Patented
Medicine Prices
Review Board

PMPRB NEWSletter

Volume 7, Issue No. 1
January 2003

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 2002.

November 25-26: the PMPRB participated in the Pharma Summit in Montréal.
- Wayne D. Critchley gave a speech – *The PMPRB Guidelines: What Lies Ahead*.
- Ron Corvari gave a presentation on the PMPRB's study: *A Comparison of Pharmaceutical R&D Spending in Canada and Selected Countries*. Highlights of the study appear on page 6. The study is posted on our website under Publications; Study Series; S-0217.

December 9: the Board held its last quarterly meeting for 2002. A summary of the Minutes appears on page 9.

December 16: the Board issued a Notice of Hearing in the matter of Schering Canada Inc. and the medicine Remicade. Highlights of the Notice of Hearing appear on page 3.

Message from the Chair

Robert G. Elgie, Chairperson

It is hard to believe that 2003 is well under way. In our last NEWSletter we were just wrapping up our Symposium.

2002 marked the PMPRB's 15th anniversary. Over the course of the year we commemorated this occasion both internally with our employees and externally, with the PMPRB Symposium 2002 as one of our major events.

Also, in the year that just passed, the Working Group on Price Review Issues completed the review of its third and final issue, the Guidelines for category 3 new drug products.

Established in 1999, the Working Group was tasked with reviewing, analyzing and providing reports for the Board's consideration on three questions: the appropriate use of U.S Department of Veterans Affairs (DVA) prices in conducting international price comparisons; the price review process for new patented drug products; and methods to conduct therapeutic class comparisons and the Guidelines for category 3 new drugs. Many of the Working Group's recommendations including the transparency initiative and methodology on use of US FSS prices in international comparison are now into effect.

I would like to take this opportunity to thank the members of the Working Group, who represented our various stakeholders, for lending their time to examine these important issues and provide valuable input towards resolving them.

In 2002, we also released the results of last winter's survey of stakeholders as part of our Environmental Scan. The Scan served as the basis of our research for developing the program for the PMPRB Symposium 2002. Under our transparency initiative, we began making publicly available the results of the reviews of new patented drugs by Board Staff for purposes of applying the PMPRB's price guidelines.

More information on the Working Group's report appears on page 3 of this NEWSletter. The Working Group's reports are posted on our website under Working Group on Price Review Issues; Reports.

Senior Staff

Executive Director:
Wayne Critchley

Secretary of the Board:
Sylvie Dupont

Director of Policy and Economic Analysis:
Ronald Corvari

Director of Compliance and Enforcement:
Ginette Tognet

Director of Corporate Services:
Robert Sauvé

Senior Counsel:
Martine Richard

On behalf of the Members and Staff of the Patented Medicine Prices Review Board, I wish to congratulate Dr. Elgie on this well-deserved honour.

Réal Sureau,
Vice-Chairperson
of the Board

Dr. Robert Elgie presents the Golden Jubilee Medal to Sylvie Dupont.

We conducted a study on comparing R&D spending by the brand name pharmaceutical industry in Canada and other major industrialized countries, the results of which are available on page 6.

We worked in close collaboration with the Canadian Institute for Health Information and federal/provincial/territorial drug plans to establish the National Prescription Drug Utilization Information System (NPDUIS). We are currently conducting studies which will provide critical analyses of price, utilization and cost trends in order that Canada's health care system has more comprehensive, accurate information on how prescription drugs are being used and on the sources of cost increases.

We published clarification and reminders with respect to patentees' filing requirements. At the end of the year, the Board issued a Notice of Hearing into the price of Remicade, a drug product sold by Schering Canada Inc. The hearing is scheduled to start in April 2003.

The release of reports on the state of health care in Canada at the end of the year highlighted Canadians' continued preoccupation and concern with universality and sustainability of our health care system. The Romanow report in particular suggested a continued and somewhat expanded role of the current drug price review scheme.

As our 15th year ends, we look forward to 2003 which promises to be a challenging and exciting new chapter for the PMPRB. ■

Welcome to the PMPRB!

- On September 19, 2002, Gina Charos joined the Policy and Economic Analysis Branch as Senior Policy Analyst. Gina comes to the PMPRB from Health Canada.
- On January 13, 2003, we welcome Jeff Marchand back to the PMPRB as Senior Economist with the Policy and Economic Analysis Branch. ■

Robert G. Elgie, Chairperson

Congratulations!

Robert G. Elgie, C.M., Member of the Order of Canada

On January 17, 2003, Her Excellency the Right Honourable Adrienne Clarkson, Governor General of Canada, announced Dr. Elgie's appointment as Member of the Order of Canada.

"A former Ontario cabinet minister, this retired neurosurgeon and lawyer has left an indelible mark on Canadian society. As chair of Ontario and Nova Scotia's Workers' Compensation boards, he was responsible for legislative reforms and new processes which provide disabled workers with improved benefits. Founder and first director of the Health Law Institute at Dalhousie University, he has worked tirelessly to preserve our health care system. Now chair of the Patented Medicine Prices Review Board, he remains a trusted guardian of the public interest, known for his wise counsel and impartial sense of judgement." January 17, 2003 press release, Governor General of Canada.

Golden Jubilee Medal

Sylvie Dupont, Secretary of the Board, was awarded the Golden Jubilee Medal on December 9, 2002 for her exemplary career as a public servant and for her leading role in organizing the PMPRB Symposium 2002. The presentation was made by Dr. Robert Elgie, Chairperson of the PMPRB.

The awarding of the Golden Jubilee Medal is one of the most significant activities commemorating the Golden Jubilee of Her Majesty Queen Elizabeth II. This program is intended to recognize citizens for an outstanding and exemplary achievement or service to the community or to Canada as a whole; or those who have a sustained contribution over and above what might reasonably be expected of paid employment or voluntary action.

Sylvie has served with great distinction and dedication in various capacities in the Public Service of Canada for over 20 years and has been Secretary of the PMPRB since 1991. ■

Notice of Hearing in the matter of Schering Canada Inc. and the medicine Remicade

On December 16, 2002, the Board issued a Notice of Hearing into the price of the medicine Remicade. The public hearing is scheduled to start on April 22, 2003.

The purpose of the hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, Schering Canada Inc.:

- is selling or has, while a patentee, sold the medicine known as Remicade in any market in Canada at a price that, in the Board's opinion, is or was excessive; and,
- if so, what order, if any, should be made.

Remicade is sold pursuant to a Notice of Compliance issued by Health Canada on June 6, 2001 for the treatment of Crohn's disease and to a Notice of Compliance issued on September 27, 2001 for the treatment of rheumatoid arthritis.

A pre-hearing conference has been scheduled for February 11, 2003, in the Board's offices. ■

The Notice of Hearing and pertinent documents are available on our website under VCUs, ARCs, Hearings and Decisions of the Board; Remicade. For any updates on the hearing schedule, please consult our website under News; What's New.

For more information on the Remicade Hearing, please contact the Secretary of the Board:

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Working Group on Price Review Issues

The Working Group on Price Review Issues recently completed the review of its third and final issue, the price Guidelines for category 3 new drug products. The Working Group submitted its final report and recommendations on this issue in two parts. Part 1 (submitted to the Board in May 2002) addressed the issues of the therapeutic class comparison (TCC), components of a TCC, and other factors, such as post-introduction reviews. Part II (submitted to the Board in October 2002) addresses the issue of the price test for category 3 drugs.

Many of the Working Group's recommendations regarding the category 3 Guidelines reaffirm the appropriateness of existing practices or suggest areas where some minor improvements could be made to the Board's processes. The Board has committed to making the operational improvements suggested.

The Working Group did not recommend any changes to the price limits established by the Guidelines, but it did recommend that the Guidelines should better reflect the relative value of new patented drugs.

Specifically, the Working Group recommended that it is appropriate for the Board to consider the value of new drug products in the price review process to a greater extent than is currently done by the category 3 Guidelines (i.e., to better reflect the incremental value of new drugs). However, the Working Group did not define what is meant by "value", nor did it address the implications of this recommendation for the Guidelines.

"Value" concepts as they relate to new drugs are complex issues. In previous consultations with stakeholders, the Board has heard concerns regarding the Guidelines, ranging from the idea they should be more flexible in order to recognize the incremental value of new drugs, to concerns that the price limits for drugs that offer little to no improvement are too high. As a result of the Working Group's recommendation, the Board has committed to undertake more research and analysis in this area. An examination of the issue of "value" will be carried out, keeping in mind our mandate under the *Patent Act* and the Board's need to have clear and distinct guidelines and an efficient price review process. This work on value will also serve to better inform the Board's planned review of the price Guidelines for category 2 drugs (i.e., breakthrough drugs).

The submission of its final report on the category 3 Guidelines represents the completion of the work of the Working Group on Price Review Issues as set out in the Terms of Reference. Once again, the Board wishes to thank the members of the Working Group for their time and effort in assisting the Board to address these issues. ■

The Working Group's reports are available on the PMPRB website at **http://www.pmprb-cepmb.gc.ca**, under Working Group on Price Review Issues; Reports.

Notice & Comment

Comments on the Notice and Comment proposal should be forwarded to the Secretary of the Board no later than **March 31, 2003**, at the following address:

Box L40
Standard Life Centre
333 Laurier Avenue West
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Ottawa, Ontario
K1P 1C1; or
By fax: (613) 952-7626; or
By e-mail: sdupont@pmprb-cepmb.gc.ca

The *Compendium of Guidelines, Policies and Procedures* is available on our website under Legislation, Regulations, Guidelines.

Schedule 7 – Comparable Dosage Forms

As stated in the previous article, the Working Group on Price Review Issues completed its review on the Guidelines for category 3 new drug products and submitted its final report to the Board in two parts. Part I (submitted in May 2002) deals with the therapeutic class comparison (TCC), components of the TCC and other factors. Part II (submitted in October 2002) deals with the price test for category 3 new drugs.

Many of the Working Group's recommendations regarding the category 3 Guidelines reaffirm the appropriateness of existing practices or suggest where minor changes could be made. In terms of immediate changes to the Guidelines, the Working Group made a specific recommendation that Schedule 7 of the Compendium of Guidelines, Policies and Procedures, be modified slightly.

Proposals for Notice and Comment

Schedule 7 – Comparable Dosage Forms

Schedule 7 is a listing of comparable dosage forms that is referred to in conducting the therapeutic class comparison (TCC), after comparable medicines have been selected. Each section of the list is divided into two sub-classes of formulations, column A and column B. The Working Group recommended that columns A and B in each section of Schedule 7 be combined and that any exceptions be identified explicitly and dealt with by the Human Drug Advisory Panel on a case-by-case basis. The Working Group also recommended that the text in the preamble to the listing of comparable dosage forms in Schedule 7 be amended to reflect that the listing is meant to provide guidance only. The Board has reviewed and agrees with these recommended changes to Schedule 7 of the Compendium of Guidelines, Policies and Procedures.

The Guidelines state that ordinarily the formulations in column A of Section 7 are not compared with those in column B, though they do not dictate that this must always occur. There are some cases when an appropriate dosage form for the purposes of comparison could be found in the other column of formulations. In these cases, it is current practice to look at the other column in selecting a comparable dosage formulation.

Combining columns A and B in each section of the listing in Schedule 7 of the Guidelines, as recommended by the Working Group, represents a minor operational change and does not significantly compromise the ability to select appropriate comparable dosage forms for the TCC. It is important to note that the listing in Schedule 7 is used as a guide in selecting comparable dosage forms after comparable medicines for the purpose of the TCC have been identified. As such, Schedule 7 is not used to include or exclude comparator drug products from the TCC.

In addition to the Working Group's recommendation, the Board is proposing to add the comparable dosage form "caplet" under the "Oral Solids" column in order to reflect the availability of this dosage form.

The Working Group reports are available from the PMPRB website under Working Group on Price Review Issues; Reports.

The Board invites comments on these amendments to the Compendium:

Schedule 7 of the Compendium of Guidelines, Policies and Procedures is amended as follows:

- In the first paragraph in the preamble leading to the table of Comparable Dosage Forms in Schedule 7, amend the first sentence to read: "This Schedule is used for the purposes of providing guidance in identifying comparable dosage forms in conducting therapeutic class comparisons of new drug products and identifying a drug product in category 1 which is a new DIN of a comparable dosage form of an existing medicine."
- In the first paragraph in the preamble leading to the table of Comparable Dosage Forms in Schedule 7, delete the sentence: "Ordinarily, the formulations in column A are not compared with formulations in column B."
- In each section of the table of Comparable Dosage Forms in Schedule 7, where there is a division in the listing into column A and column B, that the lists are combined and the column headings of A and B be deleted.
- The word "caplet" is added under the column "Oral Solids". ■

PMPRB'S Research Agenda 2003 – 2006

Issue	Description	Advisory Committee	Key Deliverables	Date
Guidelines: Category 3 Drug Prices	Review the methods to conduct therapeutic class comparisons and the guidelines for category 3 drugs, including use of pharmacoeconomics	PMPRB Working Group on Price Review Issues	1. Report – Part 1 2. Report – Part 2 3. Board's response	Complete July 2002 Complete October 2002 NEWSletter January 2003
Guidelines: Category 2 Drug Prices	Review of the appropriateness of the median price test for category 2 drugs, including use of pharmacoeconomics	Advisory Committee and schedule to be determined		
Guidelines: International Price Comparison	1. Review the appropriate test when fewer than 7 countries 2. Review the appropriateness of the "Highest Price Rule" 3. Review methodology for calculating the average price for a foreign country when conducting an International Price Comparison	Advisory Committee and schedule to be determined	Report for Notice and Comment Report	2003-2004 2003-2004 2003-2004
Foreign Price Trends	An analysis of pharmaceutical prices in foreign countries		Report - Study Series: S-0216 *Foreign Price Trends for Patented Medicines (2002)*	Complete NEWSletter January 2003
International R&D	An analysis of pharmaceutical R&D spending in foreign countries	Notice and Comment on methodology NEWSletter July 2002	Report - Study Series: S-0217 *A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries (2002)*	Complete NEWSletter January 2003
Price Review Timelines	Establish milestones and timelines for the price reviews of new patented medicines		Proposals for consultation	2003-2004
Analysis of expenditures by publicly funded drug plans	Reports on drug prices and cost utilization trends produced as a result of the National Prescription Drug Utilization Information System		1. NIHB Cost Driver Study 2. Budget Impact Analysis Methodology 3. Program Expenditure Forecasting Methodology 4. Therapeutic Cost Index Methodology	2003-2004 2003-2004 2003-2004 2003-2004
Evaluation	1. Evaluation of complaints-driven approach to regulating the price of veterinary drugs 2. Evaluation of initiatives on transparency adopted by the PMPRB in 2001		Board's response Board's response	2003-2004 2003-2004

PMPRB Studies

The PMPRB studies are available on our website under Publications; Study Series.

A Comparison of Pharmaceutical R&D Spending

The PMPRB has recently completed a study comparing research and development (R&D) spending by the brand name pharmaceutical industry in Canada and other major industrialized countries. This work updates and extends an earlier PMPRB study.[1]

The emphasis is on comparisons with France, Germany, Italy, Sweden, Switzerland, the UK and the US, the seven countries the PMPRB is required to consider for purpose of carrying out its regulatory mandate under the *Patent Act*. The analysis covers the period 1995 to 2000.

The study found that although total R&D spending in Canada increased from $626 million in 1995 to $945 million in 2000 (an increase of 51%), Canada still ranked behind the other industrialized countries by several measures. Most importantly, the ratio of R&D to domestic sales in Canada remained well below values observed in Europe and the US. The Canadian ratio stood at 10.1% in 2000, whereas the aggregate ratio for the seven countries was 19.0%. Among these countries, only Italy had a lower ratio than Canada in 2000.

The study also compared the pharmaceutical R&D-to-sales ratio in Canada to the ratios observed in a set of smaller European countries (e.g., Denmark, Belgium), and again found the Canadian ratio to be well below the average value observed in this set of countries.

Measures of pharmaceutical R&D spending relative to population and GDP also indicated low levels of pharmaceutical research investment in Canada compared to other developed countries. R&D in Canada lags the countries used for regulatory purposes, except Italy, by each of these measures. Canada accounts for a share of total pharmaceutical R&D that is roughly one-half of its share of total pharmaceutical sales. In 2000 there was total pharmaceutical R&D spending of $53.4 billion in Canada and the seven countries. R&D spending by pharmaceutical patentees in Canada accounted for 1.8% of this amount. In the same year total Canadian brand name sales accounted for 3.4% of the $275 billion in sales observed in the eight countries.

1 A Comparison of Pharmaceutical Research and Development Spending, Study Series S-9709, October, 1997.

This study is available on the PMPRB website under Publications; Study Series; S-0217.

Foreign Price Trends for Patented Medicines

The PMPRB regularly reports on trends in the Canadian prices of patented drug products.[1] It also reports on the overall ratio of Canadian prices to foreign prices. Extending these analyses, the PMPRB has recently completed a study examining trends in the prices of patented drugs observed in the seven countries the PMPRB includes in its international price comparisons.

The study relies on data filed by pharmaceutical patentees with the PMPRB giving ex-factory prices in these countries. It uses the PMPRB's standard Laspeyres price index methodology. This methodology reflects changes in the prices of drugs already on the market, but does not measure impacts on the cost of pharmaceutical therapy caused by the introduction of new drugs.

The study found that, with the notable exception of the US, all countries experienced only modest overall increases in patented drug prices over the period 1988 to 2001. As a result, the average rate of increase in Canadian patented drug prices, less than 1% per year on average over this period, falls squarely within the range of the six European countries considered in the analysis. In contrast, prices in the US increased at an average annual rate of more than 5%.

International comparisons of changes in product prices have only limited analytical significance in their own right. In particular, changes in patented drug prices cannot by themselves tell whether consumers are paying more or less for patented drugs relative to other goods and services. To this end, the study also compared trends in patented drug prices to inflation. It found that increases in patented drug prices have been less than increases in the Consumer Price Index (CPI) in all countries except the US. Adjusting for inflation, patented drug prices in Canada declined at an average annual rate of -1.8% from 1988 to 2000, which is in line with results obtained for the six European countries. This relationship persists through the more recent period 1996 to 2001.

The emergence of parallel trade in European drug markets and the concomitant decline of market segmentation have led some to predict an international convergence of drug prices. To assess this hypothesis, the study examines the variation of patented drug prices across countries. All measures indicate the existence of substantial international price variation, but give no evidence that the extent of this variation has notably changed over the last decade. ■

The Foreign Price Trends study is available on our website under Publications; Study Series; S-0216.

1 See, for example, PMPRB, *Annual Report 2001*; PMPRB, *Trends in Patented Drug Prices*, 1998.

National Health Expenditure Trends

On December 18, the Canadian Institute for Health Information (CIHI) released the 2002 edition of its annual statistical report on healthcare expenditure in Canada.[1] This report is based on information contained in CIHI's National Health Expenditure Database. Values reported for 2001 and 2002 are estimates based on a combination of provincial/territorial government budgets and forecasts of spending by the private and public sectors.

It should be noted that CIHI has significantly revised its estimates of total spending on drugs in 2000 and 2001.[2]

The estimate for 2000 has been raised from $14.3 billion to $15.0 billion, while the estimate for 2001 has increased from $15.6 billion to $16.8 billion. As a result, CIHI's estimate of the growth in total drug expenditure in 2001 has risen accordingly, from 8.6% to 11.9%. Higher estimates of private-sector spending on prescribed drugs are largely responsible for these revisions.

CIHI forecasts a moderation in the growth of total healthcare expenditure in 2002.[3] It expects total expenditure to reach $112.2 billion, up from an estimate of $105.6 billion for 2001. This implies year-over-year growth of 6.3%, less than annual growth rates estimated for 2000 (8.5%) and 2001 (8.4%).

The rate of increase in public sector spending, in particular, has slowed over the past two years. After rising 9.1% to an estimated $69.0 billion in 2000, public sector expenditure is projected to have risen to $74.7 billion in 2001 and $79.4 billion in 2002, representing annual increases of 8.4% and 6.2%, respectively.

After adjusting for inflation, expenditure growth in 2002 is expected to approximately equal the overall real growth of the Canadian economy. This too represents a departure from recent trends: since 1997 health expenditure has grown by 30% in constant dollars, while output of the economy has grown by 20%.

Internationally, CIHI reports that Canada remains among the heaviest healthcare spenders in the industrialized world. In 2000 (the most recent year for which comparable data are available) Canada, at 9.1%, had the fourth highest ratio of total healthcare expenditure to GDP among the G-7 countries.

Spending on hospitals accounts for the largest share of total healthcare expenditure in 2002, at 31.3%. Spending on prescribed and non-prescribed drugs, outside hospitals, remains the second largest component of total health expenditure. CIHI estimates retail spending on drugs[4] was $15.1 billion in 2000, representing 15.4% of total health care spending. Spending on drugs is estimated to have increased by 11.9% in 2001 to $16.8 billion and by 7.7% in 2002 to $18.1 billion. As a result, CIHI estimates that drugs made up 15.9% of total health expenditure in 2001 and 16.2% in 2002.

CIHI has previously reported a steady increase in the share of spending on prescribed drugs from private sources, from 52.3% in 1992 to 57.6% in 1998. This trend was reversed in 1999 and 2000, with the private-sector share falling to 54.8%. CIHI expects this share to increase only slightly, to 55.0%, from 2000 to 2002. ■

1 Consult the Canadian Institute for Health Information website at www.cihi.ca,to obtain *The National Health Expenditure Trends, 1975-2002.*

2 See CIHI, Drug Expenditure in Canada, 1985-2001, April 2002, for earlier estimates.

3 This measure encompasses 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.

4 CIHI's estimates of spending on drugs do not include drugs dispensed in hospitals and other healthcare institutions.

Report on New Patented Drugs

Xatral

Brand Name	Xatral
Generic Name:	alfuzosin hydrochloride
DIN:	02245565 10 mg tablet
Patentee:	Sanofi-Synthélabo Canada Inc.
Indication (as per product monograph):	For the treatment of the signs and symptoms of benign prostatic hyperplasia.
Notice of Compliance:	February 21, 2002
Date of First Sale:	February 21, 2002
ATC Class:	G04CA01 *Urologicals, Drugs Used in Benign Prostatic Hypertrophy, Alpha-adrenoreceptor antagonists*

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, for all new active substances introduced after January 1, 2002.

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 on our website, under Legislation, Regulations, Guidelines.

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 Medicines Regulations, 1994*.

Evidence/ References:

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

Application of the Guidelines

Summary:

The introductory price of Xatral was 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 price did not exceed the range of prices in other comparator countries where Xatral was sold.

Scientific Review:

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

Benign prostatic hyperplasia (BPH) is a non malignant enlargement of the prostate. Two types of medicines are used in BPH: alpha adrenergic receptor antagonists (alfuzosin, tamsulosin, terazosin, doxazosin) which relax the prostatic smooth muscle via the blockade of sympathetic adrenergic receptors and 5α-reductase inhibitors (finastride) which reduce prostatic size via hormonal mechanisms.

Members of the same 4th level ATC class as Xatral include Flomax (tamsulosin) and Hytrin (terazosin). A fourth alpha antagonist, Cardura (doxazosin) has been classified in the cardiovascular class according to the 2002 ATC Index. Despite the different ATC classification, Cardura is indicated and used for BPH therapy.

Although Xatral and Flomax are uroselective alpha antagonists and are associated with fewer postural symptoms than the older agents, available scientific literature considers Xatral, Flomax, Hytrin and Cardura to provide similar improvements in lower urinary tract symptoms. Consequently, the HDAP recommended Flomax, Hytrin and Cardura as appropriate comparators for Xatral.

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 Xatral and the comparators are based on their respective product monographs and supported by clinical literature. See table in price test section below.

Price Review:

As shown in the following table, the price of Xatral 10 mg tablet was within the Guidelines relative to the TCC test as it did not exceed the prices of the other drugs in the therapeutic class.

Name	Strength	Dosage Regimen	Unit Price	Cost Per Day
Xatral	10 mg/tab	10 mg/day	$0.95[1]	$0.95
Flomax	0.4 mg/tab	0.4 mg/day	$0.95[2]	$0.95
Hytrin	5 mg/tab	5 mg/day	$0.96[3]	$0.96
Cardura	4 mg/tab	4 mg/day	$0.86[3]	$0.86

1 PPS, July 2002
2 Liste des médicaments, Régie de l'assurance maladie du Québec, 2001
3 Ontario Drug Benefit Formulary, 2001

At the time of introduction in Canada, Xatral was being sold in France, Germany, Italy, Sweden, Switzerland, and the United Kingdom and therefore was determined to be within the Guidelines relative to the highest price component of the International Price Comparison Test. The price in Canada was the 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

Since the publication of the October 2002 NEWSletter, 30 new DINs for human use (representing 18 new medicines) were added to the list of New Patented Medicines Reported to the PMPRB for the period ending December 31, 2002. Five of these new medicines are new active substances, representing ten DINs.

The following table presents the new active substances reported to the PMPRB during the period October to December 2002. ■

Brand Name	Generic Name	Company
Aranesp HSA Free (25 mcg/mL; 40 mcg/mL; 100 mcg/mL; 200 mcg/mL; 500 mcg/mL)	darbepoetin alfa	Amgen Canada Inc.
Tamiflu (75 mg/cap)	oseltamivir phosphate	Hoffmann-La Roche Canada Ltd.
Zenapax (5 mg/mL)	daclizumab	Hoffmann-La Roche Canada Ltd.
Orgalutran (250 mcg/mL)	ganirelix acetate	Organon Canada Ltd.
Integrilin (0.75 mg/mL; 2 mg/mL)	eptifibatide	Schering Canada Inc.

The list of New Patented Medicines Reported to the PMPRB is posted on our website under Publications; Patented Medicines; 2002.

Questions and Comments

Contact Us!

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

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 through our on-line feedback. We look forward to hearing from you! ■

You can contact us at:

Toll free-line:
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Patented Medicine Prices Review Board – December 9, 2002 Meeting

At its meeting, the Board:

- Considered the Report of the Working Group on Price Review Issues on the price Guidelines for category 3 new drug products.
- Received staff briefings on
  - ongoing initiatives under the National Prescription Drug Utilization Information System (NPDUIS);
  - the study on the *Prices of the Top Selling Multiple Source Medicines in Canada*, prepared by the PMPRB for the Federal/Provincial/Territorial Working Group on Drug Prices;
  - the study, *A Comparison of Pharmaceutical R&D Spending in Canada and Selected Countries*;
  - the study on *Foreign Price Trends for Patented Medicines*; and
  - the report of the Commission on the Future of Health Care in Canada, released November 28, 2002. ■

The next Board meeting is scheduled for February 10, 2003.

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

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

Upcoming Events

February
10
Board Meeting, Ottawa

February
11
Pre-Hearing Conference in the matter of Schering Canada Inc. and the medicine Remicade, Ottawa

February
13-14
Conférence – *Litiges pharmaceutiques – Les derniers enjeux cliniques, éthiques et juridiques associés à la mise en marché des médicaments*, Hôtel Inter-Continental Montréal
- Martine Richard, Senior Counsel

February
19-20
Conference – Strategy Institute, *5th Annual Maximizing Market Access – effective strategies to gain access to formularies*, The Sutton Place Hotel, Toronto
- Wayne D. Critchley, Executive Director

March
27-28
Insight Conference – Drug Patents, Crown Plaza Hotel, Toronto
- Wayne D. Critchley, Executive Director

March-April
30-1
The Canadian Association for Population Therapeutics Annual Conference, Québec City

April
3-4
Conference – Fundamentals of Administrative Law, Ottawa
- Martine Richard, Senior Counsel

April
22
Hearing in the matter of Schering Canada Inc. and the medicine Remicade, Ottawa

April
30
April 2003 NEWSletter

May
22-23
Board Meeting, Ottawa

September
22-23
Board Meeting, Ottawa

December
8-9
Board Meeting, Ottawa

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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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