Patented Medicine Prices Review Board

NEWSletter

Volume 3, Issue No. 1 January 1999

Many thanks and best wishes to Dr. Judith Glennie

It was with regret that Dr. Elgie announced the resignation of Dr. Judith Glennie as a member of the Patented Medicine Prices Review Board, effective December 31, 1998. Dr. Glennie made a significant contribution to the work of the Board since her appointment as Board Member in March 1995.

Dr. Glennie leaves the Board in order to take on new challenges as Manager of the Socio-Economic Evaluation Division of the Therapeutics Products Programme at Health Canada. We join with her many friends in wishing her success in her new endeavours.

Inside…

Perspectives on 1998

1998 proved to be one of the most challenging and exciting years in the life of the Board with the conclusion of a year-long consultation on its role and future direction.

The Board sought to engage a broader range of stakeholders and the results of the consultations, reflected by the comments and ideas of stakeholders, suggest that, to a large degree, we were able to meet that objective. *The Road Map for the Next Decade*, released in September, reflects our commitment to operate in an increasingly transparent, responsive and accessible fashion and sets out an ambitious agenda for action.

Since then, we have received constructive feedback on the *Road Map* at a Stakeholders' Meeting on November 20 and we have invited nominations for a Working Group on Price Review Issues as described further in this publication. The main objectives of the Working Group are to review, analyse and provide reports for the Board's consideration on:

- the use of the U.S. Department of Veterans Affairs (DVA) formulary prices in the international price comparison;
- the price review process for new patented drug products; and,
- category 3 drug prices.

In this edition of the NEWSletter, readers will find the terms of reference for the Working Group. In future editions of the NEWSletter and through our web site, we will keep you abreast of the Working Group's activities as well as our continuing efforts to implement the *Road Map for the Next Decade*.

Robert G. Elgie
Chairperson ■

Since our last issue, October 1998…

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

Oct. 6	PHARMAC 98, Toronto *Future Directions for the Patented Medicine Prices Review Board*, by Dr. Robert G. Elgie
Nov. 18	Fall Conference of the Canadian Institute of Law and Medicine on The Law, Ethics and Accountability of Scientific Investigation in Health Care, Toronto *Ensuring the Appropriate Use of Health Technologies — Regulatory Models*, by Dr. Robert G. Elgie
Nov. 20:	PMPRB Stakeholders' Meeting, Ottawa, "As It Was Said" report
Nov. 24:	Canadian Pharmaceutical Industry Conference, Montréal *Road Map for the Next Decade*, by Dr. Robert G. Elgie
Dec. 8:	Presentation before the Standing Committee on Health, Ottawa, on the Auditor General's Report on the Patented Medicine Prices Review Board, by Dr. Robert G. Elgie
Dec. 10-11:	Board Meeting, Ottawa Consistent with the Board's commitment to make its operations more transparent, we are now posting the summary of the Minutes of our Board meetings on our web site at **http://www.pmprb-cepmb.gc.ca, What's New** section.
Jan. 3, 1999:	Publication of the list of New Patented Medicines Introduced in 1998

Please contact us at our toll-free number: **1-877-861-2350** to obtain copies of any materials.

The Road Map for the Next Decade is available on our web site: http://www.pmprb-cepmb.gc.ca, What's New section, or by contacting us at our toll-free number: 1-877-861-2350.

The Board hosts a Stakeholders' Meeting

The Board held a day-long meeting with representatives of its stakeholder groups in Ottawa on November 20, 1998. The purpose of the meeting was to receive feedback on the *Road Map for the Next Decade*, the recent report of the Auditor General of Canada, and the Board's Research Agenda. Here is the list of participants.

Patented Medicine Prices Review Board Stakeholders' Meeting November 20, 1998

LIST OF PARTICIPANTS

PMPRB Board Members	• Robert G. Elgie, Chairperson • Réal Sureau, Vice Chairperson • Judith L. Glennie • Ysolde Gendreau
Provinces *In consultation with Conference of Ministers of Health and the Federal/Provincial/Territorial Pharmaceutical Issues Committee*	• Bob Nakagawa, Director, Pharmacare, B.C. Ministry of Health • Kevin Wilson, Director, Pharmacare, Saskatchewan Ministry of Health • Patrick Crawford, Pharmacy Consultant, P.E.I. Health and Community Services Agency • *Ontario — unable to attend* • *Québec — unable to attend*
Consumer Groups	• Jean Jones, Chair, National Health Council, Consumers' Association of Canada • *Fédération nationale des associations de consommateurs du Québec — unable to attend* • Vernon K. Chiles, Vice Chair, Green Shield Canada • Michael McBane, Executive Director, Canadian Health Coalition, representing Dr. Joel Lexchin • Rolf Calhoun, Government Liaison, Canadian Association of Retired Persons • Mary Eady, Congress of Union Retirees of Canada
Patient Advocacy Groups	• Peter E. Harvey, Chair, National Advocacy Council, Canadian Diabetes Association • *Dr. Gregory Robinson, AIDS ACTION NOW! — unable to attend*
Pharmaceutical Industry	• Philippe Hébert, Vice-President Marketing, Merck Frosst Canada Inc., representing the Pharmaceutical Manufacturers' Association of Canada • David Martin, President, Pharmacia & Upjohn • Joyce Groote, President, BIOTECanada • Peter Cummins, Chair, Task Force on the PMPRB, Nonprescription Drug Manufacturers' Association of Canada • Jim Keon, President, Canadian Drug Manufacturers' Association
Health Associations	• Katherine Tregunne, Director, Policy Development, Canadian Healthcare Association • Leroy Fevang, Executive Director, Canadian Pharmacists' Association

Following is the Executive Summary of the "As It Was Said" report prepared by the facilitators of the meeting. The report does not represent a consensus of opinions, but rather the comments expressed by individual participants as recorded on flip charts during the meeting. You can obtain a copy of the report by contacting us at our toll-free number: **1-877-861-2350** or through our web site at **http://www.pmprb-cepmb.gc.ca**, **What's New** section.

Executive Summary

Dr. Robert G. Elgie, Chairperson of the Board, welcomed participants and stated that the purpose of the meeting was to obtain feedback from the stakeholders on the *Road Map for the Next Decade*, the Report of the Auditor General on the Board and the Research Agenda.

Participants and observers were invited to introduce themselves. Participants' expectations of

the meeting were noted as were the group norms. The process used during the session was as follows: brief presentation on the document, short period of questions for clarification concluding with stakeholder feedback on the document in the form of likes, concerns and suggestions for improvement.

A presentation of the first document, the *Road Map for the Next Decade*, was made by Dr. Judith Glennie, Board member. Feedback was solicited on each section in the form of likes, concerns and suggestions for improvement for each element.

Following a brief presentation by Wayne Critchley, PMPRB Executive Director, and a period of questions for clarification, participants were then invited to give their feedback on the Report of the Auditor General on the Board. Once again, feedback was solicited in the form of likes, concerns and suggestions on how to overcome the concerns.

Dr. Elgie made the final presentation on the Research Agenda. In his presentation, he announced that the co-chairs of the PMPRB Working Group on Price Review Issues will be Laura Reinhard, Director of Compliance and Enforcement and Ron Corvari, Director of Policy and Economic Analysis. He also announced that in addition to reviewing and reporting on the first two items on the Research Agenda (the price review process and category 3 drug prices), the Working Group would also look into the appropriate use of U.S. Department of Veterans Affairs (DVA) formulary prices in conducting international price comparisons. Following his presentation, feedback was solicited in the form of likes, concerns and suggestions for improvements. Participants were also invited to suggest additions or deletions to the Research Agenda.

A list of items that could not be dealt with directly by the Board was captured in a "Parking Lot". These items will be passed on by the PMPRB to the Ministers of Health and Industry.

At the end of the day, Dr. Elgie explained the next steps following this meeting. He thanked all the participants for their participation and his staff for the good work that was put into the preparation of the day. The session concluded with the review of expectations and a brief evaluation. ■

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

Patented Medicine Prices Review Board — December 10 & 11, 1998 meeting

At their meeting of December 10 and 11, 1998, the Members of the PMPRB:

- Were informed that Dr. Judith L. Glennie has resigned her position as Board member as of December 31, 1998, to pursue a career with the Therapeutics Products Programme at Health Canada.
- Approved the Terms of Reference for the Working Group on Price Review Issues and selection criteria for the membership of the Group. Letters will be mailed at the beginning of January inviting major stakeholder organizations to nominate potential members for consideration by the Board. The Terms of Reference will also be posted on the web site and published in the January 1999 NEWSletter.
- Approved a Communications Policy.
- Approved its meeting schedule for 1999. The Board's next meeting will be held February 25 & 26, 1999.
- Discussed the November 20, 1998, Stakeholders' Meeting. The "As It Was Said" report will be mailed to the participants and posted on the web site.
- Received the Compliance Report for the period ending November 30, 1998.
- Received an update on the consultations on the proposed amendments to the regulation of veterinary drug products. Board members will receive recommendations for approval at their next meeting.
- Were briefed on work being done by Board staff in the context of the activities of the Federal/Provincial/Territorial Task Force on Pharmaceutical Prices.
- Received an oral presentation from representatives of the Health Industries Branch of Industry Canada on Industrial Development in Canada's Pharmaceutical Industry.

For any additional information, please contact the Secretary of the Board at **1-877-861-2350** or (613) 954-8299 or by e-mail at sdupont@pmprb-cepmb.gc.ca. ■

In selecting members of the Working Group, the Board will take the following into consideration:

- balanced representation of major stakeholder groups;
- expert knowledge;
- interest;
- participation in recent consultations; and,
- commitment to participate.

Launch of the Working Group on Price Review Issues

The mandate of the Working Group on Price Review Issues is to review, analyse and provide reports for the Board's consideration on:

- the use of the U.S. Department of Veterans Affairs (DVA) formulary prices in the international price comparison;
- the price review process for new patented drug products; and,
- category 3 drug prices.

The Working Group will be co-chaired by the Board's Director of Compliance and Enforcement and the Director of Policy and Economic Analysis. In addition, the Working Group will consist of up to 12 members. It is anticipated that its mandate will extend for up to two years and that it will hold four meetings a year with its first status report this summer. The reports of the Working Group will be carefully considered by the Board.

In accordance with the *Patent Act*, any changes to the Guidelines would require full consultation with stakeholders.

Summaries of the minutes of meetings and reports of the Working Group will be publicly available.

The terms of reference of the Working Group are available on our web site at: **http://www.pmprb-cepmb.gc.ca** or may be requested by e-mail at **pmprb@pmprb-cepmb.gc.ca**, or by calling our toll-free number **1-877-861-2350**. Nominations must be received no later than **February 4, 1999**. For further information, you may contact the co-chairs of the Working Group:

Laura Reinhard — (613) 952-7619 or by e-mail at lreinhard@pmprb-cepmb.gc.ca;

Ron Corvari — (613) 952-3305 or by e-mail at rcorvari@pmprb-cepmb.gc.ca. ■

PMPRB Working Group on Price Review Issues Nomination Form

Please return the nomination form to the PMPRB by February 4,1999:

Patented Medicine Prices Review Board
Box L40
Standard Life Centre
333 Laurier Avenue West, Suite 1400
K1P 1C1

Telephone: (613) 952-7360
Facsimile: (613) 952-7626
TTY: (613) 957-4373
Toll free number: 1-877-861-2350
E-Mail: pmprb@pmprb-cepmb.gc.ca

Please ensure that any individual you nominate is willing and able to make the time commitment required as a member of the Working Group. Please refer to the terms of reference for the Working Group.

Name of Nominee: _____

Organization: _____

Address: _____

Phone Number: _____ Facsimile Number: _____

E-Mail Address: _____

Please explain briefly why you feel this individual should be selected as a member of the Working Group: _____

Submitted By: _____

Organization: _____ Date: _____

PMPRB List of Publications

January 1999

Legislation, Regulations, Guidelines…

- *Patent Act*
- *Patented Medicines Regulations*
- Compendium of Guidelines, Policies and Procedures
- Patentees' Guide to Reporting (1995)

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

Board Meetings — Summary of Minutes (December 1998)

Annual Report Series (1989 to 1998)

NEWSletter Series (1997 to 1999)

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 HDAP Article "The Difficulty in Assessing the Relative Therapeutic Merit of New Antineoplastic Drugs", 1996

VCUs and Decisions of the Board (1993 to 1998)

- Humalog (1998)

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

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: _____

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Telephone/Fax: _____

E-mail: _____

Please return the completed form to the PMPRB, at:

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Standard Life Centre
333 Laurier Avenue West
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Ottawa, Ontario
K1P 1C1

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