 4, 2000 Meeting

The Working Group on Price Review Issues held its fifth meeting in Ottawa, October 3 & 4, 2000.

The Working Group was joined by two new members: Marilyn Thornton, Assistant Branch Head, Pharmaceutical Policy and Programs Branch, Alberta Health and Wellness, has replaced Kevin Wilson, Director of Professional Services, Saskatchewan Drug Plan; Marnie Mitchell, Director of Pharmacare, British Columbia Ministry of Health and Ministry Responsible for Seniors, will be replacing Bob Nakagawa, Regional Director of Pharmacy, Simon Fraser Health Region.

On the first day of the meeting, the Working Group finalized its report to the Board on the price review process for new patented medicines. This report will be referred to the Board at its December 7 meeting.

On the second day of the meeting, the Working Group began its consideration of the final issue of its mandate, that is the review and analysis of category 3 drug prices, including the use of pharmacoeconomics.

The PMPRB's Associate Director of Compliance gave an overview presentation on the Guidelines pertaining to category 3 new patented medicines as well as the Therapeutic Class Comparison (TCC) methodology.

The Working Group identified items related to the current price review Guidelines for category 3 drug products. These items will be scheduled for discussion in subsequent meetings.

The next Working Group meeting is scheduled for January 30 & 31, 2001. ■

We want to hear from you

The Board is committed to the principles of transparency, openness and public accountability. We believe that honouring these principles depends on effective communications with our stakeholders.

In our *Road Map for the Next Decade* we expressed our intention to reach stakeholders through the development and consolidation of a network of partners in the health services community. It was proposed that the Communication Partners Network function as an informal process for disseminating information. This will permit us to reach a broader range of consumers.

Feedback is essential to our building closer, more effective links with our stakeholders. It is also a first step in establishing the partners network for exchanging information. We invite your comments:

- ✔ ***Are you aware of our toll-free telephone line, website, NEWSletter, Study Series, Annual Report?***
- ✔ ***Are these tools useful to you? Is this information of assistance to your organization, to your community?***
- ✔ ***Is your organization interested in participating in our communication partners network?***
- ✔ ***What role do you see your organization playing in the network?***

Let us know! We look forward to hearing from you.

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If you have any questions on the Communication Partners Network, please contact Sylvie Dupont, through our toll-free line or directly at (613) 954-8299.

"... It is in anticipation of continued stakeholder participation that we will chart the way ahead for the PMPRB to ensure it continues to play a useful role in the Canadian health system."

Message from the Board,
Road Map for the Next Decade,
September 1998, page 1

Patented Medicine Prices Review Board - September 14 & 15, 2000 Meeting

At the September 14-15, 2000 meeting, the Members of the Board:

- approved a proposal to relieve patentees of the requirements to file certain information not used in the application of the Guidelines. Detailed information is published in this NEWSletter on page 3.
- heard oral presentations by:
  - Heather Sheehy, Policy Analyst, Health Canada on "Canadians' Access to Insurance for Prescription Medicines", (study funded by the Health Transition Fund).
  - Dr. Ingrid Sketris, Board Member and Professor of the College of Pharmacy and School of Health Services Administration, Dalhousie University, on "Using the Defined-Daily-Dose for Drug Utilization Review: The Example of Comparing Three Canadian Pharmacare Programs".
- received oral briefings on:
  - a draft report of the PMPRB/Statistics Canada Task Force on the Review of Drug Price Indices;
  - Canada/U.S. pharmaceutical price differentials as recently reported in the Canadian and American press;
  - some recent literature on international price comparisons;
  - the status of the work of the PMPRB's Working Group on Price Review Issues; and
  - the PMPRB's final report on its follow-up activities to the September 1998 Report of the Auditor General.
- received the Compliance Report. ■

The next Board meeting is scheduled for December 7 & 8, 2000.

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.

CITT issues public interest recommendation in its hearing on certain iodinated contrast media products

On August 28, 2000, the Canadian International Trade Tribunal (CITT) issued its recommendations to the Minister of Finance, following its July 2000 public hearing pursuant to section 45 of the *Special Import Measures Act*. The CITT report is available on the its web-site: **www.citt.gc.ca**.

The CITT recommends the reduction of the anti-dumping duties on 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 May 16, 2000 decision by the CITT confirmed the determination of dumping made by the Canada Customs and Revenue Agency (CCRA). A copy of that March 30, 2000 report is available on the CCRA website **www.ccra-adrc.gc.ca**.

On May 27, 2000, the NAFTA Secretariat issued a Notice of a Request for Panel Review of the CCRA's Final Determination. The NAFTA Secretariat also issued a Notice of a Request for Panel Review of the CITT's May 16, 2000 decision. Those reviews are on hold at the request of the parties pending the final decision of the Minister of Finance. ■

PMPRB Upcoming Events

November 20-22:	Speech by the Executive Director of the PMPRB to the Canadian Pharmaceutical Industry Conference (CPIC) 2000
November 27-28:	Meeting of the Human Drug Advisory Panel (HDAP)
December 7-8:	Board meeting
January 30-31, 2001:	Meeting of the Working Group on Price Review Issues

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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.

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