Patented Medicine Prices Review Board

PMPRB NEWSletter

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Inside...

Board Members

Chairperson:
Robert G. Elgie, C.M., LL.B., M.D., F.R.C.S. (C), LL.D. (hon.)

Vice-Chairperson:
Réal Sureau, F.C.A.

Member
Tim Armstrong, Q.C., O. Ont.

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 April 2004.

May 6:	Dr. Elgie and Wayne Critchley participated in the Canadian Policy Briefings for the Harkness Fellows and Associates hosted by the Canadian Health Services Research Foundation. The Harkness Fellowships are a key component of the U.S. Commonwealth Fund's International Program in Health Care Policy and Practice, which seeks to build a worldwide network of policy-oriented health care researchers and stimulate innovative thinking on health policy and practice in the United States and other industrialized countries. More information on The Commonwealth Fund and the Harkness Fellows is available at **http://www.cmwf.org**.
May 13-14:	Wayne Critchley gave a presentation at the Cambridge Pharma Consultancy Conference, in the U.K.
May 13 and June 25:	Members of Board Staff met with representatives of the Republic of South Africa on the role of the PMPRB.
May 13 and 20:	Réal Sureau gave presentations to members of *Les Fonds d'investissement de la fédération des médecins omnipraticiens du Québec*, in Québec City and in Montréal, on the role of the PMPRB.
May 18:	The Board held its second quarterly meeting of 2004. A summary of the Minutes of the meeting are available on page 8.
May 25:	The Board issued a Notice of Hearing in the matter of Sanofi-Synthelabo Canada Inc. (Sanofi) and the price of the patented drug product Fasturtec. On June 25, the Board concluded proceedings by accepting a Voluntary Compliance Undertaking (VCU) by Sanofi. More information on this matter appears on page 6. Relevant documents are available on our website under Publications; Voluntary Compliance Undertakings; Fasturtec.
May 25:	Wayne Critchley gave a presentation at the Australia-Canada Conference on Population Health, held in Ottawa. His presentation, *Pharmaceutical Price Controls in Canada*, is available on our website under Publications; Speeches; 2004.
May 31:	The Human Drug Advisory Panel (HDAP) held a web/teleconference.
June 3:	The Chairperson issued an Advance Ruling Certificate (ARC) in the matter of Gilead Sciences, Inc. and the price of the patented drug product Viread, following the publication of a Notice and Comment. All relevant documents on this matter are available on our website under Publications; Advance Ruling Certificates; Viread.
June 20-23:	Dr. Elgie, Réal Sureau, Wayne Critchley, Martine Richard and Sylvie Dupont attended the Third International Justice Conference held by the Canadian Council of Administrative Tribunals (CCAT), in Toronto. Martine Richard gave a one-day workshop on "Ethics for Decision Markers: From Intuition to Application". More information on the conference and on CCAT is available at **www.ccat-ctac.org**.

Senior Staff

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Wayne Critchley

Secretary of the Board:
Sylvie Dupont

Director of Policy and Economic Analysis:
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Comings and Goings!

- The PMPRB welcomes three co-op students: Krista Robertson, Robert Lovell and Wei Zhao.
- Louis-Philippe Dubrule, an articling student, also joined the Legal Services team for a period of 10 months.
- We wish the best of luck to our colleague Monique Lesage who accepted an assignment with the Library of Parliament.
- Denise Lemire joined the Policy and Economic Analysis Branch to replace Monique Lesage during her assignment. Denise was formerly with the Public Service Commission.
- Kim Pyefinch left the PMPRB to pursue her studies. We wish Kim the best of luck.
- We welcome Bindu Islam from Health Canada who joined the Policy and Economic Analysis Branch as Senior Economist.
- Colette Plourde of the Compliance and Enforcement Branch has accepted an assignment at the Canada Revenue Agency. Best of luck. ■

Message from the Chair

Over the last few years, we have witnessed Canadians' growing concern with the future of our public health care system and its sustainability. We have been reminded of the increasingly important role played by drugs in our health care system. We have also noted the desire for more information on how the system works and what is needed to make it more responsive to the needs of Canadians. As part of its reporting role, the PMPRB provides comprehensive analysis on pharmaceuticals to better assist decision makers.

In this issue of the NEWSletter, we present a series of brief articles which deal with several aspects of pharmaceutical trends as reported by the PMPRB, the Canadian Institute for Health Information (CIHI) and the Organisation for Economic Co-operation and Development (OECD). ■

Robert G. Elgie
Chairperson

Pharmaceutical Trends in 2003

As part of its reporting mandate, the PMPRB informs Canadians on price trends of all patented medicines and on all medicines, and on research and development (R&D) by pharmaceutical patent holders.

In 2003, total sales of all drugs for human use by manufacturers in Canada increased 14.5% from 2002 to $15.0 billion, while sales of patented drugs increased by 14.8% to $10.1 billion. Patented drugs accounted for 67.4% of total drug sales, unchanged from the previous year.

Manufacturers' prices of patented drugs, as measured by the Patented Medicine Price Index (PMPI) fell by 1.1% in 2003. This result continues the pattern of declines and near-negligible increases in the PMPI that began in 1993.

From 1995 to 2001, Canadian prices for patented drugs were between 5% and 12% below the median of foreign prices in the seven countries used for price comparison purposes (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States). In 2002, the prices of patented medicines in the Canadian market were about 1% higher than the median of foreign prices. However, in 2003, prices returned to the mid-1990s levels, about 5% lower than the median of foreign prices in the seven countries.

As for R&D, patentees reported total expenditures of $1.19 billion in 2003, a decrease of 0.5% over the $1.2 billion in the previous year. The R&D-to-sales ratio for all patentees declined to 8.8% in 2003 from 9.9% in 2002 as did the R&D-to-sales ratio for members of Rx&D to 9.1% from 10.0% the previous year. Expenditures on basic research fell by 9.3% in 2003 relative to 2002, totaling $180 million in 2003 and representing 15.7% of current R&D expenditures.

More detailed information will be available on our website once the Annual Report for 2003 has been tabled in Parliament and made public. ■

National Drug Expenditure Trends

In June 2004, the Canadian Institute for Health Information (CIHI) released its latest edition of *Drug Expenditure in Canada*. This report is recognized as the national reference for retail spending on drugs in Canada and is based on CIHI's National Health Expenditure database. The report provides annual estimates of spending by Canadians on drugs from 1985 through to 2003. Included as drugs are prescribed medications, over-the-counter drugs and personal health supplies. Excluded from the estimates are drugs dispensed in hospitals and in other institutions.

CIHI estimates total expenditure for drugs and personal health supplies other than in hospitals and institutions to have grown to $19.6 billion in 2003, an increase of 8.1% from $18.1 billion in 2002. This compares with a 9.6% average annual growth rate over the 1985 to 2002 period. The share of health expenditure devoted to drugs has risen from 9.5% in 1985 to 16.2 % in 2003. Among the provinces in 2003, the share is highest at 18.7 % in Quebec and lowest at 12.1% in British Columbia.

Prescribed drugs have accounted for an increasing share of total drug spending, rising from 67.5% in 1985 to an estimated 81.6% in 2003. CIHI estimates the public sector share of prescribed drug expenditure at 47.2% in 2003. This share ranges across provinces from a low of 29.8% in Prince Edward Island to a high of 53% in Manitoba.

The average Canadian spent $537 on drugs in 2001. Per capita spending jumped to $578 in 2002 and to $620 in 2003 – increasing annually at rates of 7.6% and 7.2% respectively.

The CIHI report provides an international comparison of drug spending in 2001 for 11 member countries of the Organisation for Economic Co-operation and Development. Canada has the fourth highest ratio of drug expenditure to total health expenditure – behind Hungary (1), France (2) and Japan (3).

Public sector spending on drugs has risen from 14.7% of the total drug bill in 1975 to an estimated 38% in 2003. During the five-year span from 1997-1998 to 2002-2003, total provincial and territorial program spending rose by an average rate of 4.9% per year[1], health budgets increased on average by 7.4% and drug spending rose by 13.5%.

The PMPRB is collaborating with the CIHI on the assessment of drug utilization and expenditures within the public sector as part of the National Prescription Drug Utilization Information System. The data from *Drug Expenditure in Canada* provides a valuable reference for this collaboration. ■

1 Source: Finance Canada Fiscal Reference Tables at **www.fin.gc.ca**.

OECD Report on Pharmaceutical Expenditure

In June 2004, the Organisation for Economic Co-operation and Development (OECD) released its annual update of health system statistics for developed countries, for the year 2002. In our July 2003 NEWSletter, we reported the key trends in pharmaceutical expenditure for the years 1990, 2000 and 2001. Figure 1 provides an update of pharmaceutical expenditure for 2002 as reported in the 2004 version of the OECD's health care database. This summary is limited to data for Canada and the seven countries used by the PMPRB in international price comparisons.

Figure 1 – Pharmaceutical Expenditure as a Share of Total Health Care Expenditure

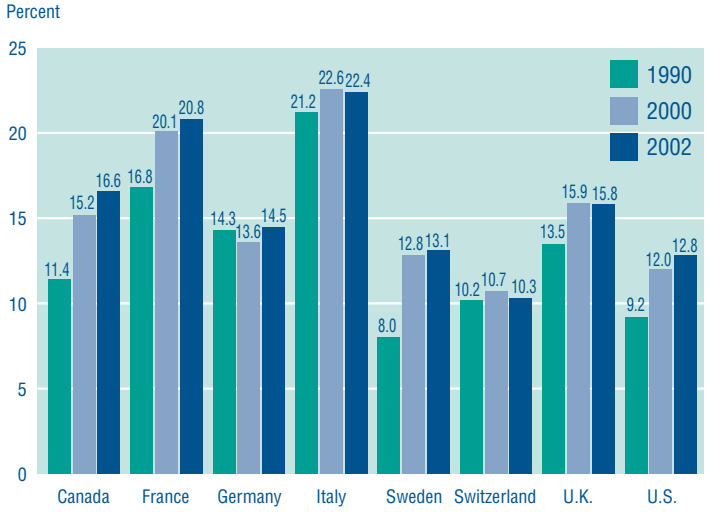

Figure 2 – Pharmaceutical Expenditure as a share of GDP

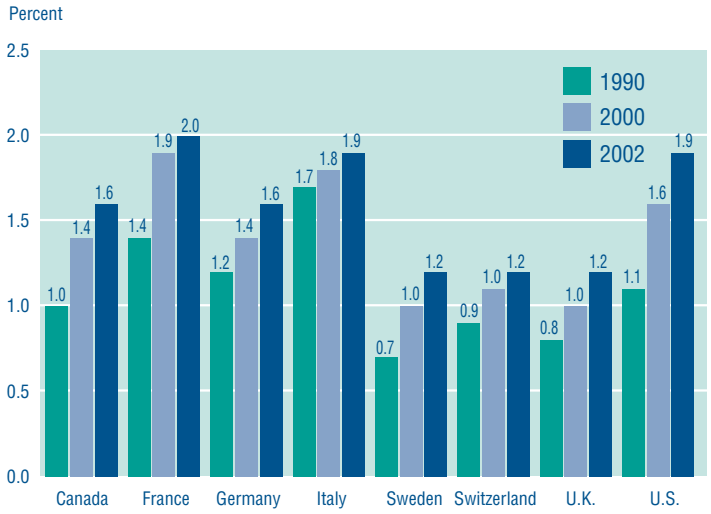

Figure 3 – Pharmaceutical Expenditure per capita

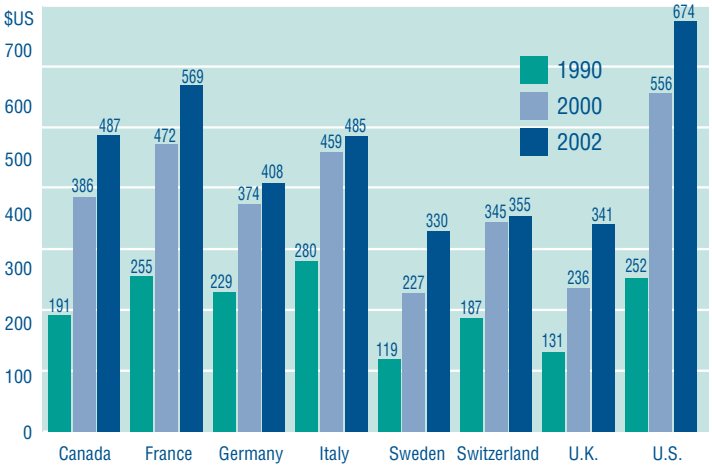

Figure 1 shows pharmaceutical expenditure[2] as a share of total health care expenditure for the years 1990, 2000 and 2002. Pharmaceutical expenditure accounted for 16.6% of total health care expenditure in Canada in 2002, up from 15.2% in 2000 and 11.4% in 1990.[3] Increases have also occurred in France, Sweden and the United States. In contrast, the share of pharmaceuticals has varied little in Germany, Italy and Switzerland. Shares range widely among countries represented in Figure 1, from 10.3% in Switzerland to 22.4% in Italy. Canada's share puts it near the center of this range.

Figure 2 portrays pharmaceutical expenditure as a percentage of Gross Domestic Product (GDP). All countries spent a greater share of GDP on drugs in 2002 than they had in 1990, and all have seen increases relative to 2000. Canada's ratio, at 1.6%, remains well within the range of values reported for the other countries.

Figure 3 shows pharmaceutical expenditure per capita in U.S. dollars for 1990, 2000 and 2002 (converted at OECD's Purchasing Power Parity exchange rates). Canadian per capita pharmaceutical spending more than doubled between 1990 and 2002, rising by about 25.9% between 2000 and 2002. All other countries saw similar increases. ■

2 The OECD defines "pharmaceutical expenditure" as "total expenditure on pharmaceutical and other medical non-durables." This comprises "medical preparations, branded and generic medicines, drugs, patent medicines, serums, and vaccines, vitamins and minerals and oral contraceptives." It also includes non-pharmaceutical items such as toothpaste and condoms. The statistics reported encompass expenditure by both private and public sectors. Pharmaceutical expenditure may or may not include the value of drugs dispensed in hospitals, depending on the country.

3 In reporting results for Canada, the OECD uses estimates from the Canadian Institute for Health Information (CIHI) for both pharmaceutical expenditure and total health care expenditure. The pharmaceutical expenditure share for Canada in Figure 1 differs from CIHI publications due to differences in reporting of total health care expenditure to the OECD, which excludes research, training and certain elements of hospital expenditure.

The Chair issues an Advance Ruling Certificate – Viread

On April 13, 2004, the Board published a Notice and Comment proposing to issue an Advance Ruling Certificate (ARC) with respect to the patented medicine Viread.

Viread (tenofovir disoproxil fumarate) is used in the treatment of HIV-1 infection and has been sold in Canada by Gilead Sciences, Inc. since March 2004. Following negotiations, Gilead and Board Staff agreed that Gilead would propose to sell Viread in Canada at an average price not to exceed $15.1250 per 300 mg tablet.

Ministers of Health in the provinces and territories and other interested parties were invited to make submissions regarding the proposed ARC on or before May 7, 2004. Gilead and Board Staff were given the opportunity to submit written responses to any submissions no later than May 25, 2004.

Board Staff has recommended that it is appropriate for the Board to conclude that it would not have sufficient grounds to make an order under section 83 of the *Patent Act* (Act) with respect to Viread, taking into consideration the factors set out in section 85 of the Act, for these reasons:

a. The proposed Canadian price in 2004 is well below the median of the international prices; it will be the second lowest of the seven comparator countries;

b. It reflects the relationship of the price of Viread to other medicines in the same therapeutic class in countries other than Canada;

c. It is consistent with the policies of the Board that patentees should seek advisory assistance with respect to the proposed price of a patented medicine;

d. Price changes in future years will be subject to the Guidelines.

The Board received one submission in response to the Notice from the Canadian Treatment Action Council (CTAC). There were no submissions from the Ministers of Health in the provinces and territories. Gilead and Board Staff filed written submissions in response to the submission from CTAC. Copies of these submissions may be obtained from the Secretary of the Board.

CTAC was of the view that the ARC should not be issued. In addition to concerns about escalating prescription drug prices generally, the price of Viread in particular, and the potential for the strategic introduction of drug products in order to maximize prices, CTAC raised two concerns specific to the application of the Guidelines: the results of the Therapeutic Class Comparison (TCC) test; and the ability for Gilead to seek and obtain from the PMPRB a recategorization of Viread as a category 2 medicine and potential price increases should that occur.

As set out in the Notice, the review by Board Staff concluded that the proposed price of Viread exceeds the maximum non-excessive (MNE) price under the Guidelines based on the TCC test and, in particular, exceeds the price of Ziagen on a cost per day basis. For purposes of an ARC, however, it is necessary to consider if there would be grounds to make an order under section 83 of the Act taking into consideration all of the factors set out in section 85. Subsection 85(1)(c) of the Act states that the Board shall take into consideration "the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada." Among other things, Viread as the first and only nucleotide in the 4th level of the Anatomical, Therapeutic, Chemical (ATC) System class of nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs) is sold at a premium to the nucleosides in the class in all seven comparator countries. The proposed maximum non-excessive price of $15.1250 per tablet is based on the median of the ratios of the prices of Viread to Ziagen, the pivotal comparator in a TCC test and the most recent entrant in the same 4th level ATC class, in those countries. The proposed price for purposes of the ARC is 18% below the median international price for Viread and the second lowest as compared to the seven countries in the international price comparison.

With respect to concerns about the potential for a recategorization of Viread and the implications for price increases in the future, it is important to note that price changes in future years are subject to the Guidelines which will limit price increases for patented drugs to changes in the Consumer Price Index (CPI). The Guidelines make no provision for recategorization once a benchmark price has been established. In its written submission in response to the CTAC submission, Gilead acknowledged that it recognizes that Viread will be subject to the provisions of the Guidelines that limit price increases to increases in the CPI.

Having considered the submissions of CTAC, Gilead and Board Staff, and based on the facts available at this time, the Chairperson has concluded that there would not be sufficient grounds to make an order under section 83 of the Act and that it is in the public interest to issue the ARC with respect to the proposed price of the medicine Viread. The PMPRB will continue to monitor the price of Viread to ensure that it complies with the Board's Guidelines while it remains under the PMPRB's jurisdiction.

In accordance with subsection 98(4) of the Act, any review conducted for the purposes of issuing an ARC is based on the material facts available at the time of the review. Furthermore, the information relied upon for one review may not necessarily reflect the scientific information or therapeutic alternatives at the time a subsequent drug is reviewed. Neither the TCC test nor any other information provided in the context of the ARC should be relied upon for any purpose other than its stated purposes 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. ■

Nicoderm, Hoechst Marion Roussel Canada Inc. – Update

In our April 2004 NEWSletter, we reported that although judicial review applications in the HMRC case had not yet been heard on the merits, a number of interlocutory matters had been dealt with by the Federal Court and the Federal Court of Appeal. It was recently announced that the Federal Court will be hearing the judicial review applications in the HMRC case on **November 22, 2004**.

The Nicoderm matter was first initiated in April 1999 with the issuance of a Notice of Hearing by the Chairperson of the Board to consider whether, under sections 83 and 85 of the *Patent Act* Nicoderm is being, or has been sold by 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.

VCUs accepted during the last quarter

Fasturtec – Sanofi-Synthelabo Canada Inc.

PMPRB

Fasturtec is a medicine indicated for the treatment and prophylaxis of hyperuricemia in paediatric and adult cancer patients, and is administered intravenously in a hospital setting. It has been sold under Health Canada's Special Access Program since May 21, 2002.

All documents relevant to this matter are available on our website under Publications; Voluntary Compliance Undertakings; Fasturtec.

The Board has concluded proceedings commenced in May 2004 in regard to the medicine Fasturtec by accepting a Voluntary Compliance Undertaking (VCU) by Sanofi-Synthelabo Canada Inc. (Sanofi). Under the terms of the VCU, Sanofi shall lower the price of Fasturtec from $295.00 per vial to about $125.00 per vial, effective by July 26, 2004.

Among other things, the VCU benefits Canadian consumers and the healthcare system by immediately reducing the price of Fasturtec to less than half the current average selling price and ensures that no customer in Canada shall pay a price higher than the maximum non-excessive (MNE) price in the future. Under the terms of the VCU, the price will now be within the PMPRB Guidelines and will remain so while it is under the Board's jurisdiction, at least until 2015.

The terms of the VCU require that the average selling price for 2004 not exceed the MNE price of $124.7854. Furthermore, Sanofi will offset excess revenues received from May 21, 2002 to December 31, 2003 by providing rebates directly to each of the customers, 28 hospitals, that purchased Fasturtec over this period at the higher price.

In its submission, Board Staff noted that Sanofi intends to maintain a list price for Fasturtec which is substantially higher than the reduced price, despite its undertaking that no customer in Canada would pay a price higher than the reduced price. As this may raise a novel issue, Board Staff has recommended to the Board that it initiate a policy review. The Board will report further on this matter in the fall.

The Fasturtec matter was initiated on May 20, 2004 with the issuance of a Notice of Hearing to consider whether under sections 83 and 85 of the *Patent Act* the medicine Fasturtec had been, or was being, sold by Sanofi at a price that exceeds the Guidelines. A pre-hearing conference was scheduled for July 6, 2004, and the hearing was to commence on August 23, 2004. On June 25, 2004, Sanofi filed a VCU negotiated with Board Staff to resolve the issues raised by the Notice of Hearing. Sanofi and Board Staff each made submissions supporting approval of the VCU. The acceptance of the VCU concluded the proceeding commenced by the issuance of the Notice of Hearing. ■

Prolastin – Bayer Inc.

PMPRB

Prolastin is a drug product derived from human plasma that is indicated for a rare genetic disorder, specifically, chronic replacement therapy of individuals having congenital deficiency of alpha 1-PI (alpha 1-antitrypsin deficiency) with clinically demonstrable panacinar emphysema.

On July 9, the Chairperson accepted a VCU submitted by Bayer Inc. with respect to the price of the patented drug product Prolastin.

The terms of the VCU require that for purposes of the Board's Price Guidelines, the maximum non-excessive (MNE) price of Prolastin in 2003 is $288.00; the average transaction price of Prolastin in 2003 does not exceed $288.00 per vial.

Bayer has also undertaken to sell Prolastin in Canada during 2004, 2005 and 2006 at a price that will not exceed the lower of (a) the $288.00 MNE price in 2003 adjusted for CPI increases in 2004, 2005 and 2006 and (b) the median international prices in those years. In the event that Bayer proposes to increase the price of Prolastin in any succeeding year after 2006 by more than its CPI-adjusted price as determined in accordance with the methodology established in the Guidelines, it further undertakes to provide written notification to the PMPRB and satisfactory written evidence in support of the rationale for any such price increase. In light of the particular circumstances of this case, the Chairperson accepted the VCU. The PMPRB reserves its right to commence an investigation in appropriate circumstances pursuant to its Compliance and Enforcement Policy. ■

Starnoc – Servier Canada Inc.

PMPRB

Starnoc is indicated for the short-term treatment and symptomatic relief of insomnia in patients who have difficulty falling asleep. Under the *Patent Act*, the Board has no authority to order that funds paid to the Government of Canada to offset excess revenues be used for certain purposes. Pursuant to section 103 of the Act however, the Minister of Health may enter into agreements with provincial and territorial counterparts regarding the distribution of funds collected in respect of a VCU.

VCUs are available on our website under Publications; Voluntary Compliance Undertakings.

The PMPRB has concluded an investigation into the price of the drug product Starnoc, resulting in a price reduction of more than 40%.

On July 15, the Chairperson accepted a VCU by Servier Canada Inc., the terms of which require that, for the purposes of complying with the Board's Price Guidelines, Servier will lower the prices of Starnoc 5 mg and 10 mg capsules from $1.00 and $1.23 to $0.4964 and $0.7475, respectively.

To offset excess revenues received during the period from January 1, 2004 to June 30, 2004, Servier will make a payment of $739,739.99 to the Government of Canada. To offset the remaining excess revenues of $3.8 million from sales in previous years, Servier will maintain the prices of all of its patented medicines at levels below the maximum prices allowed under the Guidelines until the end of June 2006. In the event that any excess revenues have not been offset by the end of June 2006, Servier has undertaken to make a payment to the Government of Canada by July 30, 2006 for such amount.

Starnoc has been sold in Canada since 2000. The Chairperson decided to approve the VCU to close this investigation in light of the particular circumstances of this case. The prices of Starnoc will remain under the PMPRB's jurisdiction until the expiry of the patent in June 2007. ■

A Conference on Drug Utilization Indicators, Drug Standards and Drug Statistics Methodologies

will be held on November 24 and 25 in Ottawa. The purpose of the conference is to offer an opportunity for the convergence of practices and thinking with regards to drug standards and drug statistics methodologies.

The conference will present to Canadian stakeholders and participants:

- the importance of standards to support the appropriate use and interpretation of drug information;
- education and discussion opportunities on the development of standards and drug statistics methodologies; and
- various national initiatives that are underway and will benefit from access to standardized data and methodologies.

This conference is being organized by the Canadian Institute for Health Information (CIHI), the Patented Medicine Prices Review Board (PMPRB), the Canadian Coordinating Office for Heath Technology Assessment (CCOHTA) and the Therapeutic Product Directorate (TPD) at Health Canada.

This event will assemble a group of experts from within and outside Canada. We are hoping that many of our stakeholders will be able to attend.

Additional information on the program will be available on the PMPRB website in the fall. ■

New Patented Medicines Reported to the PMPRB

As of June 30, 2004, there were 45 new DINs for human use (representing 26 medicines) reported to the PMPRB for the year 2004. Nine of these new medicines are new actives substances, representing 18 DINs.

The following table presents the new active substances reported to the PMPRB for the period January to June 2004. ■

Brand Name	Generic Name	Company
Neulasta (10 mg/ml)	pegfilgrastim	Amgen Canada Inc.
Iressa (250 mg/tab)	gefitinib	AstraZeneca Canada Inc.
Levitra (5 mg/tab; 10 mg/tab; 20 mg/tab)	vardenafil hydrochloride	Bayer Inc.
Gadovist 1.0	gadobutrol	Berlex Canada Inc.
Viread (300 mg/tab)	tenofovir disoproxil fumarate	Gilead Sciences Inc.
Avodart (0.5 mg/cap)	dutasteride	GlaxoSmithKline Inc.
Axert (6.25 mg/tab; 12.5 mg/tab)	almotriptan malate	Janssen-Ortho Inc.
Cetrotide (0.25 mg/vial; 3 mg/vial)	cetrorelix acetate	Serono Canada Inc.
Adderall XR (5 mg/cap; 10 mg/cap; 15 mg/cap; 20 mg/cap; 25 mg/cap; 30 mg/cap)	mixed salt amphetamine	Shire BioChem Inc.

Form 2: Filing electronically

In our April 2003 NEWSletter, we strongly encouraged electronic reporting of the information required under the *Patented Medicines Regulations*. In order to facilitate the processing of this electronic information, patentees who send this information by e-mail are asked to submit it to compliance@pmprb-cepmb.gc.ca. The compliance officer responsible for the patentee can also be copied on the message.

For detailed information on the method that a patentee should use to file its price and sales data electronically, please refer to the April 2003 NEWSletter. ■

The next Board meeting is scheduled for September 23, 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.

Patented Medicine Prices Review Board – May 18, 2004 Meeting

At its meeting, the Board

- approved:
  - The 2003 Annual Report.
- received briefings on:
  - The study of the *Pharmaceutical Trends of Non-Insured Health Benefits (NIHB) Program*. The study was conducted as a National Prescription Drug Utilization Information System (NPDUIS) project and is scheduled for release in the fall;
  - Summary Report of results of price review: Bextra;
  - Ongoing activities under the NPDUIS. ■

Report on New Patented Drugs – Axert

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.

Brand Name:	Axert
Generic Name:	almotriptan
DIN:	02248128 6.25 mg tablet 02248129 12.5 mg tablet
Patentee:	Janssen-Ortho Inc.
Indication – as per product monograph:	For the acute treatment of migraine with or without aura in adults.
Notice of Compliance:	September 29, 2003
Date of First Sale:	January 9, 2004
ATC Class:	N02CC05 *Nervous system, Analgesics, Antimigraine Preparations, Selective Serotonin (5HT1) Agonists, Almotriptan.*

Application of the Guidelines

Summary

The introductory prices of the Axert drug products 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 range of prices in other comparator countries where Axert is sold.

Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Axert be reviewed as a category 3 new drug product (provides moderate, little or no therapeutic advantage over comparable medicines).

Migraine is characterized by severe headaches accompanied by chronic head pain, nausea, vomiting, and photophobia. The exact mechanism of migraines still remains not fully understood, however, they are thought to be caused by alterations in the activity of serotonin 5-hydoroxytyptamine (5-HT).

Axert is a selective 5-HT1 receptor agonist and belongs to a group of drugs also known as "*triptans*". The HDAP identified four agents in the same 4th level ATC that are indicated for the treatment of acute migraine with or without aura in adults, Imitrex (sumatriptan), Amerge (naratriptan), Maxalt (rizatriptan) and Zomig (zolmitriptan).

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 Axert and the comparators are based on the respective product monographs and supported by clinical literature.

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 PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs.

Price Review

Under the Guidelines, the introductory price for 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*.

The introductory prices of Axert were within the Guidelines as the daily cost of therapy did not exceed the cost of therapy with the comparator medicines.

Name	DIN	Strength	Dosage Regimen/Day	Cost per Day
Axert (almotriptan malate)	02248128	6.25 mg	1 tablet	$12.95[1]
Imitrex DF (sumatriptan succinate)	02239738	25 mg	1 tablet	$12.29[2]
Amerge (naratriptan hydrochloride)	02237821	2.5 mg	1 tablet	$12.95[3]
Maxalt (rizatriptan benzoate)	02240520	5 mg	1 tablet	$12.95[3]
Maxalt RPD (rizatriptan benzoate)	02240518	5 mg	1 wafer	$12.95[3]
Zomig (zolmitriptan)	02238660	2.5 mg	1 tablet	$12.95[3]
Axert (almotriptan malate)	02248129	12.5 mg	1 tablet	$12.95[1]
Imitrex DF (sumatriptan succinate)	02212153	50 mg	1 tablet	$12.95[3]
Maxalt (rizatriptan benzoate)	02240521	10 mg	1 tablet	$12.95[3]
Maxalt RPD (rizatriptan benzoate)	02240519	10 mg	1 wafer	$12.95[3]

Amerge and Zomig are not included in the TCC for Axert 12.5 mg. Amerge and Zomig are not available at a higher strength, only as 2.5 mg tablets. The above TCC shows that the market for the triptan drug products is one where although many of the drugs are available in two strengths, all drugs are priced at the same level regardless of strength.

1 Price filed by Janssen-Ortho Inc.
2 *Association québécoise des pharmaciens propriétaires (AQPP)*, October 2003
3 *Liste de médicaments, Régie de l'assurance maladie du Québec*, October 2003

At the time of introduction, Axert 6.25 mg was also being sold in the United States and Axert 12.5 mg was sold in six of the seven countries, including France, Germany, Italy, Sweden, the United Kingdom, and the United States. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in these countries; the price of Axert 6.25 mg was lower than the price in the United States, and the price of Axert 12.5 mg was the second highest of the six countries in which it was sold, above the median international price.

Evidence/ References:

The references are available on the PMPRB website, under Publications, Patented Medicines; Reports on New Patented Drugs; Axert.

The comparators and dosage regimen referred to in the Summary Report have been selected by Board 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. This publication is also part of the PMPRB's commitment to make its price review process more transparent.

The information contained in the PMPRB's Summary Report 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. ■

Access our enhanced website!

As mentioned in our last issue, we launched our enhanced website in June. It offers visitors access that is more user-friendly, interactive and appealing.

Among the site's new features is the opportunity to subscribe to our mailing list to receive paper or electronic copies of our publications (NEWSletter, Annual Report). The site's layout and presentation have also been re-designed in order to ensure easier navigation and better meet the needs of Internet surfers.

We hope that the PMPRB's new website will help patentees, consumers and other stakeholders gain a better understanding of our mandate and role.

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.

Have a pleasant visit! ■

For more information on our website, please contact our Communications Officer, Anne-Marie Labelle, at alabelle@pmprb-cepmb.gc.ca. Subscriptions to the PMPRB e-mail or mailing lists, as well as requests for publications, should be forwarded to Elaine McGillivray at Elaine@pmprb-cepmb.gc.ca.

We look forward to hearing from you!

Upcoming Events

July
27
Rx&D Industrial Pharmacy Studentship Program, Toronto

August 31-September 1
31-1
International Quality and Productivity Centre: Drug Patent Law Reform, Ottawa

August
12
Rx&D Industrial Pharmacy Studentship Program, Montréal

September
23
Board Meeting, Ottawa

October
6
Human Drug Advisory Panel (HDAP)

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

November
1
October NEWSletter

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

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

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

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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