



PMPRB NEWSletter

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Board Members

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Vice-Chairperson:

Dr. Brien G. Benoit,

B.A., M.D., M.Sc., FRCSC, F.A.C.S.

Members:

Tim Armstrong,

Q.C., O. Ont.

Anthony Boardman,

B.A., Ph.D

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 that occurred since the end of July 2005.

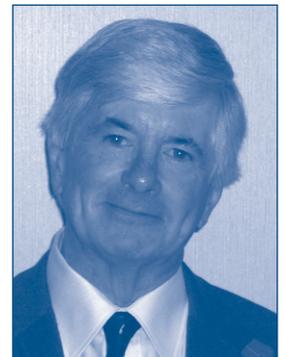
- August 31: Barbara Ouellet and Martine Richard gave presentations at the 1st International Conference on Pharmaceutical Drugs, in Montréal.
-
- September 12-16: The Board held a second session in its hearing in the matter of
 October 14: LEO Pharma Inc. and the medicine Dovobet. The hearing resumes on November 29, 2005.
-
- September 22-23: The Board held its quarterly meeting. Summary of the Board Minutes is available on page 9.
-
- September 23: The PMPRB bid farewell to Mr. Réal Sureau after his ten-year tenure as Vice-Chairperson.
-
- September 23-24: Catherine Lombardo, Compliance Manager, attended the Federal/Provincial/Territorial Pharmacy Therapeutic Committee, in Montréal.
-
- September 29: Barbara attended the Canadian Health Services Research Foundation (CHSRF) Meeting – *What is the Evidence*, in Ottawa.
-
- September 30: Barbara gave a presentation on the PMPRB at the Cancer Systemic Therapy Search Conference, in Toronto.
-
- October 19: Barbara gave a presentation on the PMPRB price controls to the Canadian Institute's 4th Annual Forum on Pharma Patents, in Toronto.
-
- October 20-21: Martine Richard gave a presentation to the Canadian Institute's 5th Annual 'Advanced Law & Practice' Conference: "*Fundamentals of Administrative Law Practice*", in Ottawa. ■

News from the Vice-Chairperson

The PMPRB's contribution to F/P/T collaboration on pharmaceuticals management in Canada

Having been appointed member of the Patented Medicine Prices Review Board in May and having assumed the position of Vice-Chairperson in October, my experience with the organization has so far been challenging and educational.

As a practicing surgeon, I am reminded on a daily basis of the importance pharmaceuticals play in the lives of Canadians. Over the last few months, I have had the opportunity to better understand and appreciate some of the more complex facets of pharmaceuticals management in Canada.



Dr. Brien G. Benoit,
Vice-Chairperson
of the PMPRB

If you wish to know more about the PMPRB, please contact us at our toll-free number or consult our Web site:

Senior Staff

Executive Director:
Barbara Ouellet

Secretary of the Board:
Sylvie Dupont

Acting Director of Policy
and Economic Analysis:
Paul De Civita

Director of Compliance
and Enforcement:
Ginette Tognet

Director of Corporate Services:
Robert Sauvé

Senior Counsel:
Martine Richard

Under the *Patent Act*, if the Chairperson is absent or incapacitated or if the office of Chairperson is vacant, the Vice-Chairperson has all the powers and functions of the Chairperson during the absence, incapacity or vacancy.

United Way Campaign 2005

We believe at the PMPRB that we can make a difference towards building a strong, healthy, safe community for all. Our contributions change peoples' lives and make an incredible impact. We are dedicated and focused on results for a better future for all.

Pharmaceutical policy has been the subject of considerable debate in Canada over the years. The main constant in this important debate has been the issue of how best to bring Canada's intellectual property regime in line with new international agreements, while providing access to affordable medications for all Canadians. In more recent years, rising pharmaceutical expenditures have taken centre stage with public programs and consumers. The Canadian Institute for Health Information reported that drugs represented over 16% of total health care spending in 2004, surpassing physician spending as the second largest category of health care spending after hospitals.

Public drug programs have introduced new measures to contain costs and promote appropriate prescribing and utilization practices as federal, provincial and territorial (F/P/T) Ministers of Health continue to explore new approaches to collaboration.

The National Prescription Drug Utilization Information System (NPDUIS) is but one example of F/P/T collaboration. Through critical analyses of price, utilization and cost trends, the PMPRB provides Canada's health system with more comprehensive and accurate information on how prescription drugs are being used and on cost drivers.

Building further on F/P/T collaboration, First Ministers signed a *10-Year Plan to Strengthen Health Care* in 2004. Part of this agreement

included the development and implementation of a National Pharmaceuticals Strategy. Recently, Health Ministers reiterated their commitment to better align their regulatory and reimbursement regimes to ensure the best possible outcomes for Canadians. Among other initiatives announced at their annual meeting in October of this year, the Ministers agreed that the PMPRB should be given the responsibility to monitor and report on non-patented prescription drug prices. Beginning in the spring of 2006, we will publish quarterly reports on a number of key areas: Canadian sales and price trends; generic to brand name price comparisons; Canadian to foreign price comparisons; and cost of therapy and utilization patterns, to name a few.

Important advances in health care policy are being made to respond to the changing needs of Canadians. However, this is an ongoing process – we face new challenges every day. By raising the issues, and encouraging open debate, we can contribute to better decision-making, and ultimately improve health care for all Canadians. It is my privilege to be part of this process. ■



Brien G. Benoit
Vice-Chairperson

The PMPRB and the Government of Canada Workplace Charitable Campaign 2005 (United Way)

The PMPRB is happy to undertake its usual active role in the Government of Canada Workplace Charitable Campaign 2005 by providing continued support towards the community.

Elaine McGillivray has once again accepted to represent the PMPRB as Campaign Leader.

The theme of this year's campaign is **Rock & Roll**. ■



Halloween for United Way!

Comings and Goings

- ◆ Dave Latour, PMPRB Network Architect, has accepted a secondment with Health Canada.
- ◆ Catherine Jesty has joined the Policy and Economic Analysis Branch as Assistant to the Director.
- ◆ Marta Rivas has joined the Corporate Services Branch team as Records Manager. ■

Of particular interest to patentees

Actual vs. Forecast Consumer Price Index (CPI)

The April 2003 issue of the NEWSletter reported on the CPI-Adjustment Factors for 2004. The forecast CPI for 2004 was 124.57. This was based on the actual CPI figure for 2002 and the latest available inflation projections of 2.4% for 2003 and 2.2% for 2004. Based on a 2004 forecast

inflation of 2.2%, a one-year price increase in 2004 could not result in a price being more than 3.3% over the price in 2003 (1.5 times forecast inflation). The information in the table below was also reported in the April 2003 NEWSletter.

2004 CPI-Adjustment Factors for All Patented Drug Products (based on forecast)

	Benchmark Year		
	(1) 2001	(2) 2002	(3) 2003
Base CPI	116.41	119.03	NA
2004 Forecast CPI	124.57	124.57	124.57
2004 Adjustment Factor	1.070	1.047	1.022

The Base CPI for 2003 was not known when the CPI-Adjustment Factors for 2004 were published in April 2003. The Base CPI (or actual CPI) was subsequently determined to be 122.32 for 2003 and 124.56 for 2004. The 2004 Adjustment Factor for 2003 based on the actual 2003 and 2004 CPI rather than forecast CPI is 1.018, or 124.56 divided by 122.32. The result is that the actual maximum allowable one-year price increase was 2.7% of the price in 2003 (i.e. 1.8×1.5).

The PMPRB's Excessive Price Guidelines contain a provision that recognizes that, in circumstances where a patentee bases a price increase solely on forecasted inflation, rather than on actual CPI, the use of such methodology will not automatically give rise to a price review (Excessive Price Guidelines, Paragraph 9.3 <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=230&mid=205>). In the

absence of any other evidence that might give rise to further review of the price of a particular patented medicine, the price will be considered to be within the Guidelines.

Although the Guidelines contain provision for this approach when the forecasted CPI exceeds the actual CPI, a patentee is expected to comply with the actual CPI in all subsequent reporting periods. As a result, the retroactive maximum non-excessive (MNE) price for 2004 for purposes of applying the CPI-adjustment methodology will be based on actual CPI for 2004. The result for patentees that took price increases based on the forecast inflation will be that this MNE (and not the average transaction price (ATP) considered to be within the Guidelines) for 2004 will be used to calculate the 2005 MNE.

Base CPI is a PMPRB term for the simple average of the monthly CPI figures published by Statistics Canada. It is calculated by the PMPRB in January, for the preceding year.

The 2004 Forecast CPI was calculated using the Base CPI for 2002 multiplied by the projected inflation projections obtained from the Department of Finance for 2003 and 2004 (2.4% and 2.2% respectively) [$119.03 \times 1.024 \times 1.022 = 124.57$].

The CPI-Adjustment Factor is calculated by dividing Forecast CPI by the Base CPI. The 2004 Adjustment Factor for 2001 is 124.57 divided by 116.41 (1.070) and for 2002, it is 124.57 divided by 119.03 (1.047). The 2004 Adjustment Factor for 2003 is the inflation projection for 2004 (1.022).

The following example is an illustration of the above.

Medicine X:

- The manufacturer's price for medicine X in 2003 is \$10.00 and it is within the PMPRB's Guidelines.
- The manufacturer increases the price for medicine X in 2004 to \$10.33 (based on a forecast rate of inflation of 2.2% and allowing for a price increase of 1.5 times

this rate). The price is considered within the Guidelines as the increase does not exceed the 2004 adjustment factor based on forecast inflation.

- The actual CPI results in a 2003 adjustment factor of 1.018.
- The 2004 MNE price is therefore \$10.27.
- The 2005 MNE price will be calculated using the 2004 MNE price of \$10.27 and not the manufacturer's price of \$10.33 as it exceeds the 2004 MNE price. ■

Prices used for comparator drug products in conducting a therapeutic class comparison

The therapeutic class comparison (TCC) compares the price of the drug product under review with the price of drug products that are clinically equivalent and sold in Canada at prices that the PMPRB considers not to be excessive. Comparable drug products are first selected, a comparable dosage regimen is then established, and their prices are compared against the drug product under review.

The Guidelines provide that ordinarily, the introductory price of the new drug product and the Ontario Drug Benefit (ODB) Formulary price of the comparable drug products, if available, will be used for the comparison. If the ODB Formulary price is not available, or the PMPRB considers it inappropriate, other prices may be used for the comparison.

Other prices used by Board Staff for the comparison may include prices from other public drug plan formularies, prices calculated using IMS data, the price published in PPS and possibly other sources.

However, given the Board's direction through its Guidelines to initially consider the ODB price, should there be no ODB price, or should it be considered inappropriate, Board Staff may give preference to other public drug plan formulary prices in determining an appropriate price for other products in the TCC test. The appropriateness of prices used in the TCC test will be determined on a case-by-case basis. Board Staff reserves the right to exclude a particular public price if it has reason to believe that it is an excessive price. ■

Filing requirements — Impact of Refunds on Average Transaction Price

The *Patented Medicines Regulations* (Regulations) provide for the reporting of the average price per package or the net revenue from each package size of a DIN. Pursuant to the Regulations, the reported average price or the net revenue takes into account reductions given in the form of rebates, discounts, refunds, free goods, free services, gifts, and any other benefits of a like nature. The average transaction price is calculated by adding all the net revenue and dividing it by the total number of units sold.

A patentee must certify that the information filed is accurate; Board Staff is not authorized to make any modifications to the data that are filed. It is the data as filed by a patentee which are reviewed to determine the

average transaction price and whether that price is within the Guidelines. Refunds are reported as negative amounts in terms of quantity sold (units sold) and net revenue. It appears that some patentees may not be taking care to ensure the accuracy of the units returned and net revenue. This can have the impact of creating what appears to be an artificially high average transaction price and may trigger the criteria for commencing an investigation.

If, based on the data filed by a patentee, the criteria for commencing an investigation have been triggered, an investigation shall be commenced, even in cases where there may appear to be some error regarding the data that are reported. ■

Voluntary Compliance Undertaking accepted during the last quarter – Ortho 7/7/7

On September 9, 2005, the Vice-Chairperson of the Board accepted the Voluntary Compliance Undertaking (VCU) for Ortho 7/7/7, submitted by Janssen-Ortho Inc.

The prices of both Ortho 7/7/7 products were reviewed in accordance with the PMPRB's Excessive Price Guidelines (the Guidelines). For the periods from January 1, 2001 through September 1, 2004, the prices of both Ortho 7/7/7 products exceeded the CPI adjusted maximum non-excessive (MNE) prices by a range of 0.0008% to 0.0121% with resulting excess revenues of \$99,892.72.

In order to comply with the Guidelines, Janssen-Ortho agreed that the 2004 MNE prices of Ortho 7/7/7 16.485 mg/21 tablets and 16.485 mg/28 tablets were respectively \$11.4301 and \$11.0616. To offset excess revenues, it made a payment to the Government of Canada in the amount \$99,892.72.

The patent on Ortho 7/7/7 expired in September 2004. ■

Ortho 7/7/7 is an oral contraceptive. It is available in 16.485 mg/21 tablets and 16.485 mg/28 tablets.

NPDUIS

Budget Impact Analysis Guidelines: Needs Assessment

The PMPRB has undertaken a number of projects under the National Prescription Drug Utilization Information System (NPDUIS), including the *Budget Impact Analysis Guidelines: Needs Assessment*.

In December 2004, the F/P/T Pharmaceutical Issues Committee endorsed Phase I of the project, which was to assess the need to develop national budget impact analysis guidelines. Phase II of this project was to develop the actual guidelines.

The Needs Assessment report (Phase I) is based on a survey of all the NPDUIS Steering Committee members; an analysis of 35 budget impact analysis (BIA) tools made available to the PMPRB by jurisdictions; and, a review of current literature.

A BIA looks at the financial impact on a drug plan's budget of the possible listing of a drug on its formulary. Public drug plans routinely use BIAs for decision making purposes. The Common Drug Review (CDR) uses BIAs when Priority Review based on cost savings is requested.

Drug plan managers often find the BIAs submitted to them by manufacturers to be unsatisfactory. The survey and the analysis

of 35 BIA tools indicated the main issues to be lack of transparency; inaccurate or mis-applied assumptions; generalized analysis – not-specific to or inaccurate for jurisdiction and/or plan; inappropriate choice of comparators; and overall quality.

The literature review indicated that there are limited guidelines on the conduct of BIAs in OECD countries although there is a plethora of economic evaluation guidelines. In Canada, some provinces offer templates for manufacturers to follow.

The use of BIAs and economic evaluations are complementary. An economic evaluation addresses the issue of "cost-effectiveness", whereas a BIA addresses the issue of "affordability". Both are necessary to make informed decisions about the possible listing of a drug on a formulary.

The findings in the Phase I report confirm the need for BIA guidelines.

The objective of developing the BIA guidelines (Phase II) is to establish a set of principles or best practices in designing and implementing budget impact analysis, hence increasing the reliability and usefulness of the BIA report. ■

The *Budget Impact Analysis Guidelines: Needs Assessment* is available on our Web site, under National Prescription Drug Utilization Information System; Analytical Study Series.

The Impact upon Public Drug Plans of Changes in Drug Distribution

Public drug plan members of the NPDUIS Steering Committee identified changes in the drug distribution system as a potential cost driver for their programs.

This study examines the retail distribution system in Canada – the changes that have occurred since the early 1990's and their impacts on provincial drug plans.

The analysis was based on aggregate level data from six provinces (British Columbia, Alberta, Saskatchewan, Manitoba, New Brunswick, and Nova Scotia) and the Non-Insured Health Benefits, Health Canada.

Drug products arrive at pharmacy outlets either directly from the manufacturers or indirectly through distribution centers and/or through wholesalers. Since the early 1990's

the distribution system has been changing in favour of more drugs being sold to pharmacies indirectly, i.e., through distribution centers and wholesalers instead of manufacturers selling directly to pharmacies. Many manufacturers who still sell directly to pharmacies have increased their minimum purchase size.

The trend towards indirect sale translates into additional costs to final payers, such as insurers (public or private) and consumers who pay out-of-pocket, in the form of up-charges or mark-ups.

This study estimated the impact upon drug plans of changes in the distribution system using provincial reimbursement data from 1997-98 to 2003-04. ■

The *Impact upon Public Drug Plans of Changes in Drug Distribution* will be posted on our Web site, under National Prescription Drug Utilization Information System; Analytical Study Series, on November 21, 2005.

Update on the 2005 Consultations

To gather stakeholder input on proposed regulatory amendments and price increases for patented medicines, we published two Notice and Comment documents in early 2005. Numerous submissions regarding both initiatives, all available on our Web site, were received from both private and public sector stakeholders. Analysis and incorporation of these comments continued.

Proposed Amendments to the *Patented Medicines Regulations, 1994*

Recognizing that timelier price reviews would better serve the needs of Canadians, the PMPRB solicited stakeholder comments regarding proposed amendments to the *Patented Medicines Regulations, 1994*. The proposed amendments were conceived as a way to expedite the price review process by assuring earlier access to the data required to conduct a review. Twenty-one stakeholder submissions were received, providing important input regarding advantages and disadvantages of each proposed amendment. Based on the comments received, the PMPRB has made some modifications to some of the proposed amendments. Subsequent to that first round of consultation, the PMPRB has begun to consult with inter-

ested federal departments and agencies. To date, consultation meetings have been held with Industry Canada, responsible for the *Patent Act*, and Health Canada – as the Minister of Health is responsible to recommend publishing and enactment of regulatory changes. Further consultations are underway with the Department of Justice, the Privy Council Office and Treasury Board. Following these discussions, the next step will be to publish the revised regulatory amendments in the Canada Gazette, Part 1. Publication is targeted for late Fall 2005/early Winter 2006.

Price Increases for Patented Medicines

No additional stakeholder consultations occurred during the summer, as Board Staff continued its review of the nineteen submissions received and formulate potential options for next steps. Analysis of both submissions and possible further analytical work were presented to the Board in September. Additional work is currently underway, both in regard to introductory prices and price increases. Next steps will be communicated in future issues of the NEWSletter. ■

New Patented Medicines Reported to the PMPRB

Since the publication of the July 2005 NEWSletter, five new DINs for human use, representing five medicines, were added to the list of New Patented Medicines Reported to the PMPRB for the period ending August 31, 2005. Two of these new

medicines are new active substances (NASs), representing two DINs.

The following table presents the two NASs reported to the PMPRB during the period July to August 2005.

As of August 31, 2005

Brand Name	Generic Name	Company
Erbix (100 mg/vial)	<i>Cetuximab</i>	Bristol-Myers Squibb Canada Co.
Velcade (3.5 mg/vial)	<i>Bortezomib</i>	Janssen-Ortho Inc. ■

Report on New Patented Drug – Telzir

Brand Name:	Telzir
Generic Name:	<i>(fosamprenavir calcium)</i>
DIN:	02261545 700 mg tablet 02261553 50 mg/mL suspension
Patentee:	GlaxoSmithKline Inc.
Indication – as per product monograph:	In combination with low dose ritonavir for the treatment of HIV-1 infection in adult patients, in combination with other antiretroviral agents
Notice of Compliance:	December 10, 2004
Date of First Sale:	January 26, 2005 700 mg tablet February 28, 2005 50 mg/mL suspension
ATC Class:	J05AE07 <i>Antiinfectives for Systemic Use, Antivirals for Systemic Use, Direct Acting Antivirals, Protease Inhibitors</i>

Under our transparency initiative, we publish 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.

Application of the Guidelines

Summary

The introductory prices of Telzir were found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison and the prices did not exceed the prices in the other comparator countries where Telzir was sold.

Scientific Review

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

The HDAP recommended Fortovase (*saquinavir*), Invirase (*saquinavir*), Viracept (*nelfinavir*), Crixivan (*indinavir*), Reyataz (*atazanavir*) and Kaletra (*lopinavir/ritonavir*) as the most appropriate comparators for Telzir 700 mg tablet, and the oral liquid dosage forms of Viracept and Kaletra for Telzir 50 mg/mL. These products share the same fourth level ATC class, and are all indicated for the treatment of HIV-1 infection in adults.

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. (See the *Compendium of Guidelines, Policies and Procedures* <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=135&mp=73> for a more complete description of the Guidelines and the policies on TCCs.)

The PMPRB's Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The recommended comparable dosage regimens for Telzir and the comparators are based on their respective product monographs and the U.S. Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents.

Price Review

Under the Guidelines, the introductory price of a new category 3 drug product will be presumed to be excessive if it exceeds the price of all of the comparable drug products in the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations* (Regulations). The prices of Telzir were within the Guidelines as the daily cost of therapy did not exceed the cost of therapy with the comparator medicines.

Name	Strength	Dosage Regimen/per day	Unit Price	Cost per day
Telzir + Norvir Sec	700mg/tablet + 100mg/capsule	2 tablets + 2 capsules	\$7.7647/tablet ¹ + \$1.3354/capsule ²	\$15.5294 + \$2.6708
				Total = \$17.1558
Crixivan + Norvir Sec	400mg/capsule + 100mg/capsule	4 capsules + 2 capsules	\$2.6933/capsule ² + \$1.3354/capsule ²	\$10.7732 + \$2.6708
				Total = \$13.4440
Crixivan + Norvir Sec	400mg/capsule + 100mg/capsule	4 capsules + 4 capsules	\$2.6933/capsule ² + \$1.3354/capsule ²	\$10.7732 + \$5.3416
				Total = \$16.1148
Fortovase + Norvir Sec	200mg/capsule + 100mg/capsule	10 capsules + 2 capsules	\$1.0200/capsule ² + \$1.3354/capsule ²	\$10.2000 + \$2.6708
				Total = \$12.8708
Fortovase + Norvir Sec	200mg/capsule + 100mg/capsule	4 capsules + 8 capsules	\$1.0200/capsule ² + \$1.3354/capsule ²	\$4.0800 + \$10.6832
				Total = \$14.7632
Invirase + Norvir Sec	200mg/capsule + 100mg/capsule	10 capsules + 2 capsules	\$1.8200/capsule ² + \$1.3354/capsule ²	\$18.2000 + \$2.6708
				Total = \$20.8708
Invirase + Norvir Sec	200mg/capsule + 100mg/capsule	4 capsules + 8 capsules	\$1.8200/capsule ² + \$1.3354/capsule ²	\$7.2800 + \$10.6832
				Total = \$17.9632
Kaletra	133.3/33.3mg/capsule	6 capsules	\$3.2944/capsule ²	\$19.7664
Viracept	250mg/tablet	10 tablets	\$1.8200/tablet ²	\$18.2000
Reyataz	200mg/capsule	2 capsules	\$9.9000/capsule ²	\$19.8000

1. PPS Pharma, 2005
2. Ontario Drug Benefit Formulary, 2005

Name	Strength	Dosage Regimen/per day	Unit Price	Cost per day
Telzir + Norvir Sec	50mg/mL oral suspension + 80mg/mL oral liquid	28mL (1400mg) + 2.5mL (200mg)	\$0.5546/oral suspension ¹ + \$1.0681/oral liquid ²	\$15.5288 + \$2.6703
				Total = \$18.1991
Kaletra	80/20mg/mL oral liquid	5mL	\$1.9767/oral liquid ²	\$9.8835
Viracept	50mg/g powder for solution	50g (2500mg)	\$0.3640/powder for solution ²	\$18.2000

1. PPS Pharma, 2005

2. Ontario Drug Benefit Formulary, 2005

In 2005, Telzir 700 mg/tablet was being sold in four of the seven countries listed in the Regulations, that is France, Italy, the United Kingdom and the United States; Telzir 50 mg/mL suspension was being sold in France, Switzerland and the United Kingdom. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in those countries; the prices of Telzir in Canada were the lowest of those countries, below the median international price.

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. ■

Patented Medicine Prices Review Board – September 22 & 23, 2005 Meeting

Board Members welcomed Dr. Brien Benoit as Vice-Chairperson. Until the position of Chairperson is filled, Dr. Benoit has all the powers and functions of the Chairperson.

The Board

- ▶ was briefed on the
 - National Pharmaceuticals Strategy
 - NPDUIS projects

- analyses in the context of its consultation on price increases
- monthly compliance and investigation activities
- environmental scan process
- ▶ approved the
 - next steps in the consultation on the proposed amendments to the *Patented Medicines Regulations, 1994* ■

Summary Reports are available on our Web site under Patented Medicines; Reports on New Patented Drugs for Human Use.

Evidence/ References:

The references are available on our Web site, under Patented Medicines; Reports on New Patented Drugs for Human Use; Telzir.

The next Board meeting is scheduled for December 15 and 16, 2005.

For additional information, please contact the Secretary of the Board at:

1 877 861-2350, or
(613) 954-8299, or at
sdupont@pmprb-cepmb.gc.ca.

Questions and Comments

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 Web site, please contact our Communications Officer at pmprb@pmprb-cepmb.gc.ca. ■

Upcoming Events



**To order our publications, 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

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TTY: (613) 957-4373