Patented Medicine Prices Review Board

Inside…

Canada

NEWSletter

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Since our last issue, October 1999 …

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

November 9:	Wayne D. Critchley, Executive Director of the PMPRB, gave a presentation at the Brogan Seminars on the current activities of the Patented Medicine Prices Review Board.
November 30:	On behalf of the Chairperson, Wayne D. Critchley gave a speech at the Canadian Pharmaceutical Industry Conference (CPIC) 1999, **Regulating Prices: Progress Report on the PMPRB's *Road Map for the Next Decade***, in Toronto. The Board's Notice and Comment period for the implementation of the recommendations of its Working Group on Price Review Issues on the use of U.S. DVA prices ended. The Board's decision is published in this issue of the NEWSletter on page 1.
December 13-16:	In the matter of Hoechst Marion Roussel Canada Inc. (HMRC) and the price of the nicotine patch Nicoderm, the Hearing Panel heard the parties on Part II of the jurisdictional issues raised by HMRC. A brief update on this case is available on page 3.
December 17:	The Board held its last quarterly meeting for 1999. The Minutes of the meeting are available on page 6.

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Implementation of the Use of U.S. FSS Prices in International Price Comparisons

In the October 1999 issue of the NEWSletter, the Board announced that it had accepted the recommendations of its Working Group on Price Review Issues and invited submissions from stakeholders and the public on the proposal to implement them in the following manner:

- Use of U.S. Federal Supply Schedule (FSS) prices in conducting International Price Comparisons (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 that the average Canadian transaction prices of these drug products do not exceed the Highest International Price Guideline by January 1, 2001.

The Board has carefully considered and taken into account the submissions received and has decided:

1. To implement the inclusion of U.S. FSS prices in calculating the average U.S. price for IPCs. This policy is effective as of the pricing period commencing January 1, 2000,

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.

as set out in the Notice and Comment in the October 1999 issue of the NEWSletter.

2. To amend the proposed one-year transition period set out in the Notice and Comment to provide a two-year transition period for existing drug products whose prices would have exceeded the Guidelines in 1999, only as a result of including the U.S. FSS prices.

   For drug products subject to the transition measures, to require patentees to take action in both years of the transition period to achieve compliance with the Guidelines by January 1, 2002. Given that some prices may need to be reduced by more than 10%, a staged reduction may be necessary.

   Patentees should consult with the compliance officer assigned to their company on how they propose to comply with this provision. Patentees may be required to submit a written proposal on their proposed approach.

   Patentees are encouraged to take advantage of the advisory assistance program to deal with issues that may arise.

3. To review the regulatory reporting requirements regarding the other three prices listed in the U.S. DVA formulary.

4. To expand the planned review of the Guidelines for category 2 drug products to include consultation on the methodology for calculating the average price for a foreign country when conducting an IPC.

Patentees are encouraged to contact the compliance officer assigned to their company for information on the implementation of the use of U.S. FSS prices in IPCs.

Reasons for Decision

The Board has carefully considered all the submissions it has received from interested parties. The Board received submissions from the following parties in response to the Notice and Comment:

Wyeth-Ayerst Canada Inc., Canada's Research-Based Pharmaceutical Companies, Federal Superannuates National Association, Azko Nobel (Organon Canada Limited), Novartis Pharmaceuticals Canada Inc., Hoechst Marion Roussel Canada Inc., Berlex Canada Inc., Pfizer Canada Inc., Glaxo Wellcome Inc., Proctor & Gamble Pharmaceuticals Canada Inc., Brogan Inc., Schering Canada Inc., Eli Lilly Canada Inc., Bayer Inc.

The Board wishes to thank all of the parties who have provided comments.

Industry stakeholders indicated in their submissions that they oppose the use of the U.S. FSS prices when conducting IPCs. Many of them recommended that FSS prices be used only for the purpose of studying and monitoring price trends in the U.S. This position was reflected and considered in the Report of the Working Group on Price Review Issues.

The Board is of the view that the *Patented Medicines Regulations* require patentees to file publicly available prices listed in the U.S. DVA formulary along with the other foreign prices filed. This view has been elaborated in several places including the attachment to the *Road Map for the Next Decade* dealing with U.S. DVA prices.

Transition Period

The Board recognizes that the inclusion of the U.S. FSS price in calculating the average U.S. price for an IPC may result in some drug products which currently comply with the Guidelines becoming the highest priced of all comparator countries only as a result of including the U.S. FSS price in the calculation. The Board originally proposed that a one-year transition period be provided to patentees to comply with the Guidelines in those cases.

Industry stakeholders strongly urged a transition period of two years. They submitted that the Board had previously applied a two-year transition period when it adopted changes to the Guidelines in 1993. Furthermore, they argued that the inclusion of the U.S. FSS prices places additional regulatory burden on some of the smaller pharmaceutical companies.

The Board acknowledges the concerns raised by industry stakeholders but is also concerned that consumers be protected in those cases where price reductions are required. An analysis for 1998 showed that the prices of fewer than 5% of patented drug products would have been affected if the change involving U.S. FSS prices had been in place in that year. Although it is expected that almost all drugs will be in compliance during 2000, and only a small number will be subject to the transitional provisions, it is possible that reductions of 10% or more may be required in a few cases.

In light of all these considerations, the Board has decided to amend its proposal to provide for a two-year transition period and, at the same time, to require that patentees take action in both years of the transition period to ensure compliance with the Guidelines by January 1, 2002. Patentees who are subject to the transitional provisions may be required to submit a written proposal on how they will comply and should consult with the compliance officer assigned to their company.

The Board considers that the two-year transition period will allow patentees adequate time to comply with the Guidelines while still ensuring consumers that in any case where the price of a patented medicine exceeds the prices in other countries, there will be timely adjustments.

Filing of additional prices of U.S. DVA formulary

Industry stakeholders submitted that it is an unnecessary regulatory burden to require patentees to file the U.S. DVA prices as they are available on the Internet and in particular to file all four prices that may be listed on the U.S. DVA formulary given that only one price will be used by the Board. The filing of publicly available prices is a regulatory requirement. The Working Group recommended that only the U.S. FSS price be used in conducting IPCs. The other three prices on the U.S. DVA formulary represent a limited number of drug products. As a result the Board has agreed to review the regulatory reporting requirements regarding the other three prices listed in the U.S. DVA formulary.

Methodology for calculating average price

The Working Group had noted that some members raised concerns on the current practice of the Board of calculating a foreign price by a simple average of the prices filed for the drug product in each country as required under the Regulations.

The Board has agreed to review the methodology used to calculate average prices in conducting an IPC. ■

Nicoderm Hearing - Update Part II on jurisdictional issues

On April 20, 1999, the Chairperson of the Board issued a Notice of Hearing respecting the price at which the medicine Nicoderm is and has been sold in Canada to consider whether, under sections 83 and 85 of the *Patent Act*, Nicoderm is or has been sold by Hoechst Marion Roussel Canada Inc. (HMRC) in Canada at a price that, in the opinion of the Board, is excessive and if so, what order, if any, should be made.

By its Notice of Motion dated May 25, 1999, HMRC challenged the jurisdiction of the Board to proceed with the matters described in the Notice of Hearing. For procedural purposes, the jurisdiction motion was divided into two parts, the first concerning allegations of the institutional bias and the second challenging the Board's jurisdiction on statutory and constitutional grounds. The Board heard argument on the first part of the motion on July 5, 1999, and issued its decision affirming its jurisdiction on August 3.

On December 13 to 16, the Hearing Panel heard evidence and argument on the second part of HMRC's motion, and in particular on its submissions that:

1. Nicoderm is not a medicine for the purpose of section 83 of the *Patent Act*;
2. HMRC is not a patentee of the patents in question and/or the patents in question do not pertain to Nicoderm;
3. Any interpretation of the *Patent Act* that would extend the Board's jurisdiction in the manner alleged by Board Staff would exceed the jurisdiction of the federal government.

Subsequently, Board Staff and HMRC have filed further written submissions on these questions and on issues regarding the confidentiality and the relevance of the evidence before the Hearing Panel.

The Hearing Panel is expected to issue its decision on these matters in March. ■

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

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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.

Research Agenda 2000-2003

In its *Road Map for the Next Decade*, the PMPRB committed to publishing the Research Agenda as part of its annual planning process. Among other things, the Research Agenda identifies initiatives that are currently, or may become, subject to public consultations.

Issue	Description	Advisory Committee	Key Deliverables	Date
New Medicine Price Review Process	Price review process for new patented drugs	PMPRB Working Group on Price Review Issues	1. Meeting of Working Group 2. Report	March 2000 Fall 2000
Category 3 Drug Prices	Review the methods to conduct therapeutic class comparisons and the guidelines for category 3 drugs, including use of pharmaco-economics	PMPRB Working Group on Price Review Issues	1. Refer to Working Group 2. Report	Fall 2000 TBA[1]
Pharmaceutical Price Indices	To review drug price indices reported by Statistics Canada and PMPRB	PMPRB/Statistics Canada Task Force	Report	Fall 2000
Category 2 Drug Prices	1. Review the appropriateness of the median price test for Category 2 drugs 2. Review the appropriateness of the "Highest Price Rule" 3. Review the appropriate test when fewer than 7 countries 4. Use of pharmacoeconomics 5. Review methodology for calculating the average price for a foreign country when conducting an International Price Comparison	Advisory Committee and schedule to be determined following review of the guidelines for category 3		
Analysis of publicly funded drug plans	Reports on price trends and cost drivers	F/P/T Working Group on Drug Prices	Reports to the Federal Minister of Health	2001
Evaluation	1. Evaluation of the Consultation Policy published in 1998 (*Road Map for the Next Decade*) 2. Evaluation of complaints-driven approach to regulating the price of veterinary drugs	TBA TBA	Report Report	2001 2002
Regulating Non-Prescription (OTC) Patented Drug Prices	Approach to non-prescription (over the counter) patented drug prices	TBA	TBA	TBA[2]

1. To be determined in consultation with the Working Group on Price Review Issues.
2. The non-prescription drug industry has advocated this initiative but other stakeholders have not expressed concerns. The PMPRB will continue to monitor the situation to determine if further work is required.

Update on items which appeared on 1998-2000 Research Agenda

Issue	Description	Status	Reference
Stakeholders Meeting	Public meeting with Board	Held November 20, 1998.	Report on PMRPB web site
United States Prices	The use of publicly available prices in the DVA formulary	The Board accepted recommendations in September 1999 Report of Working Group on Price Review Issues and sought input from all stakeholders on its proposal for implementation. The Board received input from a number of stakeholders and has decided to implement the use of the U.S. DVA formulary effective January 1, 2000.	Report on PMPRB web site Details on the implementation are included in January 2000 issue of the NEWSletter and are available on our web site under Legislation, Regulations, Guidelines ...
Regulating Veterinary Drug Prices	Proposal on an alternative approach to regulating prices of patented veterinary drugs	Implemented January 1, 1999 for a three-year transition period. An evaluation of approach will be carried out at the end of transition period.	(See 2000-2003 Research Agenda)
Non-Patented Single Source Drug Prices	Study for F/P/T Task Force: International Price Comparison of Top Selling Non-Patented Single Source Drugs	The report was submitted to the F/P/T Task Force on Pharmaceutical Issues in the fall of 1998 and was distributed as background documentation at the Ministers of Health meeting in September 1999.	This report entitled "Top Selling Non-Patented Single Source Drug Products, 1996: International Price Comparison" is available as publication number S-9914 and is available on our web site under Publications, Study Series.
Pharmaco-economics	The use of pharmaco-economics in drug price reviews	Pharmacoeconomic evaluations, when available, form part of the information that is considered in the application of the Guidelines in the review of new drugs. Issues related to pharmaco-economics will also be considered in the proposed review of the Guidelines for category 3 and category 2 drugs.	(See 2000-2003 Research Agenda)

Federal/Provincial/Territorial Working Group on Drug Prices

The Ministers of Health met on September 16, 1999 and received a Summary Report of Activities of the Federal/Provincial/Territorial Pharmaceutical Issues Committee (1998-1999), studies on Drug Utilization in Canada, and on Drug Prices and Cost Drivers 1990-1997.

They reconstituted the Task Force on Pharmaceutical Prices as the Working Group on Drug Prices which will report to the Pharmaceutical Issues Committee. The Ministers asked the PMPRB to serve in an expert, advisory capacity, providing technical advice on an ongoing basis. The PMPRB is being funded $1.5 million over a period of 2 1/2 years, to assist the F/P/T Working Group on Drug Prices in conducting analyses of the expenditures of public drug plans in Canada, including annual price trends, cost-driver studies, comparisons of Canadian and foreign prices of non-patented single-source drugs and inter-provincial drug price comparisons. The PMPRB is to submit its first progress report to the Minister of Health in February 2000. ■

Canadian International Trade Tribunal Inquiry into certain Iodinated Contrast Media

On January 4, 2000, the Canadian International Trade Tribunal (CITT) issued a Notice of Commencement of Inquiry, pursuant to 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). This is a public inquiry into the preliminary determination of dumping and whether there has been injury to the Canadian producer. A copy of the Notice is available on the CITT web site at www.citt.gc.ca.

On December 31, 1999, the Canada Customs and Revenue Agency (CCRA) issued its preliminary determination that the imported products had been dumped and imposed a provisional duty of 82% on those importations. A copy of that report is available on the CCRA web site at www.ccra-adrc.gc.ca.

The CITT sent to the PMPRB a questionnaire on January 4, 2000, in relation to that inquiry. We responded on January 24, 2000, explaining the Board's legislative authority and responsibilities with respect to the regulation of patented medicine prices in Canada. A copy of our response is available on the CITT's Public Record or by contacting the Secretary of the Board. We are monitoring the evolution of this case. ■

Working Group on Price Review Issues - October 17, 18 & 19, 1999 Meeting

THE WORKING GROUP ON PRICE REVIEW ISSUES HELD ITS THIRD MEETING IN VICTORIA OCTOBER 17 TO 19, 1999

At its meeting the Working Group was joined by a new member, Murray Elston, President of Canada's Research-Based Pharmaceutical Companies, who has replaced Robert Livingston of Merck Frosst Canada.

The Working Group began its review of the issues concerning the price review process for new patented medicines that it had previously identified at its June meeting. The discussions of the Working Group were on issues related to the Human Drug Advisory Panel (HDAP), stakeholder involvement in the price review process and the efficiency and timeliness of the price review process. The role of Drug Information Centres in the price review process was also discussed.

The Working Group's review of the issues regarding the price review process will continue at its next meeting which is scheduled to take place in Ottawa on March 16 & 17, 2000.

Key elements of discussion:

- HDAP: There was recognition that it would be impracticable to define an advisory panel which represents all therapeutic specialities. On this issue the Working Group spent much of its time discussing what kind of expertise is necessary for the HDAP and how this expertise should be reflected. The generalist drug evaluation expertise is seen to be appropriate. Expansion of the size of the panel with a quorum of three was identified as a means to ensure an adequate number of panellists for timely review. The formalization of the process for consultation with experts was identified as a possible means to expand expertise when necessary as identified by the HDAP.
- Stakeholder Involvement in Process: The non-industry members of the Working Group identified that it would be important to have information concerning the basis for the staff's review of new drug products (eg. therapeutic class comparison (TCC) comparators, dosage regimen, price test used). Industry members were not in full support of this position. Discussions will continue to explore mechanisms for input and recourse for stakeholders regarding the price review process. The PMPRB currently publishes on its web site a list of new patented drug products. It was suggested that this list be expanded to include the status of the drug review (eg. complete, under review).
- Efficiency and Timeliness of Price Review Process: Discussions focused on what would be a reasonable time frame for the process and how such a time frame could be established. Working Group members requested additional information concerning existing time lines. ■

Patented Medicine Prices Review Board - December 17, 1999, Meeting

At the December 17, 1999, meeting, the Members of the Board:

- Approved a proposal for the implementation of the use of drug prices listed on the U.S. Federal Supply Schedule (FSS) in international price comparisons (IPCs).

At its September meeting, the Board accepted the recommendations of the

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.

Working Group on Price Review Issues on the *Appropriate Use of U.S. Department of Veteran Affairs Prices* in international price comparisons and sought submissions from stakeholders and the public on a proposal through Notice and Comment published in the October NEWSletter.

Upon consideration of the submissions received, the Board amended its proposal to be effective January 1, 2000. Details on the implementation of the use of the U.S. FSS in IPCs is available at page 1 of the NEWSletter or on our web site under: Legislation, Regulations, Guidelines ...

- Received an oral update on the work by Board Staff in the context of the activities of the Federal/Provincial/Territorial Working Group on Drug Prices.
- 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 February 24, 2000. ■

Exchange Rates

The methodology for calculating exchange rates for purposes of the PMPRB's International Price Comparison is described in Schedule 3 of the Compendium of Guidelines, Policies and Procedures.

Existing Drug Products

The simple average of the monthly average noon spot exchange rates for each country for the 36-month period ending December 1999 will be used in the review of prices for existing medicines in the second half of 1999.

The international prices of an existing drug product for the period July to December 1999 can be converted to Canadian currency for comparison purposes by multiplying the local currency price in each country by the corresponding simple average exchange rate.

36-Month Average Exchange Rates Ending December 1999

Period Ending	France	Germany	Italy	Sweden	Switzerland	United Kingdom	United States
Dec 99	0.24377500	0.81844444	0.00082975	0.18263333	0.99061111	2.37723333	1.45127222

Average Exchange Rates for New Drug Products Introduced between December 1998 and May 2000

Month of Introduction	France	Germany	Italy	Sweden	Switzerland	United Kingdom	United States
Jun 98	0.25896944	0.88461944	0.00084511	0.19218056	1.07077500	2.19176813	1.37429969
Dec 98	0.25246111	0.85552500	0.00084150	0.19108889	1.03669722	2.22324574	1.38528168
Jan 99	0.25201389	0.85336667	0.00084228	0.19112778	1.03382222	2.23407389	1.39029203
Feb 99	0.25197778	0.85253333	0.00084422	0.19121944	1.03236944	2.24666681	1.39502995
Mar 99	0.25221944	0.85230556	0.00084744	0.19121667	1.03182500	2.26042183	1.40057175
Apr 99	0.25210000	0.85118056	0.00084953	0.19084722	1.02980000	2.27271985	1.40574463
May 99	0.25208333	0.85044444	0.00085158	0.19042500	1.02861111	2.28570991	1.41054273
Jun 99	0.25196111	0.84950556	0.00085289	0.19018611	1.02691389	2.29727986	1.41478313
Jul 99	0.25148611	0.84726389	0.00085264	0.18985833	1.02409722	2.30627126	1.41816647
Aug 99	0.25098611	0.84505833	0.00085206	0.18935833	1.02114444	2.31671280	1.42239319
Sep 99	0.25033056	0.84257222	0.00085075	0.18870000	1.01776667	2.32598912	1.42595721
Oct 99	0.24957500	0.83981667	0.00084858	0.18791667	1.01435556	2.33396904	1.42853928
Nov 99	0.24870556	0.83664722	0.00084583	0.18703611	1.01074722	2.34058154	1.43141719
Dec 99	0.24776667	0.83325556	0.00084308	0.18620833	1.00660556	2.34664493	1.43473538
Jan 2000	0.24694444	0.83003056	0.00084064	0.18547222	1.00237500	2.35413236	1.43808181
Feb 2000	0.24609722	0.82682222	0.00083789	0.18473611	0.99843056	2.36146944	1.44106944
Mar 2000	0.24553056	0.82472778	0.00083597	0.18408889	0.99617222	2.36995833	1.44458889
Apr 2000	0.24468333	0.82166389	0.00083314	0.18335833	0.99325000	2.37417500	1.44817500
May 2000	0.24377500	0.81844444	0.00082975	0.18263333	0.99061111	2.37723333	1.45127222

PMPRB Upcoming Events

February 24:	Board meeting
March:	Decision of the Hearing Panel in the Nicoderm case on jurisdictional issues
March 16-17:	Meeting of the Working Group on Price Review Issues

PMPRB List of Publications

Here is the latest addition to our Publications List:

- Speech to the Canadian Pharmaceutical Industry Conference (CPIC) 1999, November 30, **Regulating Prices: Progress Report on the *Road Map for the Next Decade***.

- All our speeches are available on our web site under Publications, Speech Series.

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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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