Patented Medicine Prices Review Board

PMPRB NEWSletter

Volume 8, Issue No. 4
October 2004

Inside...

Board Members

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.

Since our last issue ...

Here are some of the key events which occurred since July 2004.

July 27:	Marcin Szumski, Scientific Officer, gave a presentation at the Rx&D Industrial Pharmacy Studentship Seminar, in Toronto. Brigitte Boulet, Compliance Officer, also gave a presentation at the Montréal Seminar on August 12.
August 31:	Wayne Critchley gave a presentation, *Patented Medicines and Pricing Issues*, at the conference on Drug Patent Law Reform, in Ottawa.
September 24:	The Board held its third quarterly meeting. A summary of the Minutes are available on page 7.
October 5:	The Minister of Health, the Honourable Ujjal Dosanjh, tabled the Annual Report of the PMPRB for the year 2003 in Parliament. The report is available on our website by clicking on our home page, (http://www.pmprb-cepmb.gc.ca/english/View.asp?x=302).
October 6:	Meeting of the Human Drug Advisory Panel (HDAP).
October 22:	Martine Richard gave a presentation, *The Evolving Role of Counsel to an Administrative Tribunal: How to Wear Your Many Hats*, at the Canadian Institute's 4th Annual Advance Administrative Law & Practice conference, in Ottawa.
October 29:	The PMPRB study on pharmaceutical trends of the Non-Insured Health Benefits Pharmacy Program, for 1999-2000 to 2001-2002, is now available on our website under Publications, Studies. A brief summary of the study appears on page 4 of this NEWSletter. ■

Comings and Goings!

We welcome new team members.

- The Policy and Economic Analysis Branch has new members in Gary Warwick and James Gauthier, formerly from International Trade Canada and Statistics Canada respectively. Two new co-op students also joined the Policy and Economic Analysis team for the autumn semester: Angela Yang Cao from the University of Waterloo and Hai Zhong from McMaster University.
- Lisa Charbonneau and Richard McAteer are the newest members of the New Medicine Team, Compliance and Enforcement Branch.
- We wish the best of luck to Orlando Manti who has accepted an assignment with the Health Care Policy Directorate at Health Canada. ■

Executive Director to Step Down

Wayne Critchley, Executive Director of the PMPRB since 1990, has announced that he will be stepping down at the end of 2004 in anticipation of retiring from the Public Service in 2005. The Public Service Commission is in the process of staffing the position. Upon the recruitment of the new Executive Director, Wayne will serve as Special Advisor to the Chairperson until the Spring of 2005.

Message from the Chair

Robert G. Elgie, Chairperson

Over the past year, the PMPRB has received questions concerning published reports of price increases for patented drugs. Recent issues of our NEWSletter have included articles reminding stakeholders of the relevant provisions of the *Patent Act* and of our Price Guidelines – and we have reminded pharmaceutical patentees of the PMPRB's responsibility to ensure that prices for patented medicines are not excessive *in any market in Canada*.

The PMPRB has received information that manufacturers have advised the trade of price increases for close to 35% of all patented drug products in 2004. The extent to which these increases in published prices will translate into increases in net prices charged to customers cannot yet be determined, but the PMPRB will monitor the situation carefully and take action if any of the price increases appear to exceed the Guidelines.

As we have reported in previous years, the past decade has seen considerable stability in the prices of patented drugs in Canada due to public policy intervention through the PMPRB program and the policies of several provincial drug plans. Reports of price increases this year raise the question of whether we are seeing a change in pricing behaviour and, if so, why. Given the growing importance of pharmaceuticals in health care, and the need to ensure health care sustainability, one might also ask if price increases for patented drugs, even if allowable under current guidelines, are justified.

In addition to ensuring that prices for patented drugs are in line with the Guidelines, the PMPRB is doing further work to assess whether the reports of price increases in 2004 represent a new trend and, if so, whether the current regulations and guidelines are still appropriate. I expect to have the opportunity to comment and report further on this question over the coming months. ■

Robert G. Elgie
Chairperson

PMPRB

Previous issues of the NEWSletter are available on our website under Publications; NEWSletter, at http://www.pmprb-cepmb.gc.ca/english/View.asp?x=287&mp=68. The articles, Price Increases – Monitoring Compliance with the Guidelines, and PMPRB Price Guidelines – 2004 Price Increases, are also available on our website under Are you a Patentee; Reference Documents for Patentees, at http://www.pmprb-cepmb.gc.ca/english/view.asp?x=274.

Congratulations Lovdy!

The PMPRB recently celebrated Lovdy Desjardins' 35 years with the Public Service. To mark the occasion, Dr. Elgie presented Lovdy with a commemorative plaque and memento. Lovdy joined the PMPRB in 1988.

Lovdy Desjardins, Records Manager & Library Services

United Way Campaign!

This year, the PMPRB is again taking a very active part in the Government of Canada Workplace Charitable Campaign! It is the largest workplace campaign in Canada – and one of the most successful. That success changes the lives of thousands of men, women and children in communities across the country.

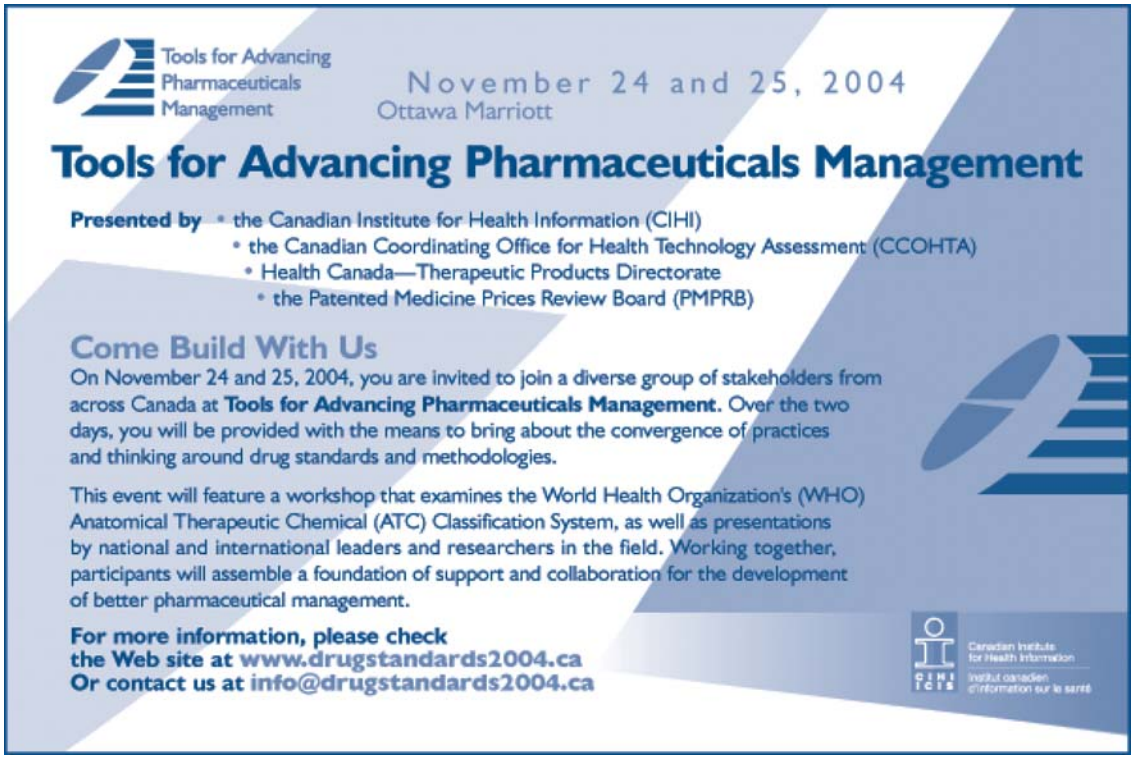
The theme of this year's campaign is "Rhythm & Blues". In that spirit, the PMPRB has pooled its resources with the Canadian International Trade Tribunal for a jazzy and successful campaign.

We have had a long history of supporting our community generously and we intend to continue. ■

PMPRB and CITT Workplace Charitable Campaign! From left to right, Pierre Gosselin, Chairperson of the Canadian International Trade Tribunal and Wayne Critchley, Executive Director of the PMPRB.

Breakfast at the PMPRB, held October 5, 2004, as part of a series of activities organized by the PMPRB and CITT. Seen on this picture, Gina Charos, Bindu Islam and Lovdy Desjardins, of the PMPRB.

Join us at the conference!



Joining in fundraising activities with our neighbour, the Canadian International Trade Tribunal (CITT), with whom we already share hearing and mailroom services, demonstrates that collaboration and team work between the two agencies is making a difference in the lives of Canadians. Contributions to the charitable campaign benefit many individuals, one of whom may be a colleague, a neighbour, a friend or even a family member.

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Manufacturers' Questions about a Possible Two-Price System for Patented Medicines

PMPRB

The Fasturtec VCU is available on our website under Publications; Voluntary Compliance Undertakings; Fasturtec – at http://www.pmprb-cepmb.gc.ca/english/View.asp?x=126&mp=68. Also, a summary of the case is available in our July 2004 NEWSletter, page 6 – http://www.pmprb-cepmb.gc.ca/CMFiles/jul04-e30KWO-832004-78.pdf.

In our July 2004 NEWSletter, we reported that the Board had concluded proceedings in June with regard to the medicine Fasturtec by accepting a Voluntary Compliance Undertaking (VCU) from Sanofi-Synthelabo Canada Inc. (Sanofi). The VCU called for a significant decrease in the price of Fasturtec to $125 per vial, from $295. However, Sanofi indicated in its submission that it intends to maintain a high list price for Fasturtec, despite undertaking that no customer in Canada will pay more than the new reduced price. Since this is a new issue for the PMPRB, the Board committed to conduct a policy review.

In recent months, the PMPRB has also received informal inquiries from patentees and industry consultants regarding the feasibility of implementing a two-price system. A common element in these inquiries has been the idea of manufacturers implementing high list prices, while providing discounts or rebates to some customers such that the average transaction price would not exceed the maximum non-excessive price under the PMPRB's Guidelines. To date, these have only been informal inquiries. No formal proposals have been made and approval from the PMPRB has not been sought.

Over the next few months, the Board will be examining both of these related two-price issues. While its work is still in a preliminary stage, there appear to be some areas of potential concern. First, and foremost, the Board is concerned about consumer protection and possible non-compliance with the pharmaceutical pricing provisions of the *Patent Act*. Further, the Board is concerned that a two-price system may reduce transparency in drug prices in Canada.

The Board will report its progress in this policy review through its Research Agenda. ■

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The Research Agenda is available on our website under Publications – at http://www.pmprb-cepmb.gc.ca/english/View.asp?x=333&mp=119.

Pharmaceutical Trends – Non-Insured Health Benefit Pharmacy Program, 1999-2000 to 2001-2002

PMPRB

This report was prepared by the PMPRB as part of the National Prescription Drug Utilization Information System (NPDUIS) initiative with the collaboration and support of public drug plans in Canada.

The Non-Insured Health Benefits Program is a federal government program that reimburses health care expenses to registered Indians, Inuit and Innu individuals for services that are not covered by provincial and territorial government public insurance programs.

This study examines spending on drugs within the Non-Insured Health Benefits (NIHB) Program of Health Canada's First Nations and Inuit Health Branch over three fiscal years: 1999-2000, 2000-2001 and 2001-2002.

In 2001-2002, pharmacy costs under NIHB accounted for $252.9 million, representing over 40% of total program expenditures and annual average growth of 10.6% for the period of the analysis.

The study assesses distributional effects and the major drivers of cost and utilization change for the NIHB Pharmacy program. Data for this study were provided by the Non-Insured Benefits Directorate of Health Canada.

Most of the analysis focuses on drugs that are dispensed in oral solid forms (e.g. pills, tablets and capsules), since other forms are not consistently measured in the drug plan database.

Highlights:

- An increasing share of the NIHB Pharmacy program spending went to patented drugs (from 56.3% to 62.1%), while spending on generics comprised a declining share (from 27.8% to 25.8%).
- The assessment of individual drug price trends shows that 17.9% of all drug prices increased by more than the growth in average annual Consumer Price Index (CPI): 92.9% of these drugs were non-patented medications.
- The drug price trends also revealed that 56.9% of generic products had price increases greater than the change in the CPI over the 1999-2000 to the 2001-2002 period.
- A price and volume index analysis reveals that average drug prices paid by the plan decreased by almost 2% in 2001-2002

relative to 1999-2000, while over the same period the quantity of drugs dispensed rose by more than 40%.

- A decomposition of the growth in program spending on oral solids over 1999-2000 to 2001-2002 shows that changes in drug quantities accounted for 95.7% of growth, and the introduction of new drugs on the formulary in 2000-2001 and 2001-2002 accounted for 11.2%. These positive effects were offset by a price effect of -4.8%, an exiting drug effect (drugs removed from the formulary) of -0.7%, and a cross effect of -1.3% (i.e., other effects from the decomposition).
- The largest shares of spending growth by Anatomical Therapeutic Chemical (ATC) classes were observed for drugs acting on the nervous system (class N, 30.2% of growth over 2 years), the cardiovascular system (class C, 28% of expenditure growth) and the alimentary tract and metabolism (class A, 21% of expenditure growth).
- Changes in program expenditure were broken down according to comparable units of dosage using the defined daily dose measure published by the World Health Organization. This analysis found that:
  – price change has had a small, typically negative effect on expenditure
  – volume effects have had a large positive effect, and
  – changes in therapeutic mix show substantial prescribing shifts in favour of higher cost drugs per daily dose in the case of drugs for acid-related disorders and drugs used in diabetes, and lower cost drugs in the case of agents acting on the renin-angiotensin system and serum lipid lowering agents. ■

For further information, please consult the full report available on our website, under Publications; Studies.

PMPRB e-Bulletin!

We would like to remind you that since May 2004, you can subscribe to the PMPRB's publications on-line. If you wish to do so, go to our website's home page and click on the box **"Subscribe to the PMPRB Mailing List!"** You can then choose to either receive our publications updates and/or other information from the PMPRB, electronically or by mail. You can also inform us of your change of address.

As always, we look forward to receiving your comments on the information available on our website and any suggestions you may have on our communications tools. We look forward to hearing from you! ■

Please forward all subscriptions to the PMPRB e-mail or mailing lists and requests for publications to Elaine McGillivray at Elaine@pmprb-cepmb.gc.ca. For more information on our website, please contact our Communications Officer, Anne-Marie Labelle, at alabelle@pmprb-cepmb.gc.ca.

New Patented Medicines Reported to the PMPRB

Since the publication of the July 2004 NEWSletter, 16 new DINs for human use (representing 14 medicines) were added to the list of New Patented Medicines Reported to the PMPRB in 2004, for a total of 61 DINs as of September 30. Six of these new medicines are new active substances, representing six DINs.

The following table presents the six new active substances reported to the PMPRB during the period July to September 2004. ■

Brand Name	Generic Name	Company
Hextend (60 mg/mL)	hetastarch	Abbott Laboratories Ltd.
Zavesca (100 mg/capsule)	miglustat	Actelion Pharmaceutiques Canada Inc.
Forteo (250 mcg/mL)	teriparatide	Eli Lilly Canada Inc.
Gynazole.1 (20 mg/gm)	butoconazole nitrate	Ferring Pharmaceuticals Inc.
Bondronat (1 mg/mL)	ibandronate sodium	Hoffmann-La Roche Canada
Ebixa (10 mg/tablet)	memantine hydrochloride	Lundbeck Canada Inc.

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Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's Price Guidelines, for all new active substances introduced after January 1, 2002.

Report on New Patented Drugs – Iressa

Generic Name:	gefitinib
DIN:	02248676 250 mg/tablet
Patentee:	AstraZeneca Canada Inc.
Indication – as per product monograph:	As monotherapy (third line therapy) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after the failure of prior platinum-based and docetaxel chemotherapy. The efficacy is based on objective response rates (surrogate endpoints) that are reasonably likely to predict clinical benefit. This authorization is conditional upon confirmation of clinical benefit. Patients should be advised of the conditional nature of the authorization.
Notice of Compliance:	Issued with conditions on 17 December 2003
Date of First Sale:	17 December 2003
ATC Class:	L01XX31 *Antineoplastic and Immunomodulating Agents, Antineoplastic Agents, Other Antineoplastic Agents.*

Application of the Guidelines

Summary:

The introductory price of Iressa was found to be within the Guidelines because the Canadian price did not exceed the median of the prices for the same drug product in those countries listed in the *Patented Medicines Regulations* (Regulations) in which it was sold.

Scientific Review:

Iressa is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) reviewed it as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable medicines).

The Therapeutic Class Comparison (TCC) test of the Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drugs that treat the same disease or condition. Comparators are generally selected from among existing drug products in the same 4th level of the Anatomical, Therapeutic, Chemical (ATC) System that are clinically equivalent in addressing the approved indication.

None of the agents in the same 4th level ATC share the same indication as Iressa, nor is there any evidence supporting the use of these agents as single third line therapy for the treatment of non-small cell lung cancer. Consequently, the HDAP recommended no comparators for the conduct of a TCC for Iressa.

Price Review:

PMPRB

The Compendium is available on our website, under Legislation, Regulations and Guidelines – at http://www.pmprb-cepmb.gc.ca/english/View.asp?x=135&mp=73.

Under the Guidelines, the introductory price of a new category 3 drug product will be presumed to be excessive if it exceeds the prices of all of the comparable drug products in the TCC test. The Guidelines further provide that when it is inappropriate or impossible to conduct a TCC, the primary weight will be given to the median of the international prices identified in an International Price Comparison (IPC) test. The price will be presumed excessive if it exceeds the median of the prices of the same drug product sold in the seven countries listed in the Regulations. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on IPCs.

As no comparable drug products could be identified for the purposes of conducting a TCC test, the price of Iressa was considered within the Guidelines as it did not exceed the median of the international prices identified in an IPC test.

The Guidelines provide that when a medicine is sold in fewer than five countries at the time of its introduction, the introductory price will be treated as the interim benchmark price. The interim benchmark price may be reviewed at the end of three years or when the medicine is sold in at least five countries, whichever comes first.

	250 mg/tablet
Canada	$71.3333
France	–
Germany	–
Italy	–
Sweden	–
Switzerland	$89.0335
UK	–
US	$69.4179
Median	$79.2257

Sources:

Canada	PPS Publication Pharma, July 2004
Switzerland	Medwin, January-June 2004
US	Wholesale Acquisition Cost (WAC), April 2004 and Federal Supply Schedule (FSS), January-June 2004.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by the PMPRB Staff and the HDAP for the purpose of carrying out the PMPRB's regulatory mandate, which is to review the prices of patented medicines sold in Canada to ensure that such prices are not excessive. The publication of these reports is also part of the PMPRB's commitment to make its price review process more transparent.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than its stated purpose and is not to be interpreted as an endorsement, recommendation or approval of any drug nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner. ■

Evidence/ References

The references are available on the PMPRB website, under Patented Medicines; Reports on New Patented Drugs for Human Use; Iressa.

Patented Medicine Prices Review Board – September 24, 2004 Meeting

At its meeting, the Board:

- had a presentation on:
  - Consumer Price Index (CPI) and its use, by the Consumer Prices Section of Statistics Canada;
- received briefings on:
  - September 13-15 First Ministers Meeting, on the renewal of health care in Canada;
  - results of the price review of Axert;
  - two-price system; and
  - ongoing activities under the NPDUIS. ■

The next Board meeting is scheduled for December 16 & 17, 2004.

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.

Upcoming Events

November
8
Canadian Treatment Action Council (CTAC) – Skills Building Session for community the focus of which is shifting landscape of drug approval, marketing and reimbursement, Toronto

November
9-10
Canadian Institute: Pharma Patents – The Legal and Strategic Guide, Toronto

November
22-23
Pharmac 2004 – Successful Sales, Marketing and Regulatory Strategies for the Canadian Pharmaceutical Industry, Toronto

November
22-23
Insight Conference – Marketing of drug products in Canada: New Challenges – how to combine regulation, marketing and accessibility, Montréal

November
24-25
Conference on Drug Utilization Indicators, Drug Standards & Drug Statistics Methodologies, Ottawa

November
26
NPDUIS Steering Committee, Ottawa

December
16-17
Board Meeting, Ottawa

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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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