Patented Medicine Prices Review Board

PMPRB NEWSletter

Volume 6, Issue No. 3
July 2002

PmPrB Symposium 2002

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 April 2002

May 15:	Wayne Critchley and Tanya Potashnik (Policy and Economic Analysis Branch) met with representatives of the Swedish Institute for Health Economics who were visiting Canada.
May 17:	The Board held its second quarterly meeting for 2002. A summary of the minutes appears on page 11.
May 23:	Dr. Elgie gave a presentation at Queen's University, *Drug Patents and Drug Prices — The Role of the PMPRB*.
June 12:	Wayne Critchley took part in a panel discussion at the BIO 2002 Conference on *Pharmaceutical Price Controls — Lessons from Canada and the European Union*, in Toronto.
June 14-15:	Orlando Manti (Policy and Economic Analysis Branch) did a presentation at a workshop at Dalhousie University – *Using Defined Daily Doses at the PMPRB – Two Examples*.
June 20:	The PMPRB's 2001 Annual Report was tabled in Parliament.

Message from the Chair

Robert G. Elgie

Our Annual Report for 2001, released last month, shows that sales by manufacturers of patented drugs increased almost 19%, similar to the rate of increase during the last half of the past decade. The latest information from the OECD, reported in this NEWSletter, shows that Canada is not alone in experiencing increased spending on pharmaceuticals. Even though price increases have been negligible throughout this period, increased total spending and the high cost of some new drugs have raised questions with respect to the evaluation of the prices of new patented drugs.

These developments suggest that our Symposium 2002, to be held on October 7 and 8 in Ottawa, will be timely. The topic for the Symposium is "Current Issues in Pharmaceutical Price Regulation in Canada." It is intended to provide a forum to share information and views on current issues in drug price regulation for the benefit of our stakeholders and the general public as well as for the PMPRB in carrying out its mandate. We are delighted that many of the experts and leaders in this field, from Canada and abroad, have agreed to participate. We hope you will be able to join the many stakeholders who have already registered to take part in this conference.

We look forward to seeing you at Symposium 2002! ■

Robert G. Elgie,
Chairperson

For more information on the Symposium and to register on-line, visit our website at **www.pmprb-cepmb.gc.ca** — click on PMPRB/CEPMB Symposium 2002.

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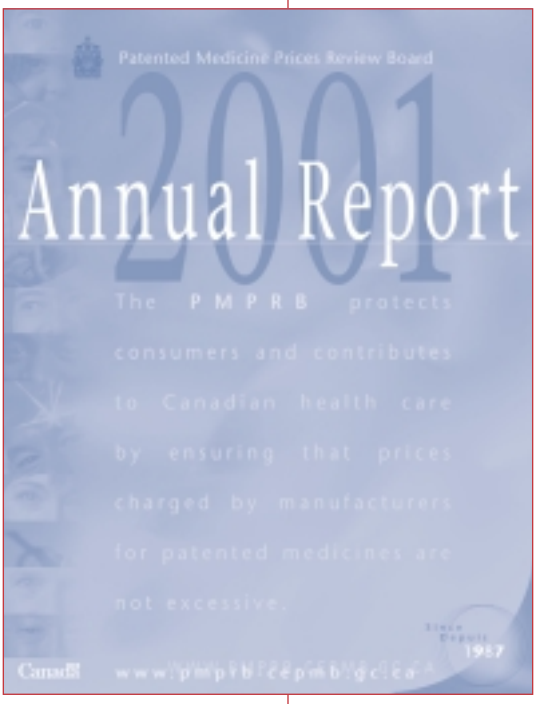
Congratulations!

Bernd E. Imken, Chief Information Systems Division for the PMPRB, has been awarded the "Best Contributed Paper in the Applications Development Section" award for his presentation at the 2002 SAS Users' Group International Conference. His presentation was entitled *Developing Master/Detail Applications Using Form & Table Viewers.* ■

PMPRB 2001 Annual Report – Highlights

The Annual Report for the year 2001 was tabled in Parliament on June 20, 2002. Here are the highlights.



Sales

Total sales of all drugs for human use by manufacturers in Canada increased 15% from 2000 to $11.5 billion.

Sales of patented drugs increased by 18.9% to $7.5 billion in 2001. Patented drugs now account for 65% of total sales, up from 43.9% in 1995.

Compliance

In total, there were 82 new patented drug products introduced in 2001, including 18 new active substances. As of March 31, 2002, 63 DINs had been reviewed. Of those, 47 were considered to be within the Guidelines and 16 were priced at levels which appeared to be outside the Guidelines and investigations were commenced.

The PMPRB Annual Report for 2001 is available on our website under Publications; Annual Report; 2001.

Price Trends

The prices of patented drugs, as measured by the Patented Medicine Prices Index (PMPI) rose by only about 0.1% since 2000. In most years since 1988, prices of patented drugs rose by less than the Consumer Price Index (CPI).

Since the mid-1990s Canadian prices for patented drugs have remained between 5% to 12% below the median of foreign prices. This trend continued in 2001 with Canadian prices 5% below median international prices in the seven countries used for price comparison purposes (lower than the U.S., Switzerland, the U.K. and Germany, and higher than Italy, France and Sweden).

Research and Development

Patentees reported total R&D expenditures of $1.0 billion in 2001, an increase of 12.6% over 2000. Over the same period, their sales of all drugs rose by 15.3% causing the R&D-to-sales ratio to decline from 10.1% in 2000 to 9.9% for all patentees. The R&D-to-sales ratio for members of Rx&D remained at 10.6%, unchanged from 2000.

Expenditures on basic research increased by 2.5% in 2001 to reach $163.1 million, but its share of total R&D continued to decline from 17.8% in 2000 to 16.1% in 2001. This is the lowest proportion of total R&D spending on basic research ever reported by patentees since the Board began reporting such information in 1988. ■

OECD Report on Pharmaceutical Expenditure

The Organization for Economic Co-Operation and Development (OECD) maintains comprehensive collection of comparable statistics on health and health systems across developed countries. When possible, the OECD updates these statistics annually and its most recent updates were released in June.

The figures shown below provide key results related to pharmaceutical expenditure taken from the 2002 version of the OECD's healthcare database.

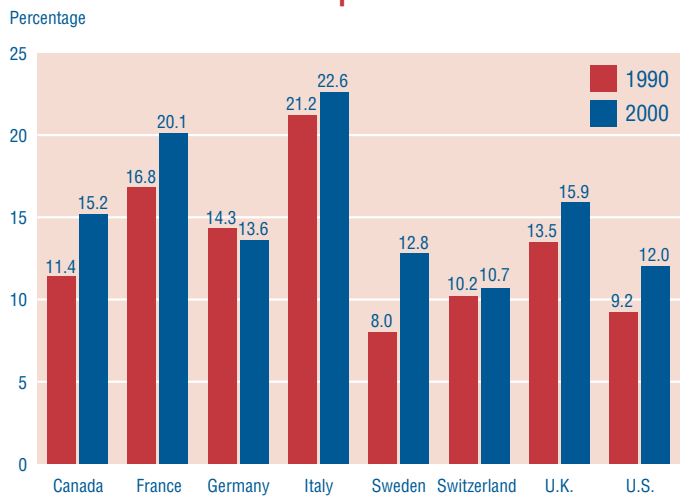
This summary is limited to Canada and the seven counties used by the PMPRB for purposes of international price comparisons.

Figure 1 shows pharmaceutical expenditure as a share of total health expenditure for the years 1990 and 2000.

The concept of "pharmaceutical expenditure" used here is what the OECD calls "total expenditure on pharmaceuticals and other medical non-durables." This comprises "medicinal 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 the public and private sectors.

All of the statistics reported here are available on-line at **www.oecd.org**. This site provides only a selection of the statistics contained by the complete OECD healthcare database, which can be purchased on CD in a user-friendly format. Each update of the database includes a set of revisions to previously released statistics. Hence, the results reported here are subject to change.

Figure 1 — Pharma Expenditure's Share of Health Expenditure



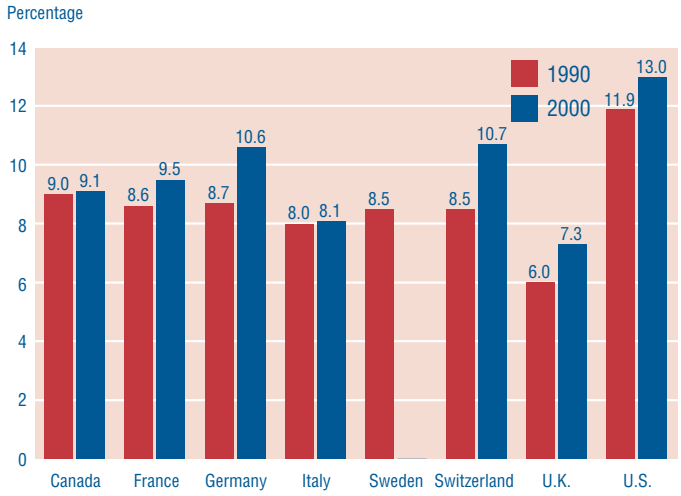
Source: OECD

Pharmaceutical expenditure accounted for 15.2% of overall health expenditure in Canada in 2000, up from 11.4% in 1990. Similar growth occurred in most other OECD countries although the shares ranged from 10.7% in Switzerland to 22.6% in Italy. Germany was the only country where pharma's share of healthcare spending fell over the past decade.

It is interesting to note that while the ratio of pharmaceutical to total health expenditure depends on both the size of pharmaceutical expenditures as well as total health expenditure, it varied considerably across the eight countries. Figure 2 shows the ratio of health expenditures as a proportion of Gross Domestic Product (GDP) for seven of the countries over the same time period. The U.S. experienced the largest ratio of spending on health expenditure at 13.0% in 2000. This explains why the U.S. has a modest ratio of pharmaceutical expenditure to total health expenditure.

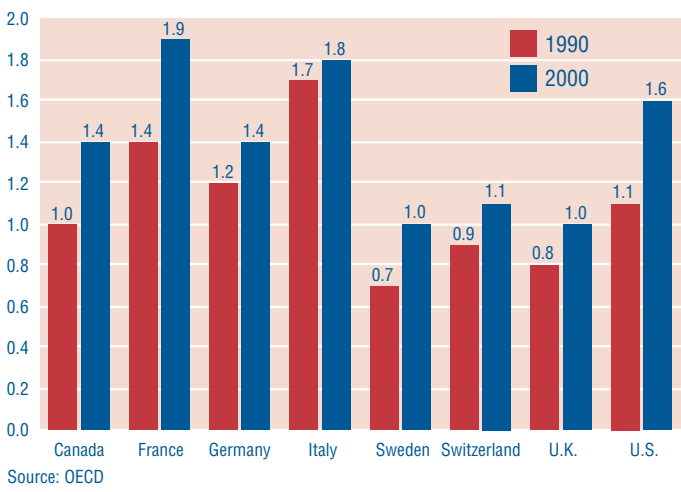
Figure 3 depicts pharmaceutical expenditure as a percentage of GDP. All countries experienced increases in their pharmaceutical expenditure-to-GDP ratio between 1990

Figure 2 — Health Expenditure As % of GDP



Source: OECD

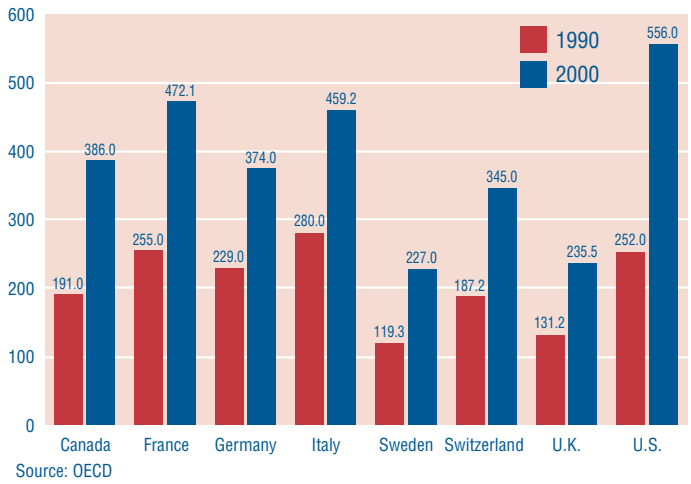
Figure 3 — Pharma Expenditure's Share of GDP



Source: OECD

Figure 4 — Pharma Expenditure per Capita

Dollars (US PPS)



Source: OECD

and 2000, with Canada's ratio rising from 1.0% to 1.4%. Canada's expenditure-to-GDP ratio nonetheless remained well within the range of shares reported for the other countries. At the upper end, Italy and France reported ratios of 1.9% and 1.8%, respectively, even though these countries enjoy relatively low patented drug prices (PMPRB, Annual Report, 2001, p. 21.)

Figure 4 shows pharmaceutical expenditure per capita for the years 1990 and 2000. The OECD reports per capita spending in $US.

As shown in figure 4, Canadian pharmaceutical expenditure per capita doubled from $191 in 1990 to $386 in 2000. Most other countries experienced a similar rate of increase. The US incurred the largest rise in per capita spending, both proportionately and in absolute amount. The increase in Canada was somewhat greater than experienced in some European countries, but overall, per capita spending on drugs in Canada remained in the mid-range of the group of countries. ■

Reports on New Patented Drugs

Under its transparency initiative, the Board publishes the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's Price Guidelines. However, the Board is not prevented from publishing the results of other reviews. In light of the interest expressed regarding the price review of Sustiva and Ziagen, as well as complaints received regarding their prices, here are the summary reviews of those two drug products which have recently been concluded.

Sustiva

Brand Name (generic): SUSTIVA (*efavirenz*)

DIN:

02239886	50mg capsule
02239887	100mg capsule
02239888	200mg capsule

Patentee: Bristol-Myers Squibb Pharmaceutical Group (previously Dupont Pharma)

Indication (as per product monograph): For the treatment of HIV-1 infection in combination with other antiretroviral agents. This indication is based on analysis of plasma HIV-RNA levels and CD4 cell counts in controlled studies of up to 24 weeks duration.

Notice of Compliance: March 19,1999

Date of First Sale: March 1999

In most cases, patents are issued before the drugs come to market. In this case, the first patent pertaining to Sustiva was issued on August 28, 2001 and it came under the PMPRB's jurisdiction at that time.

ATC Class: J05AG03
Antiretrovirals for systemic use:
non-nucleoside reverse transcriptase inhibitors (NNRTI)

Application of the Guidelines

Summary:

The introductory prices of Sustiva at the date of first sale 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 Sustiva was sold. These prices continued to be within the Guidelines in 2001 when Sustiva came under the PMPRB's jurisdiction.

Scientific Review:

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Sustiva be reviewed 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. The Guidelines provide that it may, however, be appropriate to include products from other ATC classes if they are clinically equivalent for the appropriate indication to the drug product under review. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs.

Members of the same 4th level ATC class as Sustiva include Rescriptor (delavirdine) and Viramune (nevirapine).

Like other drugs for HIV infections, Sustiva is ordinarily used in combination with other drugs. The *Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents* maintained by the HIV/AIDS Treatment Information Service (ATIS) in the U.S. (published online: **http://www.hivatis.org/trtgdlns.html#Adult**) includes Sustiva, in combination with other drugs in the list of "strongly recommended" treatments including the non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs). The *British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy* (July 2001) identify Sustiva, PIs and NNRTIs to be used in combination with dual nucleoside reverse transcriptase inhibitors (NRTIs) background therapy.

In light of the evidence that Sustiva is used in combination with two NRTIs as an alternative to a PI-based regimen, other NNRTI-based regimens or a Ziagen-based regimen in patients with HIV, the HDAP recommended NNRTIs and PIs as appropriate TCC comparators for Sustiva.

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 maintenance adult daily dose identified in individual product monographs and supported by clinical literature was recommended for comparison purposes. See table in price test section below.

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 based on the TCC test, and if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicine Regulations, 1994*.

The following TCC was established for Sustiva 200 mg capsule. It should be noted that although Rescriptor and Agenerase would have been appropriate TCC comparators from the

Name	Strength	Dosage Regimen	Unit Price[1]	Cost Per Day[2]
Sustiva (efavirenz)	200 mg capsule	600mg daily	$4.43	$13.29
Viramune (nevirapine)	200 mg tablet	200 mg twice daily	$4.65	$9.30
Crixivan (indinavir)	400 mg capsule	800 mg three times daily	$2.69	$16.14
Viracept (nelfinavir)	250 mg tablet	1250 mg twice daily	$1.82	$18.20
Norvir (ritonavir)	100 mg capsule	600 mg twice daily	$1.34	$16.08
Fortovase (saquinavir)	200 mg capsule	1200 mg three times daily	$1.02	$18.36
Ziagen (abacavir)	300 mg tablet	300 mg twice daily	$6.25	$12.50

1 Ontario Drug Benefit Formulary, 2001
2 This medication is administered on a chronic base, therefore the cost per day was used as the basis for cost comparison with the comparators.

scientific perspective, they have not been included as these drug products were under review at the time of Sustiva's review. The exclusion of these drugs does not affect the outcome of the price review.

A Reasonable Relationship Test was conducted for Sustiva 50 mg capsule and 100 mg capsule because these presentations of the medicine are intended for paediatric use and the comparators identified above are not approved for use in paediatric patients. The prices of Sustiva 50 mg ($1.11) and 100 mg ($2.22) were considered to be within the Guidelines because they bear a reasonable relationship to the price of Sustiva 200 mg. These prices appear in the Ontario Drug Benefit Formulary 2001.

The prices of all strengths of Sustiva did not exceed the price of the same drug products sold in Germany, Switzerland, the United Kingdom and the United States and therefore were determined to be within the Guidelines relative to the highest price component of the International Price Comparison Test. The Canadian prices of Sustiva were the lowest of these countries.

Evidence/ Reference considered by HDAP:

There are 17 references and they are available on the PMPRB website, under Publications, Patented Medicines; Reports on New Patented Drugs; Sustiva.

Ziagen

Brand Name (generic):	Ziagen (abacavir)	
DIN:	02240357 02240358	300 mg tablet 20 mg/mL oral solution
Patentee:	GlaxoSmithKline Inc.	
Indication (as per product monograph):	An antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection.	
Notice of Compliance:	June 4, 1999	
Date of First Sale:	June 17, 1999	
ATC Class:	J05AF06 *Antiretrovirals for systemic use:* *nucleoside reverse transcriptase inhibitors (NRTI)*	

Application of the Guidelines

Summary:

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

Scientific Review:

The PMPRB's Human Drug Advisory Panel (HDAP) reviewed Ziagen (abacavir) as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable medicines).

Members of the same 4th level ATC class as Ziagen include Videx (didanosine), 3TC (lamivudine), Hivid (zalcitabine), Zerit (stavudine) and Retrovir (zidovudine).

The *Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents* maintained by the HIV/AIDS Treatment Information Service (ATIS) in the U.S. (published online: **http://www.hivatis.org/trtgdlns.html#Adult**) include Ziagen, in combination with 3TC and Videx, among the list of "recommended as an alternative" to the "strongly recommended" non-nucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs) based regimens. The *British HIV Association (BHIVA) guidelines for the treatment of HIV-infected adults with antiretroviral therapy* (July 2001) also identify Ziagen, PIs and NNRTIs to be used in combination with dual nucleoside reverse transcriptase inhibitors (NRTIs) background therapy.

One published review of HIV therapy (Evidence/Reference 14) made the following comment with respect to choice of first-line antiviral regimens:

"On the basis of these data, it would appear reasonable to consider either a NNRTI-based regimen, a PI-based regimen or an abacavir-based regimen for first line therapy. The choice between these options should be individualized, taking account of patient preference, adherence, and lifestyle, as well as careful consideration of the future possibilities should the patient fail to achieve a sustained virologic suppression."

In light of the evidence that a Ziagen-based regimen could be considered clinically comparable to NNRTI- or PI-based regimens in some circumstances, the HDAP recommended NRTIs, NNRTIs and PIs as comparators for Ziagen.

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 maintenance adult daily dose identified in individual product monographs and supported by clinical literature was recommended for comparison purposes. See table in price test section below.

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 based on the TCC test, and if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicine Regulations, 1994*.

Ziagen 300 mg tablet:

The following TCC was established for Ziagen 300 mg tablet. It should be noted that although Rescriptor and Sustiva would have been appropriate TCC comparators from the scientific perspective, they have not been included as these drug products were under review at the time of Ziagen's review. The exclusion of these drugs does not affect the outcome of the price review.

Name	Strength	Comparable dosage regimen	Unit price	Cost per day[3]
Ziagen (abacavir)	300 mg tablet	300 mg twice daily	$6.25[1]	$12.50
Retrovir (zidovudine)	100 mg capsule	200 mg three times daily	$1.70[2]	$10.20
Retrovir (zidovudine)	300 mg tablet	300 mg twice daily	$5.10[1]	$10.20
Videx (didanosine)	100 mg tablet	200 mg twice daily	$1.54[2]	$6.16
Hivid (zalcitabine)	.75 mg tablet	.75 mg three times daily	$2.15[2]	$6.45
Zerit (stavudine)	40 mg capsule	40 mg twice daily	$4.25[1]	$8.50
3TC (lamivudine)	150 mg tablet	150 mg twice daily	$4.40[1]	$8.80
Viramune (nevirapine)	200 mg tablet	200 mg twice daily	$4.65[1]	$9.30
Crixivan (indinavir)	400 mg capsule	800 mg three times daily	$2.69[1]	$16.14
Viracept (nelfinavir)	250 mg tablet	750 mg three times daily	$1.82[1]	$16.38
Norvir (ritonavir)	100 mg capsule	600 mg twice daily	$1.34[1]	$16.08
Fortovase (saquinavir)	200 mg capsule	1200 mg three times daily	$1.02[1]	$18.36

1 Ontario Drug Benefit Formulary, 2001
2 Liste de médicaments, Régie de l'assurance maladie du Québec, 2001
3 This medication is administered on a chronic base, therefore the cost per day was used as the basis for cost comparison with the comparators.

Ziagen 20 mg/mL:

The following TCC was established for Ziagen 20 mg/mL oral solution. The comparators are of the same or comparable dosage form as Ziagen 20 mg/mL.

Name	Strength	Dosage Regimen	Unit Price	Cost Per Day[3]
Ziagen (abacavir)	20 mg/mL	600 mg daily	$0.42/mL[1]	$12.60
Retrovir (zidovudine)	10 mg/mL	600 mg daily	$0.18/mL[2]	$10.80
3TC (lamivudine)	10 mg/mL	300 mg daily	$0.29/mL[1]	$8.70
Norvir (ritonavir)	80 mg/mL	1200 mg daily	$1.07/mL[1]	$16.05
Viracept (nelfinavir)	15 mg/g	45 mg daily	$0.36/g[1]	$16.20

1 Ontario Drug Benefit Formulary, 2001
2 Liste de médicaments, Régie de l'assurance maladie du Québec, 2001
3 This medication is administered on a chronic base, therefore the cost per day was used as the basis for cost comparison with the comparators.

Evidence/ Reference considered by HDAP:

There are 34 references and they are available on the PMPRB website, under Publications, Patented Medicines; Reports on New Patented Drugs; Ziagen.

The prices of all strengths of Ziagen did not exceed the price of the same medicine sold in France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. The Canadian prices of Ziagen were the second lowest of these countries.

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. ■

New Patented Medicines Reported to the PMPRB

The list of New Patented Medicines Reported to the PMPRB is posted on our website under Publications; Patented Medicines.

Since the publication of the April 2002 NEWSletter, 12 new DINs for human use (representing eight medicines) were added to the list of New Patented Medicines Reported to the PMPRB for the period ending June 30, 2002. Three of these new medicines are new active substances, representing five DINs.

The following table presents the three new active substances reported to the PMPRB during the period April to June 2002.

Brand Name	Generic Name	Company
Starlix (60 mg/tab; 120 mg/tab; 180 mg/tab)	nateglinide	Novartis Pharmaceuticals Canada Inc.
Novorapid (100 unit/mL)	insulin aspart	Novo Nordisk Canada Inc.
Xatral (10 mg/tab)	alfuzosin hydrochloride	Sanofi-Synthelabo Canada Inc.

Filing Requirements: Patent Pending Policy

In the April 2002 NEWSletter, our article on "Filing Requirements" focused on the necessity for patentees to file timely and accurate information. The purpose of this article is to address a specific filing issue: the filing of price and sales data where the medicine is sold prior to issuance of the first patent.

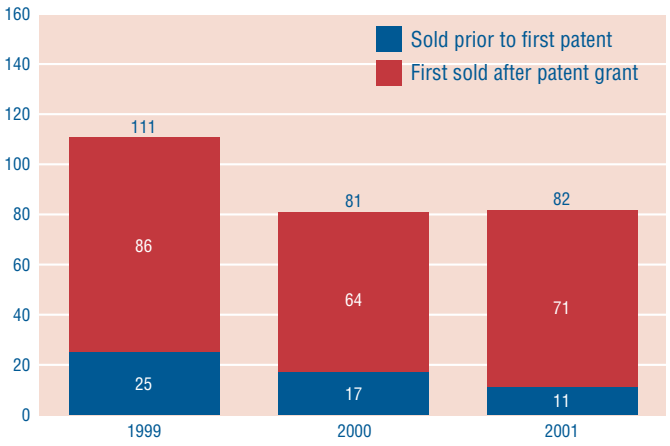
In its Bulletin dated January 1995 (Issue No. 15), the Board published its policy regarding medicines which have been sold while a patent was pending. In this regard the Board stated as follows:

> When a medicine subject to a pending patent is being sold, the Patented Medicine Prices Review Board will, when the patent is issued, **review the price at which the medicine was sold during the pre-grant infringement period**. In such cases, the Board may find that a patented medicine had been sold at an excessive price before the patent was issued and make a remedial order. [Emphasis added]
>
> The effect of this interpretation is that once a patent issued, the Board's price review jurisdiction extends retroactively to include that portion of the patent pending period for which the patentee receives retroactive patent infringement protection.

While the *Patent Act* does not require a patent applicant to file price and sales information before it actually becomes a patentee, the Board encourages patent applicants to seek the advice of the Board in establishing non-excessive prices during the patent pending period. This of course requires a preliminary review by Board Staff of the price and sales information which is submitted voluntarily by the patent applicant.

As shown in figure 1, a significant number of new patented drugs reported in recent years were being sold prior to the issuance of the first patent. The length of time between first sale and first patent varies from several months to several years. Since the issuance of the Board's directive on Patent Pending, a number of manufacturers have voluntarily filed price and sales information during the patent pending period.

Figure 1 — New Drug Products Reported to PMPRB, 1999–2001



Source: PMPRB Annual Reports

In the event they do not, the practice has been for Board Staff to request, upon the issuance of the first patent, price and sales data related to the period for which the medicine was sold during the patent pending period. Patentees who do not voluntarily file the price and sales information during the patent pending period are nonetheless reminded to ensure that this information is recorded and kept for ultimate submission to the Board.

Pre-grant infringement period is the period of time between the date upon which the patent was laid open for public inspection, ordinarily 18 months after the filing of the patent application, and the date upon which the patent is granted.

To identify new drugs that had been sold before they came under the PMPRB's jurisdiction, see the Annual Reports as of 1997.

The application of the Guidelines to drugs sold during the patent pending period raises the question of the appropriate benchmark period. In this regard, the PMPRB wishes to clarify that the appropriate benchmark period for drugs sold prior to issuance of the first patent will be the date of first sale of the medicine unless circumstances warrant otherwise. Date of first sale means the date the medicine was first sold in Canada during the pre-grant infringement period.

This clarification is consistent with the Board's position that once a patent is issued, the Board's jurisdiction extends retroactively and also with the objective of the Guidelines to review the prices of new medicines at the time of introduction.

This clarification of the Board's policy on Patent Pending is to be considered as a reminder to patentees that the price and sales data relating to a medicine during the patent pending period will be reviewed to determine the benchmark price of the patented medicine and that accordingly it is the patentee's responsibility and legal obligation to maintain such records.

Lastly, patentees are reminded that they may, during the patent pending period, request advisory assistance or an Advance Ruling Certificate for greater certainty that the proposed price of the medicine will be considered to be within the Guidelines. ■

PMPRB

If patentees have any questions on this issue, they may wish to contact the Compliance Officer assigned to their company.

A Comparison of Pharmaceutical Research and Development Spending

PMPRB

For more information on the study:

Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

by fax: (613) 952-7626

by email at:
sdupont@pmprb-cepmb.gc.ca

As announced in our Research Agenda in January 2002 and subsequent communications, we are conducting work on a study comparing R&D spending by the brand name pharmaceutical industry in Canada and other major industrialized countries. This work is meant to update and extend an earlier PMPRB study, *A Comparison of Pharmaceutical Research and Development Spending*, Study Series S-9709, released in October 1997. It is hoped that the report will be completed this fall.

Measures to be updated include:

- total R&D pharmaceutical expenditure
- R&D expenditure by type of activity
- ratios of pharmaceutical R&D to sales
- pharmaceutical R&D per capita
- the distribution of pharmaceutical R&D and sales across countries.

It is expected the study will rely on three principal data sources: R&D and sales figures reported to the PMPRB by individual manufacturers, information reported publicly by the national pharmaceutical industry associations and data collected and reported by the OECD.

The PMPRB has prepared a document outlining the proposed methodology for this study. This document is available on our website under Publications; Study Series; *A Comparison of Pharmaceutical Research and Development Spending 2002 — Methodology.* Anyone wishing to provide comments should do so in writing by August 30. ■

Questions and Comments

Contact Us!

You can now reach us on-line through our new electronic feedback form at **www.pmprb-cepmb.gc.ca** under Contact.

The feedback form is another way that you can communicate with us. If you have any questions, comments or ideas we would love to hear from you. Your feedback is important to us and there are a variety of ways you can reach us: e-mail, telephone, fax or mail and now through our on-line feedback. Let us know what you think! ■

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or write to us at:

Box L40
Standard Life Centre
333 Laurier Avenue West
14th floor
Ottawa, Ontario
K1P 1C1

Patented Medicine Prices Review Board – May 17, 2002 Meeting

At its meeting, the Board:

- Received:
  - Part 1 of the Report of the Working Group on Price Review Issues on the Guidelines for Category 3 Drugs. The Report is available on the PMPRB web-site under Working Group on Price Review Issues; Reports.
- Reviewed:
  - the 2001 Annual Report. ■

The next Board meeting is scheduled for October 8, 2002.

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.

Exchange Rates

As part of our price review process, we conduct international price comparisons (IPCs). The purpose of the IPC is to compare the price of a drug product under review with the median of prices of the same drug product sold in the seven countries listed in the *Patented Medicines Regulations, 1994*. This is designed to assist patentees in setting prices that are not excessive, in advance and to ensure that Canadian prices are not the highest of the seven countries.

For purposes of reviewing the introductory price, the exchange rates used are the simple average of the 36 monthly exchange rates for each country as published by the Bank of Canada for the 36 months ending four months before the introductory pricing period. The introductory period is the period during which the drug product is first sold as a patented medicine. ■

The exchange rates are published on our website under Frequently Requested Items. For more information on the price review process, consult the *Compendium of Guidelines, Policies and Procedures* posted on the website under Frequently Requested Items.

Upcoming Events

August
12
Deadline for the **Early Bird** registration for the **PMPRB Symposium 2002**

September
23
Presentation by Dr. Elgie to the Institute for Research on Public Policy conference: *Toward a National Strategy on Drug Plans and Coverage*, Toronto.

October
8
Board Meeting

October
7-8
PMPRB Symposium 2002 – *Current Issues on Pharmaceutical Price Regulation in Canada*, Ottawa

November
8
October 2002 NEWSletter

October
29
Presentation by Dr. Elgie to the Pharmaceutical Pricing and Reimbursement Conference, Toronto

November
25-26
Presentations by Wayne Critchley and Ron Corvari to the Pharma Summit, Montréal

December
9-10
Board Meeting

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

To ensure that our mailing list is up to date and that we better serve our readers, please take a few moments to complete this form or fax us your business card.

Name:

Title/Organization:

Address:

Postal Code:

Telephone: Fax:

E-mail:

Please return the completed form to the PMPRB, at:

Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

Fax: (613) 952-7626

E-mail:
pmprb@pmprb-cepmb.gc.ca

Toll-free number:
1 877 861-2350

Tel: (613) 952-7360

TTY: (613) 957-4373

Registration

October 7 & 8, 2002
Fairmont Château Laurier, Ottawa, Ontario

PmPrB Symposium 2002

First Name: _____ Last Name: _____

Title: _____

Organization: _____

Address: _____

City: _____ Province: _____

Country: _____ Postal Code: _____

Email: _____

Telephone: _____ Fax: _____

Special Requirements: (dietary, accessibility, other) _____

_____

Space is limited – register early!!! Registration fees include all sessions, breakfasts, lunches and a reception. 175 seats available! In order to ensure the opportunity for all PMPRB stakeholders to be represented a differential registration fee structure has been established and it may be necessary to cap the participation of certain groups.

REGISTRATION FEES	**Early Bird** (until August 12, 2002)	**Regular** (after August 12, 2002)
Non-Profit Organization Delegate (consumer and patient advocacy groups)	$425.00	$475.00
Government Delegate and Academia	$500.00	$550.00
Other Delegates	$850.00	$950.00

Symposium Registration Fee = $ _____

Plus 7% GST (# 124063884RT) = $ _____

Total Registration Fees to be paid _____ = $ _____

Method of Payment: ❑ Cheque made payable to "PMPRB/CEPMB Symposium 2002"

❑ VISA ❑ MASTERCARD ❑ AmEx

Name of Cardholder: _____

Signature of Cardholder: _____

Card Number: _____ Expiry Date: _____ /_____

Note: "Golden Planners Inc." will appear on your credit card statement.

Cancellations in writing will be accepted up to August 12, 2002, after which date no refunds will be issued. Replacements will be accepted up to September 27, 2002.

Hotel Accommodation

Fairmont Château Laurier
1 Rideau Street, Ottawa, ON

($199.00 single / double room plus applicable taxes / night)

All reservations must be made through Golden Planners Inc.
The hotel will not accept reservations directly but will issue a reservation confirmation. All reservations must be guaranteed with a credit card and must be received no later than **September 4, 2002** to reserve at the special conference rate.

Occupancy: ❑ Single ❑ Double / sharing with (name): _____

Room Type: ❑ Non-smoking ❑ Smoking

Arrival Date/Time: _____ Departure Date: _____

❑ **I authorize Golden Planners Inc. to use the above credit card to guarantee my hotel reservation,**

❑ or to use the following:

❑ VISA ❑ MASTERCARD ❑ AmEx Account Number: _____

Name of Cardholder: _____ Expiry Date: _____/_____

Signature of Cardholder: _____ Date: _____

Please complete and return the registration form with payment to:

PMPRB/CEPMB Symposium 2002, c/o Golden Planners Inc.
126 York Street, Suite 301, Ottawa, Ontario K1N 5T5
Tel: 613-241-9333 Fax: 613-565-2173 Email: info@goldenplanners.com

PmPrB Symposium 2002