Patented Medicine Prices Review Board

NEWSletter

Volume 4, Issue No. 3 July 2000

Since our last issue, April 2000 ...

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

May 25 & 26:	The Board held its second quarterly meeting for 2000. A summary of the minutes of the Board meeting is available on page 5.
June 14:	The PMPRB's 1999 Annual Report was released. A brief summary of the Report is available on page 4.
June 28 & 29:	The Hearing Panel in the Nicoderm case completed its hearing on the jurisdiction motion filed by Hoechst Marion Roussel Canada Inc. A summary of the Panel's decision is available on page 2.
June 30:	Following Notice and Comment, the Board accepted a Voluntary Compliance Undertaking submitted by Bristol-Myers Squibb Pharmaceutical Group and Sanofi-Synthélabo Canada Inc., with respect to the patented medicine Plavix.
July 13-15:	Dr. Robert G. Elgie, Chairperson of the Board, attended the 6th Four Country Conference in The Netherlands. The purpose of this conference is to enhance the quality of debate on health care policy by creating an atmosphere for well-informed and critical discussion between health care managers, policy makers, policy analysts and others. The 6th Conference focussed on pharmaceutical policies. In addition to Canada and The Netherlands, also participating were Australia, Germany, the United Kingdom, and the United States.

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. Ingrid Sketris receives a Research Chair - *Developing and Applying Drug Use Management Strategies and Policies for Nova Scotia's Provincial Drug Programs*

In June, Dr. Ingrid Sketris of the College of Pharmacy, Dalhousie University, and member of the PMPRB, was awarded a prestigious Research Chair in health services and nursing research from the Canadian Health Services Research Foundation (CHSRF). This Chair will receive $1.1 million over three years. It is jointly funded by the CHSRF, the Canadian Institutes of Health Research (CIHR), the Nova Scotia Health Research Foundation, and Dalhousie University.

Through their research, Dr. Sketris and her team will endeavour to narrow the gap between current drug use and best practice, balance the risk, benefits and costs of new drug therapies, improve outcomes and use resources efficiently. Their studies will provide important information to federal, provincial and regional governments and health agencies on improving drug use and drug policy.

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.

Inside...

Canada

In addition, Dr. Sketris will develop a graduate elective course in applied health services research and will create a graduate student placement program to allow students and their supervisors to work together with decision-makers.

For more information on the Chair Awards, access the CHSRF web site at www.chsrf.ca.

Dr. Anthony Boardman - Van Dusen Professor of Business Administration

Dr. Anthony Boardman, of the Faculty of Commerce and Business Administration at the University of British Columbia, and member of the Board, was appointed to the Van Dusen Professorship of Business Administration. This appointment is in recognition of Dr. Boardman's academic accomplishments over the past few years. This award allows the recipient to devote more time to research. ■

Nicoderm Hearing - The Hearing Panel issues its decision on jurisdictional issues - Part II

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

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

As reported in previous issues of the NEWSletter, the Board issued a Notice of Hearing on April 20, 1999, concerning allegations by Board Staff that Hoechst Marion Roussel Canada ("HMRC") had sold the medicine Nicoderm in Canada at excessive prices.

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

On May 25, 1999, HMRC brought a motion for an order that the Board rescind the Notice of Hearing on the grounds that the Board is without jurisdiction to inquire into the matters raised in the Notice of Hearing. The motion listed a number of grounds for the relief sought and, on the agreement of all parties, the Board's consideration of the motion was divided into two distinct parts based on the grounds for the relief sought.

The first part of the motion dealt with allegations of bias and whether or not the Notice of Hearing was sufficiently detailed for its purpose. The Board issued its decision on that part of the motion on August 3, 1999, concluding that the matters that were complained of in that part of the motion did not deprive the Board of jurisdiction. The second part of the motion concerned HMRC's allegations that the Board has no statutory jurisdiction to regulate the price of Nicoderm. In particular, HMRC argues that Nicoderm is not a "medicine" within the meaning of the *Patent Act* or, if it is a medicine, then (1) only one of the patents recited in the Notice of Hearing pertains to Nicoderm; and (2) the patent applications referred to therein are not relevant to the Board's jurisdiction.

The matter of which patents pertain to Nicoderm and the relevance of the patent applications are significant because patents were granted, and applications were made and laid open, on different dates and thus there is an issue as to the date from which the pricing of Nicoderm has been subject to the Board's jurisdiction. The determination of that issue will define the period during which the Board will examine the allegations of Board Staff concerning excessive pricing by HMRC.

The Board's jurisdiction under the *Act* to prevent excessive pricing is limited to patented medicines. In other words, for the Board to have jurisdiction over the pricing of a product, the product in question must be a "medicine" within the meaning of the *Act* and it must be sold in a market in Canada by a person who is a patentee of a patent that pertains to the product within the meaning of the *Act*.

HMRC alleges in its motion that Nicoderm is not a medicine, but a delivery device for the administration of nicotine. HMRC states that of the three patents identified in the Notice of Hearing and alleged by Board Staff to pertain to Nicoderm – the 1,338,700; 1,333,689 and 1,331,340 patents – (the '700 patent, the '689 patent and the '340 patent) only the '700 patent pertains to Nicoderm, and it is only the '700 patent of which HMRC could be said to be a "patentee" within the meaning of the *Act*. Finally, HMRC argues that the two patent applications

identified in the Notice of Hearing – the 2,032,446 and 2,040,352 applications – (the '446 and '352 applications) have no bearing on the Board's jurisdiction.

The Board has reached the following conclusions with respect to the matters in issue in this proceeding:

- Nicoderm is a "medicine" within the meaning of the *Act*;
- The '700, '689 and '340 patents pertain to Nicoderm;
- HMRC is a "patentee" of the '700 and '689 patents;
- HMRC is not a "patentee" of the '340 patent. The Chairman of the panel has delivered a dissenting opinion on this conclusion;
- HMRC has been a "patentee" of the patents for which application has been made in the '352 and '446 patent applications from the date on which those applications were laid open to public inspection;
- the pricing of Nicoderm has been subject to the jurisdiction of the Board since the introduction of Nicoderm to the Canadian market in 1992.

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

Plavix - the Board approves a Voluntary Compliance Undertaking

In its April 2000 NEWSletter, the Board gave notice to Ministers of Health in the provinces and territories and other interested persons of a Voluntary Compliance Undertaking (VCU) made by Bristol-Myers Squibb Pharmaceutical Group (BMS) and Sanofi-Synthélabo Canada Inc. (Sanofi) regarding the patented medicine Plavix. The Board indicated that it would consider submissions in this matter in determining whether to accept the VCU.

Submissions were required to be filed with the Secretary of the Board on or before June 9, 2000. Board Staff, BMS and Sanofi were given the opportunity to submit written responses to any submissions made within 15 days thereafter.

One submission was received, from the Province of Saskatchewan, suggesting that the Board consider any future changes to the product monograph resulting from a review by Health Canada. To date, there have not been any changes to the product monograph, but the Board agrees it should continue to monitor any action by Health Canada in this regard.

Having considered the submission of the Province of Saskatchewan as well as all the other evidence before it, the Board has decided to accept the VCU submitted by BMS and Sanofi with respect to the patented medicine Plavix.

In compliance with the terms of the VCU, the Board received a payment in the amount of $583,065 to offset excess revenues received from the sale of Plavix at prices higher than the maximum non-excessive price (MNE) from October 1998 to February 29, 2000; and copies of credit notes issued to pharmacies, wholesalers, hospitals and other customers for the difference between actual prices paid and the MNE of $2.4015 for the year 2000, to offset excess revenues received from the sale of Plavix from March 1, 2000 to April 9, 2000.

The Board will continue to monitor changes to the product monograph and review this matter again if the circumstances warrant. The Board notes that it would not be precluded from reviewing the price of Plavix and taking proceedings under the *Patent Act* in the future if the circumstances so warrant. ■

The Board's VCUs are posted on our web site: **www.pmprb-cepmb.gc.ca**, under Publications, VCUs.

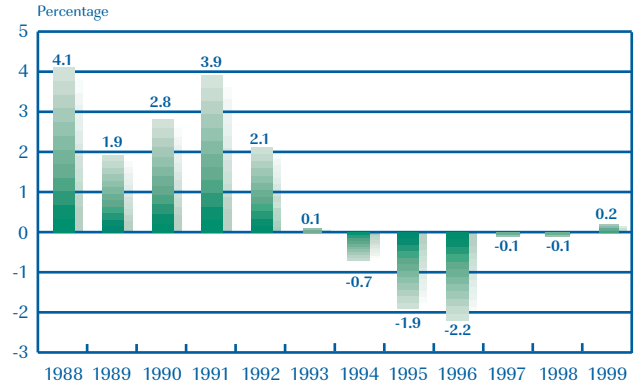
1999 PMPRB Annual Report

The 1999 Annual Report is available on our web site under Publications, Annual Report.

"Increases in drug prices have continued to be lower than overall changes in the Consumer Price Index (CPI). Nevertheless, drugs continue to represent the fastest growing component of health care expenditures", stated Dr. Robert G. Elgie, Chairperson of the Board, upon release of the PMPRB 1999 Annual Report, on June 14, 2000.

Dr. Elgie explained that in fulfilling its consumer protection role, the PMPRB limits the maximum prices charged by manufacturers for patented drugs to ensure that they are not excessive. In 1999, manufacturers' prices of patented drugs in Canada increased slightly by an average of 0.2%, as compared to the CPI which increased by 1.7%. Prices of patented drugs in Canada are still in line with prices in European countries.

Year-over-Year Changes in the PMPI, 1988-1999



Source: PMPRB
Beginning in the year 1999, the PMPI reflects changes in the prices of patented drugs for human use only.

Since 1987, Canadian prices for patented drugs have declined over 30% compared to foreign prices.

Total sales by manufacturers of all drugs in Canada are estimated to have increased by 16.8% to $9.1 billion in 1999, while sales of patented drug products increased by 27% to $5.4 billion. Patented drugs accounted for 61% of the total sales of all drugs. There were 111 new patented drug products for human use introduced in 1999. Of these, the prices of 84 were within the Guidelines, 22 are still under review, and five are the subject of further investigation as they appear to be outside the Guidelines.

R&D expenditures as filed by 78 reporting patentees totalled $894.6 million, an increase of $96 million from 1998. Nonetheless, the R&D-to-sales ratio declined to 10.8% from 11.5% in 1998, the lowest ratio since 1993. Patentees reported expenditures of $155.9 million on basic research. Although spending on basic research increased by 6.2% from 1998, its share of total R&D continued to decline from 19.6% in 1998 to 18.4% in 1999. This is the lowest proportion of total R&D spending on basic research ever reported by patentees since the PMPRB began collecting the information in 1988.

In reporting on the Board's activities, Dr. Elgie also noted a number of its achievements in 1999 towards a more open, transparent and accountable approach to fulfilling its mandate. ■

New Human Drug Products Identified as Category 2 Medicines in 1999

The PMPRB categorizes new patented drug products for price review purposes. An independent panel of experts, the Human Drug Advisory Panel (HDAP), reviews submissions by patentees and the available scientific evidence in order to make recommendations as to whether a drug product meets the criteria to be classified as breakthrough or substantial improvement (category 2 new medicine). The categorization of a drug does not represent an endorsement by the PMPRB. Manufacturers may decide not to make a submission to support a category 2 recommendation if the categorization does not affect the price review.

In 1999, the HDAP recommended that one new patented drug product, Rebetron (combination of ribavirin capsules and interferon alpha-2b injection, manufactured by Schering Canada Inc.), should be classified as a category 2 new medicine. Rebetron is approved for the treatment of chronic hepatitis C (HCV).

The combination of ribavirin and interferon alpha-2b has been demonstrated to be a substantial improvement over interferon-2b monotherapy in the treatment of HCV. Depending upon the study, the efficacy of Rebetron was two to ten times greater than that observed with interferon alone, and relapse was at least twice more frequent with interferon alone than with the combination. Although the impact on the need for liver transplants has yet to be determined, a

number of published randomized controlled clinical trials (RCTs) have consistently demonstrated the rate of sustained virologic response (defined as an undetectable serum HCV RNA level 24 weeks after treatment was completed) and biochemical response (measured by serum alanine aminotransferase levels) was higher among patients who received combined ribavirin/interferon alfa-2b therapy. Rates of histologic response (hepatic inflammation) were similar to virologic and biochemical responses.

Neither ribavirin nor interferon alpha-2b are new active substances. Interferon alpha-2b injection has been used in the treatment of HCV for several years. Ribavirin in a dosage form for inhalation (Virazole, manufactured by ICN) was approved in the mid-80's for the treatment of respiratory tract infections in children due to respiratory syncitial virus (RSV); Virazole was the subject of an order by the Board in 1996. Ribavirin capsules have not previously been marketed in Canada. ■

Patented Medicine Prices Review Board - May 25 & 26, 2000 Meeting

At the May 25 & 26, 2000 meeting, the Members of the Board:

- approved the 1999 Annual Report; and
- received oral briefings on the:
  - First Nations and Inuit Health Program, by Paul Cochrane, Assistant Deputy Minister of the Medical Services Branch, Health Canada;
  - PMPRB comparative analysis of the PMPRB average transaction prices and the Ontario Drug Benefit Plan prices;
  - Canada/U.S. pharmaceutical price differentials as recently reported in the Canadian and American press;
  - Reports on the Cost Drivers, prepared by the PMPRB in the context of its activities in the Federal/Provincial/Territorial Working Group on Drug Prices and submitted to the Minister of Health as per the Memorandum of Understanding;
  - Canadian International Trade Tribunal inquiry into certain iodinated contrast media;
  - PMPRB's follow-up activities to the September 1998 Report of the Auditor General;
  - Current workload pressures;
  - May 1 and 2, 2000 Conference of the Canadian Association for Population Therapeutics. ■

The next Board meeting is scheduled for September 14 & 15, 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.

Canadian International Trade Tribunal holds a public interest hearing into certain iodinated contrast media

On May 16, 2000, the Canadian International Trade Tribunal (CITT) issued its reasons for its May 1, 2000 decision under 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). A copy of the CITT decision and reasons is available on the CITT web site (www.citt.gc.ca).

On June 15, 2000, the CITT issued a Notice of Commencement of a public hearing pursuant to section 45 of the *Special Import Measures Act* into whether it should make recommendations to the Minister of Finance about the public interest. The hearing was held from July 19 to 21, 2000. That Notice and the schedule for that second hearing are available on the CITT web site. A decision is expected by August 18, 2000.

The May 16, 2000 decision by the CITT confirmed an earlier 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 web site (www.ccra-adrc.gc.ca) or in Part I of the Canada Gazette.

On May 27, 2000, the NAFTA Secretariat issued a Notice of a Request for Panel Review of the CCRA's Final Determination. An official copy of that notice is published in Part I of the Canada Gazette. In addition, the NAFTA Secretariat received applications for a Panel Review of the CITT's May 16, 2000 decision and issued a Notice of Request. An official copy of that notice is also published in Part I of the Canada Gazette.

The PMPRB staff is monitoring the evolution of these cases. ■

PMPRB Upcoming Events

September 14 & 15:	Board meeting
October 3 & 4:	Meeting of the Working Group on Price Review Issues
October 27:	Release of the October 2000 NEWSletter
November 20-22:	Canadian Pharmaceutical Industry Conference (CPIC) 2000

PMPRB List of Publications

Here are the latest additions to our Publications List:

- 1999 PMPRB Annual Report
- HMRC / Nicoderm Hearing: Hearing Panel's Decision on Jurisdictional Issues - Part II, August 8, 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.

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