Patented
Medicine Prices
Review Board

PMPRB NEWSletter

Volume 8, Issue No. 1
January 2004

## Inside...



## Board Members



The Patented Medicine Prices Review Board is a quasi-judicial tribunal with the mandate to ensure that manufacturers' prices of patented medicines sold in Canada are not excessive.

# Since our last issue...

**Here are some of the key events which occurred since October 2003.**

| | |
|---|---|
| November 12: | Wayne Critchley gave a presentation at the Canadian Pharma Summit, *Pharmaceutical Regulations, Policies and Guidelines*, in Toronto. |
| November 27: | Martine Richard gave a speech, *Price Controls*, to the Group Insurance and Pharmaceutical Committee, hosted by GlaxoSmithKline, in Toronto. |
| December 2: | Sylvie Dupont and Ellen King, Scientific Officer, met with a delegation from the Ministry of Health of Jordan on the role of the PMPRB in drug price regulation in Canada. |

# Comings and Goings!

## Human Drug Advisory Panel

The mandate of the Human Drug Advisory Panel is to provide credible, independent and expert scientific advice to the PMPRB respecting the development and application of the PMPRB Guidelines related to the scientific evaluation of patented medicines.

Last November we bid farewell to Dr. Patrick du Souich as a member of the Human Drug Advisory Panel (HDAP). His expert advice and invaluable contribution to the scientific review of new patented medicines since 1996 will be long remembered. We wish him success in his future endeavours.

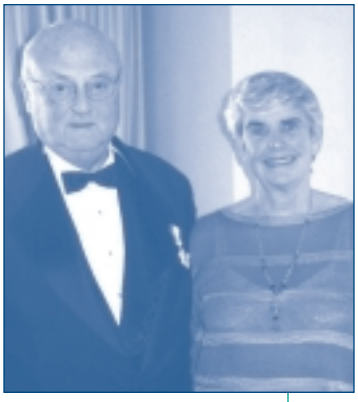
We also welcome Dr. Jean Gray as a member of the HDAP. Professor of medicine and pharmacology at Dalhousie University, Dr. Gray brings extensive experience to the HDAP which will no doubt further enhance the scientific review process.

Welcome Dr. Gray.

## Board Staff

January has been a busy month.

- We welcome the new Director of Policy and Economic Analysis, **Roger Guillemette**. Roger has extensive experience in the Public Service, most recently as Assistant Director, Canada Health Act Division at Health Canada where, amongst other things, he was responsible for the production of the *Canada Health Act Annual Report* in collaboration with the F/P/T departments of Health and other federal departments and agencies. Previously, he worked as a Senior Policy Analyst at Health Canada and as Senior Economist at Human Resources Development Canada.
- Also joining the PMPRB, **Anne-Marie Labelle**, as Communications Officer. Anne-Marie is formerly from the Military Police Complaints Commission.
- We bid farewell to **Tanya Potashnik**, Senior Economist, who accepted a position with the Health Policy and Communications Branch at Health Canada. ■



# Congratulations!

**Dr. Robert G. Elgie**, Chairperson of the PMPRB and his wife, Dr. Nancy Elgie, following the presentations of the Order of Canada by the Governor General of Canada on October 24, 2003. As reported in our January 2003 NEWSletter, Dr. Elgie was named a Member of the Order of Canada last January.

**Normand Savard**, Financial Officer, Corporate Services Branch, celebrated 15 years with the federal Public Service in November 2003. Normand Joined the PMPRB in February 1999 after previous assignments with Health Canada. ■

## Senior Staff

Executive Director:
**Wayne Critchley**

Secretary of the Board:
**Sylvie Dupont**

Director of Policy and Economic Analysis:
**Roger Guillemette**

Director of Compliance and Enforcement:
**Ginette Tognet**

Director of Corporate Services:
**Robert Sauvé**

Senior Counsel:
**Martine Richard**

# Message from the Chair

Over the past few months, there have been several media reports of some price increases by drug manufacturers. These reports prompted the PMPRB to publish an article in the last NEWSletter (October 2003) reminding patentees and the public of the pricing provisions of the *Patent Act* and the PMPRB's policies to ensure that prices of patented medicines in any market in Canada are not excessive.

In response to questions, this NEWSletter contains an article with a reminder of the allowable price increases under the Guidelines for patented drugs in 2004. The PMPRB will be monitoring prices as reported by manufacturers in accordance with the *Patented Medicines Regulations*, and will apply the Compliance and Enforcement Policy as necessary. Under the Regulations, patentees are required to report price and sales information for the last six months of 2003 by January 30, 2004. Prices for the first half of this year must be filed by July 30, 2004. We will also be reporting on price trends to the end of 2003 in our Annual Report to Parliament which is expected to be submitted to the Minister of Health at the end of May.

In addition, the PMPRB will follow up on complaints or other available information that a manufacturer may have increased the price of a patented drug by more than the allowable amount. The PMPRB does not have jurisdiction over price increases for non-patented medicines but will refer complaints about those price increases to the Minister of Health.

In our Annual Report for 2002, the PMPRB reported that prices for existing patented drugs had declined 1.2% from the previous year and prices for all patented drugs overall were slightly above the median of prices in the seven countries used for comparison purposes: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. We will continue to monitor those price trends and report information for 2003 in our Annual Report this year. ■

# PMPRB Price Guidelines: 2004 Price Increases

Our October 2003 NEWSletter article on *Price Increases: Monitoring Compliance with the Guidelines* attracted considerable interest and some questions. **(http://www.pmprb-cepmb.gc.ca/CMFiles/newsletter-oct2003e21NDR-12122003-5082.pdf**, page 3.) Among other things, some non-industry stakeholders have asked for more detailed information on the maximum allowable price increases under the Guidelines for 2004.

Prices of all patented medicines, new and existing, prescribed or not, are reviewed according to factors set out in the *Patent Act* and the PMPRB's Guidelines. Under the Act, the Board is required to consider changes in the Consumer Price Index (CPI) in determining if the price of an existing patented medicine is excessive. The Guidelines, which have been developed in consultation with stakeholders, are based on the factors

in the Act. Among other things, they provide that increases in the price of an existing patented drug should not be greater than increases in the CPI.

## Calculating the CPI-Adjusted Price

With a view to promoting compliance with the legislation and the Guidelines, and in order to ensure predictability, the Guidelines set out a methodology for forecasting changes in the CPI and calculating the CPI-adjusted price. In summary, the Guidelines limit price increases to changes in the CPI, calculated over a three-year period. In the event that this formula would allow an increase in one year greater than the annual increase in the CPI (for example, if there had not been a price increase in the previous year), the Guidelines also limit the annual increase to 1.5 times the increase in the forecast CPI. The CPI-adjustment factors are published annually in the April NEWSletter and on the web site.

Allowable price increases for patented drug products in 2004 are based on the forecast increase in the Consumer Price Index of 2.2%. In some cases, the Guidelines allow a larger increase, but never more than 3.3%.

## Filing Price Information

Under the *Patented Medicines Regulations*, patentees file price information on each patented drug product twice a year: in July, for the period of January to June, and in January of the following year, for the period of July to December. Patentees are required to file prices net of discounts, rebates, and other concessions by class of customer and province. For purposes of the Guidelines, the PMPRB calculates the average transaction price across Canada, on an annual basis, based on all sales of each patented drug product. The PMPRB expects that all prices will be within the Guidelines.

Schedule 4 of the Compendium of Guidelines, Policies and Procedures states that the price of an existing medicine during the year under review will be presumed to be excessive if it exceeds the benchmark price of the DIN adjusted for the cumulative change in the CPI from the benchmark year to the year under review. For patented drugs first marketed in Canada more than three years prior to the forecast period, the benchmark year is the calendar year three years preceding the forecast period. For example, for 2004, the corresponding benchmark year is 2001. The usual practice is to calculate the average of the prices at which a drug product was sold to all classes of customers in all provinces during the period under review.

The formula was developed in consultation with stakeholders. For a more detailed explanation, you will want to consult Schedule 4 (**http://www.pmprb-cepmb.gc.ca/CMFiles/2004compendium-e21LTW-152004-1350.pdf**, page 37.)

It is important to note that there is no requirement for a manufacturer to seek the approval of the PMPRB before implementing a price increase. The PMPRB expects that manufacturers will comply with the Guidelines. As part of its regulatory mandate, the PMPRB will continue to monitor prices to ensure this is the case.

## Investigations

In the event that the increased price is not within the Guidelines, Board Staff will conduct an investigation which may result in a Voluntary Compliance Undertaking by the patentee or a public hearing.

The criteria for commencing an investigation are:

- a price is 5% or more above the maximum non-excessive price and there are cumulative excess revenues of $25,000 or more;
- cumulative excess revenues are $50,000 or more; or
- complaints with significant evidence.

In the event that the Board holds a hearing and concludes that a price is excessive, it can order a price reduction. Section 83 of the Act provides that the Board may make such a finding and order in respect of the price at which a patented medicine is being sold ***in any market in Canada***. It is therefore open to the Board to determine whether, in any particular circumstances, a patented drug is being sold to any class of customer or in any province at an excessive price in respect of any period of review. Under the Act, the Board may also order the manufacturer to offset double any excess revenues it received if it finds that there was a policy of excessive pricing.

For more information, the Compendium of Guidelines, Policies and Procedures is available on our website under Legislation, Regulations and Guidelines or by contacting us at 1 877 861-2350. ■

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PMPRB

# Pilot Project for a Complaints-driven Approach for the Regulation of Patented Veterinary Drug Prices: Next Steps

The PMPRB's regulatory jurisdiction under the *Patent Act* extends to all patented pharmaceutical products sold in Canada, including patented medicines for human use and veterinary use. Prior to 1999, the PMPRB had applied the same Guidelines and procedures to regulate the prices of patented veterinary drugs as it did for patented drugs for human use.

Several events throughout the mid-to-late 1990's suggested that it would be appropriate for the PMPRB to modify the reporting requirements for patented veterinary drugs. In 1995, as a response to the budget reduction proposal stemming form the Program Review initiated by the Government of Canada, the PMPRB identified veterinary drugs as an area for review. In 1998, in the consultations leading to the *Road Map for the Next Decade*, there was a consensus that drugs for human use must continue to be the Board's priority. Further, a series of discussion papers and studies submitted to the Board concluded that the veterinary drug industry differs significantly from the human drug market and that it may not be appropriate to regulate them both in exactly the same way.

In response, in January 1999 the Board implemented a trial based complaints-driven approach for regulating the prices of patented veterinary drugs. In consultations prior to implementing the pilot program, stakeholders responded favorably to the proposed changes. Under the complaints-driven approach for veterinary drugs, Board Staff reviews the prices of new patented medicines only. Existing medicines are subject to review only when a substantiated complaint has been received. Patentees are expected to ensure that their prices remain within the PMPRB's Excessive Price Guidelines and retain all price information and file it with the Board upon request.

The Board has recently reviewed how well the trial complaints-driven approach has worked with respect to maintaining prices within the Guidelines, increasing operational efficiency, and reducing the regulatory burden for patentees. The results show that overall the trial program reduced the regulatory burden on patentees and streamlined the PMPRB's operational efficiency by reducing the workload of Board Staff. No complaints have been received to date regarding the prices of patented veterinary drugs. Historically, prices of veterinary drugs have remained stable over the years and during the period of the complaints-driven trial program, prices of veterinary drugs have increased at a slower rate than prices of drugs for human use and the Consumer Price Index (CPI).

The review further concluded that it would be appropriate to implement a full complaints-driven approach for the regulation of patented veterinary drug prices – that is, in addition to existing drugs, the introductory prices of patented veterinary drugs would only be reviewed in the event of a substantiated complaint.

Given the results of this review, the Board has directed Board Staff to explore the feasibility of implementing the proposed full complaints-driven approach on a permanent basis and the required process. Over the next few months, Board Staff will work on proposing changes to the *Patented Medicines Regulations* and the PMPRB's Excessive Price Guidelines to reflect the new filing requirements that would be required for a full complaints-based approach to be implemented.

It is important to note that the Board is not proposing to relinquish any of its powers with respect to the prices of patented veterinary drugs, but is proposing an administrative change to improve and formalize the current trial complaints-driven system. The Board retains its full jurisdiction and regulatory authorities over patented veterinary drug prices, as per the *Patent Act*. The Board feels that this approach is consistent with the Government of Canada's objectives for Smart Regulation. ■

Throughout this process, the Board will consult extensively with stakeholders, particularly through the Canada Gazette process for regulatory change.

PMPRB

# Filing Requirements: Reporting Domestic Sales in Canadian Currency

This article is the third under in the series on Filing Requirements for patentees.

Patentees are initially required to submit price and sales information for the thirty-day period following the first sale of the drug product in Canada and, thereafter, each first six-month period and last six-month period of every year. The *Patented Medicine Regulations* further specify that the reporting of foreign price data to the PMPRB must be in the currency of that country.

While most sales transactions of patented medicines in Canada are conducted in Canadian dollars, there are a few instances when patentees conduct domestic sales transactions in foreign currencies. For example, a sales transaction for a patented drug in Canada could take place with a fixed U.S. dollar price, based on a contractual agreement between the patentee and the customer. In cases such as this, the Board reminds patentees that the sales information reported to Board Staff should be reported in Canadian dollars. This is consistent with the *Currency Act*, which identifies the Canadian dollar as the official monetary unit applicable in any Act of Parliament (unless otherwise stated).

For any questions regarding the appropriate exchange rate to use when reporting on domestic sales conducted in foreign currencies, patentees are advised to contact the Compliance Officer assigned to their company. ■

Filing Requirements with the PMPRB are outlined in the *Patented Medicines Regulations*, available on our website under Legislation, Regulations and Guidelines.

# New Patented Medicines Reported to the PMPRB

Since the publication of the October 2003 NEWSletter, 10 new DINs for human use were added to the list of New Patented Medicines Reported to the PMPRB for the period ending December 31, 2003. Two of these new medicines are new active substances.

The following table presents the two new active substances reported to the PMPRB during the period October to December 2003. ■

| Brand Name | Generic Name | Company |
|---|---|---|
| Lumigan (0.3 mg/mL) | bimatoprost | Allergan Inc. |
| Invanz (1000 mg/vial) | ertapenem sodium | Merck Frosst Canada Inc. |

# Patented Medicine Prices Review Board – December 18 & 19, 2003 Meeting

- At its meeting, the Board received briefings on:
  - the factors affecting the change in relationships of Canadian to foreign prices;
  - Internet Pharmacies by the Departments of Health and Foreign Affairs;
  - ongoing activities under the National Prescription Drug Utilization Information System (NPDUIS);
  - aggregate reporting of categories of new patented drugs; and
  - CPI Methodology and 2004 Price Increases ■

The next Board meeting is scheduled for February 23 & 24, 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.

# PMPRB's Research Agenda

| Issue | Description | Key Deliverables | Status |
|---|---|---|---|
| Price Review Timelines | Establish milestones and timelines for the price reviews of new patented medicines | Proposals for consultation | Consultation to begin 2004 |
| Guidelines:<br>International Price Comparison | 1. Review the appropriate test when fewer than 7 countries | Report | Expected 2004 |
| | 2. Review the appropriateness of the "Highest Price Rule" | Report | Expected 2004 |
| | 3. Review methodology for calculating the average price for a foreign country when conducting an International Price Comparison | Report | Expected 2004 |
| Evaluation | 1. Evaluation of complaints-driven approach to regulating the price of veterinary drugs | Board's response | Complete January 2004 *NEWSletter* |
| | 2. Evaluation of initiatives on transparency adopted by the PMPRB beginning in 2001 | Board's response | Evaluation methodology and timeframe to be determined |
| Guidelines:<br>Category 2 Drug Prices | Review of the appropriateness of the median price test for category 2 drugs, including the usefulness of pharmaco-economics | | Pending further work on International Price Comparison |
| ***National Prescription Drug Information System – NPDUIS*** | | | |
| Cost drivers in the Non-Insured Health Benefits Program | Examine expenditure, utilization and prices in the federal governments Non-Insured Health Benefits Program, using the PMPRB's cost-driver analysis methodology. | Report | Spring 2004 |
| Budget Impact Guidelines | Develop a methodology for performing Budget Impact Analyses (BIA), to estimate of the net impact on reimbursement program costs of listing new drug product. | Report/guidelines | 2004-2005 |
| Program expenditure forecasting method-ology | Develop a methodology for producing reliable forecasts of program expenditure by major therapeutic class over a forecast period of three years. | Report/forecasting framework | Work to begin in 2004-2005 |
| Therapeutic Cost Index Methodology | Develop a method for the calculation of pharmaceutical treatment cost indices at the therapeutic class level. | Report | Work to begin in 2004-2005 |
| Pharmaceutical Trends Overview Report | Research on price and expenditure trends, price levels and cost-drivers in public reimbursement plans. | Report | Summer 2004 |

# National Health Expenditure Trends

On December 17, 2003, the Canadian Institute for Health Information (CIHI) released the 2003 edition of its annual statistical report on healthcare expenditure in Canada. This report is based on information contained in CIHI's National Health Expenditure database.

CIHI forecasts a moderation in the growth of total health expenditure in 2003. It expects total expenditure to reach $121.4 billion, up from $113.4 billion in 2002. This implies year-over-year growth of 7.1%.

CIHI estimates the public sector share of healthcare spending remained fairly steady at roughly 70% from 1997 to 2001. It expects this pattern to continue through to 2003.

Canada remains among the heaviest healthcare spenders in the industrialized world. Healthcare took up 9.7% of GDP in 2001 (the most recent year for which comparable data are available), which gave Canada the fourth highest ratio among the G-7 nations. CIHI expects this ratio to rise to 10% in 2003.

The report includes estimates of total spending on drugs. CIHI expects such spending to rise by 8.8% in 2002 (to $18.1 billion) and by another 8.1% in 2003 (to $19.6 billion). Spending on prescription drugs is forecasted to increase by 10.0 in 2002 and 10.1 in 2003. CIHI's estimates of spending on drugs do not include drugs dispensed in hospitals and other healthcare institutions.

Spending on hospitals accounted for the largest share (30%) of total healthcare expenditure in 2003. Spending on drugs outside hospitals remains the second largest component (16.2%) of total health expenditure.

The CIHI report also includes estimates of per capita healthcare spending by age group. According to CIHI, the average Canadian between 45 and 64 years of age generated $1,984 of healthcare spending in 2001. (With the exception of infants less than a year old, spending on younger Canadians is substantially less than this amount.) Per capita spending jumps to $4,988 for those Canadians between 65 and 74 years of age, and jumps again to $8,849 for those between 75 and 84. ■

Consult the Canadian Institute for Health Information website at **www.cihi.ca** to obtain *National Health Expenditure Trends, 1975-2003*.

Total health expenditure includes spending on hospitals, other healthcare-related institutions, physicians, other healthcare professionals (i.e., dentists), drugs (both prescribed and non-prescribed), capital, public health and administration and health research.

Values reported for 2002 and 2003 are estimates based on a combination of provincial/territorial government budgets and forecasts of spending by the private and public sectors.

# Reports on New Patented Drugs – Xigris

| | |
|---|---|
| **Brand Name:** | Xigris |
| **Generic Name:** | drotrecogin alfa |
| **DIN:** | 02247129 5 mg/vial<br>02247130 20 mg/vial |
| **Patentee:** | Eli Lilly Canada Inc. |
| **Indication – as per product monograph:** | For the reduction of mortality in adult patients with severe sepsis (sepsis, may be associated with acute organ dysfunction) who have a high risk of death (e.g., as determined by APACHE II, or multiple acute organ dysfunctions), when added to current best practice. |
| **Notice of Compliance:** | January 31, 2003 |
| **Date of First Sale:** | February 12, 2003 (5 mg vial)<br>March 25, 2003 (20 mg vial) |
| **ATC Class:** | B01AD10<br>*Blood and Blood Forming Organs, Antithrombotic Agents* |

## Application of the Guidelines

**Summary:**

The introductory prices of the Xigris drug products were found to be within the Guidelines because the prices in Canada did not exceed the median of the prices of the same drug products in those countries listed in the *Patented Medicines Regulations* (Regulations) in which they were sold or did not do so by an amount sufficient to trigger any of the investigation criteria under the *Compliance & Enforcement Policy*.

For information on the Criteria for Commencing an Investigation, please see Schedule 5 of the Compendium of Guidelines, Policies, and Procedures, as posted on our website under Legislation, Regulations and Guidelines.

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.

**Scientific Review:**

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Xigris be reviewed as a category 2 new drug (breakthrough or substantial improvement) based on the following information:

- Sepsis, a severe infection, remains a major cause of death in hospitalized patients. Despite a massive research effort over the past two decades to identify innovative therapies for sepsis, current treatment strategies consist primarily of anti-infective agents and a variety of supportive measures.
- Although some forms of treatment (mainly supportive care) are available to this patient population, thus far no other drug product has received approval for the sole treatment of acute sepsis in adults and children.
- The HDAP concluded that Xigris represents a substantial improvement over all other currently available therapies. The HDAP acknowledged the potential adverse effects of Xigris, however came to the conclusion that the benefits (i.e. decreased mortality) would be expected to outweigh the potential adverse effects.
- There are a number of drug products in the same 4th level ATC class as Xigris; however none of them are clinically equivalent in addressing the treatment of sepsis. In addition, there appears to be no other medication available to this patient population and thus no alternative treatment modalities that address sepsis in the same manner and show the same efficacy as Xigris. As a result, the HDAP recommended no comparators for the conduct of a Therapeutic Class Comparison (TCC) Test.

**Price Review:**

Under the Guidelines, the introductory price of a new category 2 drug product will be presumed to be excessive if it exceeds the prices of all comparable drug products, based on a TCC Test, *and* the median of the international prices identified in an International Price Comparison (IPC) Test.

As no comparable drug products could be identified for purposes of conducting a TCC Test, the prices of the Xigris drug products were considered to be within the Guidelines as they did not exceed the median of the international prices identified in the IPC Test, or did not do so by an amount that triggered the investigation criteria.

## Evidence/ References:

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

| Xigris[1] | Canada | France | Germany | Italy | Sweden | Switzerland | UK | US | Median |
|---|---|---|---|---|---|---|---|---|---|
| 5 mg | $335.00 | $334.96 | $334.96 | $334.96 | $358.35 | $302.31 | $326.60 | $318.21 | $334.96 |
| 20 mg | $1340.00 | $1338.96 | $1338.96 | $1338.96 | $1422.75 | $1433.33 | Not Sold | $1275.16 | $1338.96 |

1 Publicly available prices as per the *Patented Medicines Regulations*

# Crestor

**Brand Name:** Crestor

**Generic Name:** rosuvastatin calcium

**DIN:**
02247162 10 mg tablet
02247163 20 mg tablet
02247164 40 mg tablet

**Patentee:** AstraZeneca Canada Inc.

**Indication – as per product monograph:** As an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol; HDL-cholesterol ratio and triglycerides and for increasing HDL-C; in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: primary hypercholesterolemia, combined dyslipidemia, and homozygous familial hypercholesterolemia.

**Notice of Compliance:** February 18, 2003

**Date of First Sale:** February 19, 2003

**ATC Class:** C10AA07
*Serum lipid reducing agents*
*Cholesterol and triglyceride reducers*
*HMG CoA reductase inhibitors*

## Application of the Guidelines

**Summary:**

The introductory prices of Crestor 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 Crestor was sold.

**Scientific Review:**

Crestor is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Crestor 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. See the PMPRB's Compendium of Guidelines, Policies and Procedures for a more complete description of the Guidelines and the policies on TCCs.

Other agents in the same 4th level ATC class, HMG-CoA reductase inhibitors (commonly known as 'statins'), available on the Canadian market, include Zocor (simvastatin), Mevacor (lovastatin), Pravachol (pravastatin), Lescol (fluvastatin), and Lipitor (atorvastatin). These statins share similar indications, have been compared directly to Crestor in clinical trials, and are referred to interchangeably in the U.S. and Canadian dyslipidemia guidelines.

In its review of Crestor, the HDAP noted that the lipid lowering effects of statins have increased, with Crestor having the greatest impact on lipid levels. The recommended comparable dosage regimens for Crestor were based on the comparative clinical trial data identified (see Evidence/References).

For purposes of the Guidelines, the HDAP attempted to identify comparable dosages of the other statins, but this was not always possible because of the greater efficacy of Crestor in lowering lipid levels. The table below shows the range of costs of treatment with the statins included in the TCC based on the range of approved dosages.

**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*. The price of Crestor was within the Guidelines as the daily cost of therapy did not exceed the cost of therapy with the comparator medicines.

| Name | Dosage Regimen/day | Cost Per Day[1] |
|---|---|---|
| Crestor (rosuvastatin calcium) | 10-40 mg | $1.36 - $1.99 |
| Zocor (simvastatin)<br>*generic simvastatin*[2] | 10-80 mg<br>10-80 mg | $1.78 - $2.20<br>$1.25 - $1.54 |
| Mevacor (lovastatin)<br>*generic lovastatin*[3] | 20-80 mg<br>20-80 mg | $1.73 - $6.39<br>$1.09 - $4.02 |
| Lipitor (atorvastatin) | 10-80 mg | $1.60 - $2.15 |

1 Liste de médicaments du Québec, October 2003
2 There are four manufacturers of this generic medication.
3 There are seven manufacturers of this generic medication.

In 2003, Crestor 10 mg, 20 mg and 40 mg tablets were also being sold in the United Kingdom and the United States. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in those countries; the prices of Crestor 20 mg and 40 mg were lower than the prices in those countries and the price of Crestor 10 mg was second lowest, below the median of international prices.

## Evidence/ References:

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

# Upcoming Events

February

**6**
Meeting of the Human Drug Advisory Panel

February

**23-24**
Board Meeting, Ottawa

March

**4-5**
Strategy Institute – *Canadian Forum on Pharmaceutical Marketing*, Toronto

March

**29-30**
Insight Conference on *Drug Patents*, Toronto

May

**13 and 20**
Les Fonds d'investissement FMPQ Inc., Québec and Montréal

May

**17-18**
Board Meeting, Ottawa

May

**31**
PMPRB Annual Report for 2003 to the Minister of Health

May

**31**
Meeting of the Human Drug Advisory Panel

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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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