



# Patented Medicine Prices Review Board

## 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...

Since our last issue ...	2
Congratulations to our staff .....	2
Working Group on Price Review Issues ...	2
Notice of Hearing: Nicoderm .....	3
Advanced Ruling Certificate: Viagra ...	4
Board Meeting .....	4
Publications .....	5
Comments .....	6

# NEWSletter

Volume 3, Issue No. 2

April 1999

## In Memory of **Harry Claude MacColl Eastman,** Ph.D., F.R.S.C.,

**FORMER CHAIRPERSON AND MEMBER OF THE PATENTED MEDICINE PRICES REVIEW BOARD**

**It was with profound sadness that we learned of Professor Harry Eastman's sudden passing on April 20, 1999.**

Professor Eastman served as member of the Patented Medicine Prices Review Board from December 8, 1987 to 1997 and as its Chairman until March 1995.

A native of Vancouver, Professor Eastman obtained a B.A. in 1947 from the University of Toronto and a Ph.D. in 1952 from the University of Chicago. As Professor of Economics at the University of Toronto, he had held various positions: Vice-President (Research and Planning) and Registrar from 1979 to 1981; Vice-President (Research and Planning) from 1977 to 1979; Chairman, Department of Political Economy from 1974 to 1977, and Associate Dean, School of Graduate Studies from 1964 to 1969. He was President of the Canadian Economics Association from 1971 to 1972.

Professor Eastman chaired the Federal Commission of Inquiry on the Pharmaceutical Industry. Created in 1984, the Commission was charged with the analysis of the functioning of generic and patent-holding firms in the pharmaceutical industry in Canada, the identification of prospects for growth of the Canadian pharmaceutical industry, and the review of programs used in other countries. The Commission's report in 1985 made its recommendations to the Government for the development of a framework of policy for the pharmaceutical industry in Canada, including policies and programs under the control of both provin-

cial and federal governments. With the subsequent creation of the Patented Medicine Prices Review Board in 1987, he was appointed as its first Chairman.

Professor Eastman's contribution to the Board was immense. He oversaw its creation and the establishment of its policies. Since his retirement from the Board in December 1997, Professor Eastman remained a valued advisor.

We at the Board are joined by former members of the Board and Staff in offering our most heartfelt condolences to Professor Eastman's family and friends. He will indeed be greatly missed.

**Robert G. Elgie**  
Chairperson ■

## The PMPRB welcomes Dr. Anthony Boardman

Dr. Boardman was appointed member of the Board on January 21, 1999. He is Professor of Strategic Management and Public Policy Analysis, Faculty of Commerce and Business Administration at the University of British Columbia. Since 1995, Dr. Boardman has been a member of the Pharmacoeconomics Initiative Scientific Committee which makes recommendations to B.C. Pharmacare on the cost-effectiveness of new drugs. Dr. Boardman is a graduate of the University of Kent at Canterbury, England, (B.A. (hons.), 1970) and Carnegie-Mellon University: H. John Heinz III School of Public Policy and Management (Ph.D., 1975).

During his career, Dr. Boardman has been a member of the editorial board of the *Economics of Education Review*, and has been referee for several academic journals. He has an impressive research record and numerous publications to his credit. Amongst his current research interests, he lists cost-benefit analysis, efficiency and productivity of the public sector, the effects of ownership on corporate performance, to name only a few.

Dr. Boardman's biographical notes are available on our web site at <http://www.pmprb-cepmb.gc.ca>, **About the PMPRB - Membership** or alternatively if needed, a copy can be obtained by contacting us at our toll-free number: 1-877-861-2350.

## Congratulations to our Staff

► Cynthia Sunstrum, Associate Director of Compliance and Enforcement was recently elected member at large of the Board of Directors of the Canadian Association for Population Therapeutics. CAPT's mission is to advance the sound development of population-based studies of therapeutic interventions and to provide a forum for the reporting, scientific discussion, and dissemination of the data derived from such studies, as an information resource for medical decision-making in the best interests of the individual patient and the public well-being.

► Robert Sauvé, Director of Corporate Services, celebrated 25 years with the federal Public Service on April 1, 1999. Robert joined the PMPRB in June 1997.

## Since our last issue, January 1999 ...

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

January 21	Appointment of Dr. Anthony Boardman to the Patented Medicine Prices Review Board
February 25-26	Board Meeting
March 29	Issuance of an Advanced Ruling Certificate to Pfizer Canada Inc. regarding the price of Viagra
March 29-30	First meeting of the Working Group on Price Review Issues
March 31	Release of the PMPRB corporate brochure, <i>Controlling the Prices of Patented Medicines in Canada</i>
April 16	Address by the Chairperson to the Drug Information Association Washington Conference, <i>Canada's Patented Medicine Prices Review Board: New Approaches</i> . The text is available on our web site, under <b>Publications</b> .
April 20	Issuance of a Notice of Hearing in the matter of Hoechst Marion Roussel Canada Inc. and the medicine Nicoderm. Pre-hearing conference: May 28; Hearing: commencing July 5.

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

## The Working Group on Price Review Issues holds its first meeting on March 29 & 30, 1999

**I**n its January 1999 NEWSletter, the Board reported on the Terms of Reference for the Working Group and invited nominations from stakeholders for potential members for consideration by the Board. The Members of the Working Group on Price Review Issues are:

Group	Member	Organization
Provincial/Territorial Ministers of Health	Linda Tennant	Director, Drug Programs Branch Ontario Ministry of Health
	Bob Nakagawa	Director, Pharmacare, Ministry of Health Province of British Columbia
	Kevin Wilson	Director of Professional Services Saskatchewan Drug Plan
	John Downton	Director, Drug Programs and Services Government of Newfoundland & Labrador
Consumer/Advocacy/ Health Associations/ Others	Sally Hall	Consumer Consultant
	Jean-François Bussières	Chief of Pharmacy Association des pharmaciens d'établissements de santé du Québec
	Roger Heath	Economist Federal Superannuates National Federation
	Vernon Chiles	Vice Chair of the Board Green Shield Canada
	Joel Lexchin	Physician, Toronto Hospital
PMAC	Rob Livingston	Director, Merck Frosst Canada Inc.
	Peter Kaldas	Manager, Corporate Pricing Glaxo Wellcome Inc.
BIOTECanada	Joyce Groote	President, BIOTECanada
PMPRB Co-Chairs	Ron Corvari	Director of Policy and Economic Analysis
	Laura Reinhard	Director of Compliance and Enforcement

The Working Group held its first meeting in Ottawa on March 29 and 30. Here is a summary of the Minutes of the Working Group.

## Summary of Minutes

1. The objective and scope of the Working Group were reviewed for the first issue. The objective for the first issue is to review, analyze and report on the appropriate use of the U.S. Department of Veteran Affairs (DVA) prices in conducting an international price comparison (IPC).
2. Brief presentations were provided on the *Road Map for the Next Decade*, the Report of the Auditor General, the PMPRB's Guidelines and the IPC methodology.
3. A presentation was provided on the market for pharmaceuticals in the U.S., the role of the U.S. Department of Veteran Affairs and sources of drug price information in the U.S.
4. Definitions of phrases were developed in relation to the objective.
  - ▶ The *best available price information in the U.S.* includes information that is publicly available, reliable and most closely represents manufacturers' average prices in the U.S.
  - ▶ *Publicly available prices* are prices which are published or may be obtained on request.
5. Criteria were developed to evaluate options. The criteria included:
  - ▶ prices to be used should be publicly available
  - ▶ prices to be used should collectively represent prices in the U.S. market
  - ▶ in keeping with the Board's objective, the U.S. DVA price information should be used in conducting an IPC
  - ▶ any option considered should be relatively easy to apply
6. Pharmaceutical industry representatives requested the addition of transition measures as an item for discussion at the next meeting in the event that there is any negative impact as a result of proposals on the use of U.S. DVA prices in the IPC. The Working Group agreed to discuss this at the next meeting.

The next Working Group meeting is scheduled for June 23-24, 1999 in Ottawa. ■

## The Chairperson Issues a Notice of Hearing in the matter of Hoechst Marion Roussel Canada Inc. and the medicine Nicoderm

**On April 20, 1999, the Chairperson of the Board issued a Notice of Hearing in the matter of Hoechst Marion Roussel Canada Inc. and the price of the nicotine patch Nicoderm. The Board will hold a public hearing commencing July 5, 1999.**

The purpose of the hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, Hoechst Marion Roussel:

- ▶ is selling or has, while a patentee, sold the medicine known as Nicoderm in any market in Canada at a price that, in the Board's opinion, is or was excessive; and,
- ▶ if so, what order, if any, should be made.

Nicoderm is a transdermal nicotine patch. It delivers nicotine, the active component of tobacco smoke, through the skin via a patch into the circulation system continuously over 24 hours. It is indicated as an aid for smoking cessation for the partial relief of nicotine withdrawal symptoms. ■

Persons who wish to intervene in the proceeding are required to apply with the Board for leave to intervene on or before May 12, 1999 and contact the Secretary of the Board for further information on the procedure. A pre-hearing conference will be held May 28, 1999, in the Board's offices, Standard Life Centre, 333 Laurier Avenue West, 18<sup>th</sup> floor, Hearing Room 2.

For any additional information on the activities of the Working Group on Price Review Issues, please contact the co-chairs of the Working Group, at our toll free line 1-877-861-2350 or at their respective number:

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**.

### For information

on the Nicoderm Hearing, please contact Sylvie Dupont-Kirby, Secretary of the Board, at:

Toll-free number:  
1-877-861-2350

Direct line:  
(613) 954-8299

Fax: (613) 952-7626

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

## The Board issues its second Advanced Ruling Certificate

On March 29, 1999, and on the application of Pfizer Canada Inc., the Board issued an Advanced Ruling Certificate regarding the price of Viagra. With the issuance of the ARC, the Board certifies that Pfizer's proposed price complies with the *Patent Act* in that it does not exceed the prices of other drugs currently on the market to treat erectile dysfunction. In addition, the proposed price is among the lowest of the prices for Viagra in the seven countries listed in the *Patented Medicines Regulations* used for price comparison purposes: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States.

Under section 98(4) of the *Patent Act*, the Board is authorized to issue an Advanced Ruling Certificate respecting the price at which a patentee is selling or proposing to sell a patented medicine. An ARC is issued only in circumstances where it can be established clearly that the price

or proposed price of the medicine would not exceed the Board's Guidelines.

The Board will continue to monitor Pfizer's price of Viagra to ensure that it does not exceed the proposed price and does not increase by more than changes in the Consumer Price Index. The certificate is not binding on the Board, which reserves the right to take action in the event of a change in the circumstances.

It should be noted that the Board's review of the price of Viagra does not imply endorsement of the product. As well, decisions on the coverage of Viagra for purposes of public and private drug plans are the responsibility of those plans. Consumers are advised to discuss their own needs with their physicians and pharmacists.

For more information on Advanced Ruling Certificates, please consult the Board's *Bulletin* No. 12 (September 1993). ■

## Patented Medicine Prices Review Board — February 25 & 26 Meeting

### **A**t its meeting on February 25-26, 1999, the Members of the PMPRB:

- ▶ Approved a proposal to implement, on a three year trial basis, a complaints-driven process as an alternative means for the price regulation of patented veterinary drugs. The proposal had been published with the *Road Map for the Next Decade* in September 1998.

*[Veterinary patentees were informed of the implementation of the new policy on March 19, 1999. The "Special Provisions for Veterinary Patentees" is also available on the web site — **Frequently Requested Items — Compendium of Guidelines, Policies and Procedures**, Chapter 2: Excessive Price Guidelines, page EPG:7]*

- ▶ Approved a proposal to proceed with the promulgation of the proposed Rules of Practice and Procedures.
- ▶ Received an update on the establishment of the Working Group on Price Review Issues.
- ▶ Received the Compliance Report for the period ending January 31, 1999.

- ▶ Were briefed on the report on the patented medicine Imitrex which was forwarded to the Standing Committee of the House of Commons on Health on February 11, 1999, in response to a request from the Committee.
- ▶ Were briefed on the Outline and Work Plan for the 1998 Annual Report.
- ▶ Received an oral update on the work by Board staff in the context of the activities of the Federal/Provincial/Territorial Task Force on Pharmaceutical Pricing.
- ▶ Received an oral briefing on the Framework to Improve the Social Union for Canadians.
- ▶ Were briefed by Vernon Chiles, Vice Chairman of Green Shields Canada Inc., on a study recently released by Green Shield: *Analysis of Drug Claim Costs 1993-1997*

The next Board meeting is scheduled for May 27, 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](mailto:sdupont@pmprb-cepmb.gc.ca) ■

---

## **PMPRB List of Publications**

---

**April 1999**

### **Legislation, Regulations, Guidelines...**

- ▶ *Patent Act*
- ▶ *Patented Medicines Regulations*
- ▶ Compendium of Guidelines, Policies and Procedures
- ▶ Patentees' Guide to Reporting (1995)
- ▶ (Proposed) Rules of Practice and Procedure (April 1999)

### **Review and Renewal**

- ▶ *Examining the Role, Function and Methods of the PMPRB*, November 1997
- ▶ *Road Map for the Next Decade*, September 1998
  - ▶ Consultation Policy
  - ▶ PMPRB Research Agenda
  - ▶ Trends in Patented Drug Prices
  - ▶ Verification of Foreign Patented Drug Prices
  - ▶ U.S. Prices: Department of Veterans Affairs Formulary
  - ▶ Price Review Process: Preliminary Outline of Issues
  - ▶ Category 3 Drug Prices: Preliminary Outline of Issues
  - ▶ Notice and Comment: Regulating Patented Veterinary Medicine Prices
- ▶ Stakeholders' Meeting, November 20, 1998 — "As It Was Said" report

### **Working Group on Price Review Issues**

#### **Board Meetings — Summary of Minutes (from December 1998 on)**

#### **Annual Report Series (1989 to 1998)**

#### **NEWSletter Series (1997 on)**

#### **Corporate Brochure - *Controlling the Prices of Patented Medicines in Canada***

#### **Bulletin Series (1988 to 1996)**

#### **New Patented Medicines Introduced in 1998**

#### **Article Series**

- ▶ Dr. H. C. Eastman Article "Pharmaceutical Price Review in Canada", 1992
- ▶ Dr. R. G. Elgie Article "Regulating Prices of Patented Pharmaceuticals in Canada: The Patented Medicine Prices Review Board", 1996
- ▶ Scientific Branch and Human Drug Advisory Panel (HDAP) Article "The Difficulty in Assessing the Relative Therapeutic Merit of New Antineoplastic Drugs", 1996

### **Voluntary Compliance Undertakings (VCUs), Advanced Ruling Certificates (ARCs), Hearings and Decisions of the Board —1999**

- ▶ ARC: Viagra (March)
- ▶ Notice of Hearing: In the matter of Hoechst Marion Roussel Canada Inc. and the nicotine patch Nicoderm (April)

### **Speech Series (1998)**

- ▶ Remarks to the Standing Committee on Health, April 28
- ▶ One Voice - Canadian Seniors Network and Ontario Coalition of Senior Citizens Organizations - Special Invitational Joint Issues Committee Meeting, June 5
- ▶ PHARMAC 1998, October 6
- ▶ Canadian Institute of Law and Medicine on The Law, Ethics and Accountability of Scientific Investigation in Health Care, November 18
- ▶ Canadian Pharmaceutical Industry Conference, November 24
- ▶ Remarks to the Standing Committee on Health [on the Report of the Auditor General on the PMPRB], December 8

## PMPRB List of Publications, April 1999 (con't)

### Speech Series (1999)

- ▶ Drug Information Association (DIA) Washington Conference, *Canada's Patented Medicine Prices Review Board: New Approaches*, April 16, Washington, D.C.

### Study Series and Discussion Papers

- ▶ S-9301: International Price Comparison
- ▶ S-9302: International Price Comparison of the Top 200 Selling Patented Products Sold in Canada
- ▶ S-9303: Further Analyses on Introductory Medicines and Top-Selling Medicines
- ▶ S-9404: The Top 200 Selling Patented Drug Products in Canada (1993)
- ▶ S-9405: Interprovincial Price Comparisons in Canada (1988-1993)
- ▶ S-9506: Estimated Savings from Compliance and Enforcement Activities
- ▶ S-9607: The Top 200 Selling Patented Drug Products in Canada (1994)
- ▶ S-9708: The Impact of Federal Regulation of Patented Drug Prices
- ▶ S-9709: A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries
- ▶ S-9710: A Description of the Laspeyres Methodology Used to Construct the Patented Medicine Price Index (PMPI)
- ▶ S-9811: Trends in Patented Drug Prices
- ▶ S-9812: Verification of Foreign Patented Drug Prices
- ▶ S-9813: Purchasing Power Parities and International Comparisons of Patented Medicine Prices
- ▶ D-9401: Measurement of Cost Savings to the Canadian Health Care System

**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:**

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