Patented
Medicine Prices
Review Board

PMPRB NEWSletter

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January 2005

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 2004.

November 8:	Wayne Critchley gave a presentation at the Canadian Treatment Action Council (CTAC) Conference: Skills Building Session for the Community, the focus of which was the shifting landscape of drug approval, marketing and reimbursement, in Toronto.
November 10:	Dr. Robert Elgie addressed the Canadian Institute conference Pharma Patents – Pricing Issues: Latest Developments in Federal Pharmaceutical Price Controls in Canada, in Toronto.
November 16:	Dr. Elgie accepted a Voluntary Compliance Undertaking (VCU) submitted by ESP Pharma to reduce the price of Busulfex and offset excess revenues. More information on this matter appears on page 11.
November 22:	Dr. Elgie and Réal Sureau delivered a speech, *The Future of Price Controls: Maintaining the Balance*, simultaneously at the Pharmac 2004 Conference, in Toronto, and at the Insight Conference – Marketing of Drug Products in Canada, in Montréal. The speech is available on our website under Publications; Speech Series 2004.
November 24-25:	The PMPRB, in collaboration with the Canadian Institute for Health Information, the Canadian Coordinating Office for Health Technology Assessment and Health Canada's Therapeutic Products Directorate, co-hosted the Conference on Drug Utilization Indicators, Drug Standards and Drug Statistics Methodologies, in Ottawa.
December 16-17:	The Board held its last meeting of the year. A summary of the Minutes are available on page 10.
January 18:	Sylvie Dupont gave a presentation to the Ottawa Council of Women, on the role of the PMPRB.
January 19:	The Board held a pre-hearing conference in the matter of LEO Pharma Inc. and the medicine Dovobet. More information on this matter appears on page 4.
January 27:	Wayne Critchley gave a presentation, *Drug Prices in Canada and the U.S.: More Than Meets the Eye?*, at the Annual Conference of the National Academy of Social Insurance, in Washington, D.C. The Academy is a non-partisan, non profit organization whose mission is promoting understanding and informed policymaking on social insurance programs. His presentation, is available on our website under Publications; Speech Series 2005. ■

Comings and Goings!

- The PMPRB is pleased to announce the appointment of Barbara Ouellet as Executive Director, effective January 31, 2005.

  Mrs. Ouellet has had extensive experience in policy development in a number of aspects of health care and has had specific responsibility for pharmaceutical policy issues since 1999. Among other positions she had held, Mrs. Ouellet was most recently Director of the Quality Care, Technology

and Pharmaceuticals Division in the Health Policy Branch at Health Canada. She was also the federal Co-Chair of the Federal/Provincial/Territorial Pharmaceutical Issues Committee and was directly involved in many of the important initiatives in recent years including the Common Drug Review and the National Prescription Drug Utilization Information System.

We take this opportunity to thank Wayne Critchley for his important contribution to the PMPRB as Executive Director over the last 15 years. He will serve as Special Advisor to the Chairperson until April.

- Roger Guillemette, Director of the Policy and Economic Analysis Branch, has completed his assignment and returned to Health Canada. We would like to thank Mr. Guillemette for his contribution to the PMPRB during his secondment and we wish him every success in his endeavours. In the interim, Gina Charos has accepted to take on additional duties as acting Director as of January 1, 2005.

  We also wish best of luck to Denise Lemire who has accepted a position with Health Canada. Adam Russell, a co-op student from the University of Waterloo, has joined the team and will be working on NPDUIS projects.

- Stéphanie Patenaude has joined the Compliance and Enforcement Branch.

- Lyne Bélisle has joined the Secretariat as Communications Officer while Anne-Marie Labelle is on secondment with Foreign Affairs Canada.

We want to convey our very best wishes for success to all. ■

Chairperson's Message

Robert G. Elgie

How the landscape has changed since 1995! As Chairperson of the Patented Medicine Prices Review Board, I have had the privilege to be part of an extraordinary ten-year journey.

Created in 1987, the PMPRB was still a young organization when I was appointed as its Chairperson in 1995. In those early years, we had our share of growing pains and challenges as the Board was still developing tools and clarifying its policies. Along with me, during that same year, three new Board Members were appointed, including a new Vice-Chairperson, Réal Sureau who has made a valuable contribution during what turned out to be a period of significant change. Professor Harry Eastman, first Chairman of the Board, agreed to stay on as Member of the Board for a short period, helping to ensure a smooth transition. His breadth of experience and in-depth knowledge of the pharmaceutical industry proved invaluable to me as the new Chairperson at a time of intense activity and change. The PMPRB was entering a new era. It was an exciting time and an exciting place to be.

In 1997, a legislated parliamentary review of the pharmaceutical provisions of the *Patent Act* lead the Board to undertake a full review of its activities and operations. Board Members and Staff alike took part in a two-year long project that resulted in major adjustments in the PMPRB's outlook and way of doing business. With a discussion paper in hand, the Board embarked on its first major consultation with stakeholders. Touring the country in the middle of winter had its limited charm, but meeting stakeholders brought a whole new dimension to our activities.

Close on the heels of our consultation on the PMPRB's role and functions, we published the PMPRB's *Road Map for the Next Decade* in September 1998. In the midst of our major review, the Auditor General released a report on the PMPRB's activities in September. During this period, we initiated new studies, held a policy hearing, and launched our Research Agenda. We also established a Working Group on Price Review Issues, which included representatives of all our main stakeholder groups.

Amidst all of this activity, we drew on our consultation experience during which we had received valuable feedback from stakeholders, all pointing to a need to increase transparency in our price review policies and procedures. This prompted us to substantially increase our focus on transparency. In this area, as in many others, the changes that followed the release of the *Road Map* were profound and lasting.

The PMPRB's regulatory and reporting activities did not take a back seat during this period. In fact, Staff somehow found ways and means to ensure a more efficient and timely delivery of the Program.

In 2001, the Ministers of Health announced several initiatives, among which the establishment of the National Prescription Drug Utilization Information System (NPDUIS). The NPDUIS is designed to provide critical analyses of price, utilization and cost trends so that Canada's health system has more comprehensive, accurate information on how prescription drugs are being used and on sources of cost increases. The PMPRB and the Canadian Institute for Health Information (CIHI) partner in implementing the NPDUIS.

We pursued the gradual implementation of our *Road Map*, while the Working Group examined and reported on several issues which led to more changes in our operations and greater transparency. In 2002, we marked the 15th anniversary of the PMPRB by hosting a Symposium which brought together Canadian and international representatives of healthcare, academia, pharmaceutical and public sectors, along with consumers and seniors. The Symposium provided an opportunity to share information on a wide range of issues related to drug prices.

Through the years, new federal-provincial-territorial agreements in the area of health and pharmaceuticals, the creation of new national programs, and new partnerships, have propelled the PMPRB in new directions – all the while drawing on Staff's expertise. Recently, the First Ministers agreed to the creation of the National Pharmaceutical Strategy in which the PMPRB will play an active part.

We have been able to coordinate activities with other organizations so as to better serve Canadians and contribute to more informed decisions and policy making.

While change has been the constant over the last ten years, an equally constant element has been the importance of healthcare to Canadians. The PMPRB has continually worked to ensure that it remains responsive to the needs of Canadians. This would have been impossible to achieve without the active participation of our Board Members and of our very talented and dedicated Staff. I want to take this opportunity to thank each member of the PMPRB Staff, present and past, for his/her invaluable contribution, hard work and dedication to this Program. In particular, I want to thank Wayne Critchley, who has served the PMPRB over the last 15 years as Executive Director. He has made an outstanding contribution to this organization for which I am profoundly grateful. As he leaves the PMPRB in the capable hands of Barbara Ouellet to meet new challenges, I offer him my sincere thanks and best wishes of success.

I have enjoyed my stay at the PMPRB. It has been a uniquely exciting challenge. I thank all of you for having given me the opportunity to represent the PMPRB as its Chairperson for ten remarkable years.

I wish the PMPRB Board Members and Staff every success in all future endeavours. Thank you for your support, your dedication and, above all, your service to your fellow Canadians. ■

Robert G. Elgie

Senior Staff

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

Congratulations to all!

We are proud to announce that the PMPRB has exceeded its goal by **26%**. Once again, the PMPRB Staff has demonstrated continued support towards the community by generously contributing to the United Way Campaign.

Special thanks go to Elaine McGillivray, the PMPRB Campaign Leader, for her dedication and continued efforts towards the success of the campaign. ■

The Board issues two Notices of Hearing

	LEO Pharma Inc. – Dovobet	Janssen-Ortho Inc. – Evra
Pre-Hearing Conference	January 19, 2005	February 24, 2005
Hearing to start	March 9, 2005	May 11, 2005

… in the matter of LEO Pharma Inc. and the medicine Dovobet

On November 29, 2004, the Board issued a Notice of Hearing into the price of the medicine Dovobet. The public hearing is scheduled to start on March 9.

The purpose of the hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, LEO Pharma Inc. is selling or has sold the medicine known as Dovobet 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.

A pre-hearing conference was held on January 19, 2005. The Board heard arguments on preliminary matters in preparation for the March 9 hearing.

Dovobet is a dermatological drug that is administered for acute flare-ups of psoriasis. It has been sold in Canada since December 17, 2001.

… in the matter of Janssen-Ortho Inc. and the medicine Evra

On December 23, 2004, the Board issued a Notice of Hearing into the price of the medicine Evra. The public hearing is scheduled to start on May 11.

The purpose of this hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, Janssen-Ortho Inc. is selling or has sold the medicine known as Evra 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.

The Board has scheduled a pre-hearing conference for February 24, 2005, to hear arguments on preliminary matters in preparation for the May 11 hearing.

Evra is a transdermal contraceptive patch indicated for the prevention of pregnancy in women who elect to use hormonal contraceptives. ■

The Notices of Hearing are available on our website under Publications; Hearings.

For more information on these matters and the hearing process, please contact the Secretary of the Board:

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Price Increases for Patented Medicines: Consultation with Stakeholders

In November 2004, Dr. Elgie called for a dialogue with stakeholders on the issue of price increases for patented medicines (http://www.pmprb-cepmb.gc.ca/english/view.asp?x=271&id=21). While the combination of federal and provincial restraints on drug prices has resulted in stability in prices over the last decade, there have been a number of reports in the last several months of price increases that raise questions. The information available to date suggests that manufacturers of about 35% of the patented medicines under the PMPRB's jurisdiction notified the trade of price increases in 2004.

Price increases in line with changes in the Consumer Price Index (CPI) are permitted under the PMPRB's Excessive Price Guidelines (Guidelines). The reported price increases appear to have been within the limits allowed under the Guidelines. However, the Board is monitoring these developments very closely to ensure that this is not the beginning of a new trend towards higher prices.

The extent to which these reports could translate into an actual increase in the average prices of patented medicines in Canada is not known at this time. In keeping with its consumer protection mandate, the PMPRB has an obligation to not only monitor these reports, but also to be prepared to review and amend its Guidelines, if necessary.

At this time, the Board is studying this issue, and has not developed any position or policy proposal. As it reviews its Guideline on price increases, it will be important for the

The discussion paper will be available on our website on or before February 28, under Publications; Notice and Comment; Price Increases for Patented Medicines.

Comments on the discussion paper should be directed to the Secretary of the Board, **no later than April 15, 2005**.

Board to hear from its stakeholders on their views on issues related to price increases. To facilitate this dialogue, the Board is issuing a discussion paper that outlines price trends, how the Guideline for price increases has evolved over time, and the factors that suggest that it may be time for a change. Most importantly, the discussion paper identifies a number of questions that the Board would like stakeholders to consider and provide feedback on. ■

Proposed Amendments to the *Patented Medicines Regulations* for Consultation with Stakeholders

The *Patented Medicines Regulations, 1994* (Regulations) set out patentees' filing requirements with respect to the PMPRB. The Regulations specify the information that patentees must file with the PMPRB in accordance with their obligations under the *Patent Act* (Act), and the timeframes for doing so.

The Regulations have not had any substantial amendments since 1994, when they were amended to reflect changes to the Act at the time. A decade later, the Regulations need to be modernized in some areas to better reflect the information needs to conduct price reviews. This became clear when the PMPRB initiated its Timelines Project. In studying ways to improve the timeliness of the price review process, it was evident that the timeliness of reviews depends very much on what patentees file (or do not file). In some cases, Board Staff must go out of its way to obtain information that should be a standard part of a patentee's submission (e.g., product monograph or proposed price for a new drug review).

Also, the Regulations do not reflect changes in PMPRB procedures that have been implemented since 1994. For example, approximately 87% of patentees now file their sales and price data electronically with the PMPRB. But, since the Regulations do not recognize the company officer's electronic signature, patentees must go through the redundant step of also mailing a copy to the PMPRB.

Another change that has been made since the Regulations were last amended relates to the submission requirements of veterinary patentees. In September 2003, the PMPRB decided to implement a full complaints-driven approach for the regulation of patented veterinary drug prices. This decision was communicated to stakeholders in the PMPRB's January 2004 NEWSletter. Since the Regulations do not distinguish between the filing requirements for human drug patentees and veterinary drug patentees, they need to be amended to clarify the different reporting requirements of each.

The full text of the Notice and Comment proposal to amend the *Patented Medicines Regulations* is available on our website under Publications; Notice and Comment; *Patented Medicines Regulations*.

Following stakeholder input on this Notice and Comment, the PMPRB will make a formal submission to amend the Regulations, as per the Government of Canada's process for regulatory change. As with any proposal for regulatory changes, there will be further opportunity to comment through the Canada Gazette. ■

Comments on the Notice and Comment proposal should be forwarded to the Secretary of the Board **no later than April 15, 2005** at the following address:

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PMPRB

NPDUIS Update

The announcement of the National Pharmaceuticals Strategy (NPS) by First Ministers in September 2004, in particular the initiative to enhance analysis of cost drivers and cost-effectiveness, including best practices, illustrates a commitment to continue the work being done under the NPDUIS.

The challenge for the NPDUIS and the PMPRB is to ensure that its analytical work in the area of pharmaceuticals contributes to the NPS. To this end, the PMPRB will conduct a needs assessment. The purpose of the needs assessment is to determine what information is required to make informed decisions about strategic pharmaceutical management issues. It is anticipated that the needs assessment will be completed in 2005-2006. ■

PMPRB'S Research Agenda

Issue	Description	Key Deliverables	Status
CPI Guideline Policy Review	Review the Guideline for price increases	Discussion paper for consultation	January 2005 NEWSletter
		Report on submissions received	To follow after consultation
Patented Medicines Regulations	Propose amendments to the *Patented Medicines Regulations*, which set out patentees' filing requirements	Notice and Comment proposal	January 2005 NEWSletter
		Report on results	To follow after consultation
Price Review Timelines	Establish milestones and timelines for the price reviews of new patented medicines	Proposals for consultation	Pending work on *Patented Medicines Regulations*
List Prices	Review issues related to manufacturers publishing a list price that is not reflective of the average selling price	Updates as required	Last update October 2004 NEWSletter
Guidelines: International Price Comparison	1) Review the appropriate test when fewer than 5 countries	Board's response	January 2005 NEWSletter
	2) Review the appropriateness of the Highest Price Rule	Board's response	January 2005 NEWSletter
	3) Review methodology for calculating the average price for a foreign country when conducting an International Price Comparison	Board's response	January 2005 NEWSletter
Guidelines: Category 2 Drug Prices	Review of the appropriateness of the median price test for category 2 drugs, including the usefulness of pharmacoeconomics	Board's response	January 2005 NEWSletter
Foreign Price Trends	An analysis of pharmaceutical prices in foreign countries	Report	Fall 2005
Evaluation	Evaluation of initiatives on transparency adopted by the PMPRB beginning in 2001	Board's response	Methodology and timeframe to be determined
National Prescription Drug Utilization Information System – NPDUIS			
Cost drivers in the Non-Insured Health Benefits Program	Examine expenditure, utilization and prices in the federal government's Non-Insured Health Benefits Program, using the PMPRB's cost driver analysis methodology	Report	September 2004
Pharmaceutical Trends Overview Report	Research on price and expenditure trends, price levels and cost-drivers in public reimbursement plans	Report	Winter 2005
Budget Impact Analysis Guidelines	Develop a methodology for performing Budget Impact Analyses (BIA), to estimate the net impact on reimbursement program costs of listing new drug products	Report/guidelines	Summer 2005
Program expenditure forecasting methodology	Develop a methodology for producing reliable forecasts of program expenditure by major therapeutic class over a forecast period of three years	Report/forecasting framework	Spring 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 2005

Review of Policies and Procedures: International Price Comparisons

The PMPRB uses international price comparisons for both its regulatory and reporting mandates. The comparator countries are set out in the *Patented Medicines Regulations*, and include: France, Germany, Italy, Sweden, Switzerland, U.K. and U.S. Given the importance of international price comparisons for both the regulatory and reporting mandates, the PMPRB regularly reviews its operations in conducting them. Most recently, three elements of the PMPRB's procedures with respect to international price comparisons were reviewed and validated. These projects were on the PMPRB's Research Agenda.

1) Review the Appropriate Test when Fewer than Five Countries

In cases where the median IPC is the pivotal price test in a price review, a comparison is made between the introductory price in Canada and the median price of that drug in the comparator countries. When the medicine is sold in fewer than five countries, it is possible that the median could change as the medicine is later introduced into other countries. As such, the Guidelines provide that an interim benchmark price is assigned, with a review conducted at the end of the three years or when the medicine is sold in at least five countries, whichever comes first. The PMPRB reviewed its internal processes in managing these cases. Overall, there are not many products that received an interim benchmark price because they were sold in fewer than five comparator countries at the time of introduction. For those products that did have an interim benchmark price, it was found that the PMPRB effectively monitored their prices in relation to the international median. Further, it was found that at the end of the interim period, the prices of all of the products reviewed continued to be within the Guidelines.

2) Review of the Highest Price Rule

The PMPRB's Guidelines require that the price of a patented medicine in Canada cannot be the highest of the seven comparator countries. This Guideline was implemented a decade ago and has contributed to ensuring that the prices of patented medicines in Canada on average are in line with the median of prices in the comparator countries. While the policy objective of this Guideline continues to be valid, the PMPRB reviewed its operations to determine if there were any issues in its implementation. The review found that there is sufficient flexibility in the PMPRB's Guidelines and operations to address situations where there is a change in the composition of international prices that is outside of the control of a patentee (e.g., if a drug is removed from the market of a comparator country). To ensure appropriate flexibility, the PMPRB will continue to address any such situations on a case-by-case basis.

3) Methodology for Calculating the Average Price for a Foreign Country

The method used by the PMPRB for the calculation of average prices in the seven comparator countries is an average of prices for each customer class and pack size submitted by patentees, as per their requirements under the *Patent Act*. The PMPRB regularly verifies the international price information filed by patentees using publicly available prices published in the comparator countries. We publish our findings in our Foreign Price Verifications studies, which are conducted approximately every three years. Most recently, we reviewed our methodology again to ensure that it continues to supply an accurate indication of international prices. As with our published Foreign Price Verification studies, this recent review confirmed that our methodology continues to supply an accurate picture of international prices. For more information on our Foreign Price Verification studies, refer to our Studies Series on our website.

Since there do not appear to be any significant issues in how the PMPRB implements its international price comparison guidelines, further study of these issues is not warranted at this time. Related to these reviews on the Research Agenda is the item on reviewing the median international price test for category 2 new medicines. This item was placed on the Research Agenda at the time when the reviews of our international price comparison methodologies were also listed for study. Given that there are no operational problems with conducting international price comparisons, there does not appear to be any need at this time to review the median international price test. Furthermore, price trends, as reported in our Annual Reports, continue to indicate that prices in Canada are on average in line with the median of prices in our comparator countries. Thus, the policy objective of this guideline continues to be met. In the meantime, we will continue to monitor and report on Canadian prices and those in our comparator countries and we will revisit this issue in the future, as needed. ■

PMPRB e-Bulletin! Questions and Comments

Your comments – Your views

You want to share your thoughts? You want more information on activities related to the PMPRB?

Let us know

We want to hear from you. We appreciate any ideas or suggestions on topics you wish to see covered in the NEWSletter.

We welcome your comments and questions. Enjoy reading them in our NEWSletter
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Human Drug Advisory Panel (HDAP) Process

The role of the Human Drug Advisory Panel (HDAP) is to provide recommendations for the categorization, the selection of comparable drug products and dosage regimens for all new active substances. The HDAP may also recommend that a new drug product which may or may not be a new active substance product, be considered a breakthrough or substantial improvement (i.e. category 2). Recommendations of the HDAP are based on the criteria set out in the PMPRB's *Compendium of Guidelines, Policies and Procedures*. The approach is evidence based and the recommendations reflect medical and scientific knowledge and current clinical practice.

The HDAP is composed of three members who hold qualifications as a physician, pharmacist or other professional designation with recognized expertise in drug therapy and who have experience in clinical research methodology, statistical analysis and the evaluation of new drugs. The current members are: Dr. Jean Gray, Dr. Mitchell Levine and Dr. James McCormack.

The HDAP meets four times a year. The meetings for **2005** are scheduled as follows: **February 17, May 18, August 15 and November 17**.

The HDAP reviews and evaluates scientific information available to the PMPRB including submissions by patentees. Each member of the HDAP conducts an independent review of the drug product which will be discussed during the HDAP meetings or conference calls. The recommendations of the HDAP are based on a majority vote.

In order to provide for fairness to the patentee, assurance that a drug will in fact be scheduled for discussion at a meeting and to also expedite the process, Board Staff requires that a patentee provide a product monograph or draft product monograph (if the product has not yet been approved for sale in Canada) at least three months prior to an HDAP meeting.

If a patentee wishes to make a submission with respect to category and comparable drugs and dosage regimens, the submission must be made two months prior to an HDAP meeting. For more details on what should be included in a company submission, please refer to the *Compendium of Guidelines, Policies and Procedures, Scientific Review Procedures*, Section 6 and 7. Board Staff will refer this submission as well as any additional information that it has collected, to the HDAP at least one month before an HDAP meeting.

The recommendations of the HDAP are made available to the patentee.

The HDAP's recommendations on new active substances and all category 2 drug products are published in a summary report on the results of the price review and included on the PMPRB website under Patented Medicines.

Summary of Meetings for 2005 and Information to be Submitted

Date of HDAP Meeting	Information	Deadline
February 17, 2005	• 1 copy of product monograph or draft product monograph	• November 17, 2004
	• 7 copies of company submission	• December 17, 2004
May 18, 2005	• 1 copy of product monograph or draft product monograph	• February 18, 2005
	• 7 copies of company submission	• March 18, 2005
August 15, 2005	• 1 copy of product monograph or draft product monograph	• May 15, 2005
	• 7 copies of company submission	• June 15, 2005
November 17, 2005	• 1 copy of product monograph or draft product monograph	• August 17, 2005
	• 7 copies of company submission	• September 17, 2005 ■

Report on New Patented Drugs – Cetrotide

Brand Name: Cetrotide

Generic Name: cetrorelix

DIN:

02247766	0.25mg/vial	Injection
02247767	3.0mg/vial	Injection

Patentee: Serono Canada Inc.

Indication – as per product monograph: For the prevention of premature ovulation in patients undergoing controlled ovarian stimulation (COS)

Notice of Compliance: August 13, 2003

Date of First Sale: February 25, 2004

ATC Class: H01CC02
Systemic Hormonal Preparation, Excl. Sex Hormones and Insulins; Pituitary and Hypothalamic Hormones and Analogues; Hypothalamic Hormones; Anti-Gonadotropin-Releasing Hormone

Application of the Guidelines

Summary:

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

Scientific Review:

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Cetrotide be reviewed as a category 3 new drug product (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.

Cetrotide is used in assisted reproduction techniques to prevent premature luteinising hormone (LH) surges in women undergoing controlled ovarian stimulation (COS), allowing the follicles to mature for planned oocyte retrieval. The HDAP identified Orgalutran as the most appropriate comparator to Cetrotide. This agent belongs to the same 4th level ATC, shares the same indication and is clinically equivalent in addressing the approved indication.

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 Cetrotide and its comparator are based on the respective product monographs and supported by clinical literature.

Price Review:

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

Name	Strength	Dosage Regimen	Unit Cost[1]	Cost per Treatment
Cetrotide	0.25mg/mL	1.25mg (5mL)	$90.00	$450.00
Orgalutran	0.25/0.5mL	1.25mg (2.5mL)	$94.71	$473.55
Cetrotide	3mg/3mL	3mg (3mL)	$340.00	$340.00
Orgalutran	0.25/0.5mL	1.25mg (2.5mL)	$94.71	$473.55

1. PPS, July 2004

Evidence/ References:

The references are available on the PMPRB website, under Patented Medicines; Reports on New Patented Drugs for Human Use; Cetrotide.

In 2004 Cetrotide 0.25mg/mL was also sold in France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States, and Cetrotide 3mg/3mL was also sold in France, Germany, Sweden, Switzerland, 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 price of Cetrotide 0.25mg/mL in Canada was third lowest, below the international median price, and the price of Cetrotide 3mg/3mL was second lowest, below the international median price.

The comparators and dosage regimens referred to in the Summary Report have been selected by Board Staff and the HDAP, for the purpose of carrying out the PMPRB's regulatory mandate which is to review the prices of patented medicines sold in Canada to ensure that such prices are not excessive. This publication is also part of the PMPRB's commitment to make its price review process more transparent.

The information contained in the PMPRB's Summary Report should not be relied upon for any purpose other than its stated purpose and is not to be interpreted as an endorsement, recommendation or approval of any drug nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner. ■

New Patented Medicines Reported to the PMPRB

Since the publication of the October 2004 NEWSletter, 18 new DINs for human use (representing 11 medicines) were added to the list of New Patented Medicines Reported to the PMPRB for the period ending December 31, 2004. Five of these new medicines are new active substances, representing six DINs.

The following table presents the five new active substances reported to the PMPRB during the period October to December 2004.

As of December 31, 2004

Brand Name	Generic Name	Company
Humira (40 mg/syringe)	adalimumab	Abbott Laboratories Ltd.
Amevive (15 mg/vial)	alefacept	Biogen Idec Canada Inc.
Reyataz (150 mg/capsule) Reyataz (200 mg/capsule)	atazanavir sulfate	Bristol-Myers Squibb Pharmaceutical
Alimta (500 mg/vial)	permetrexed disodium	Eli Lilly Canada Inc.
Remodulin (5 mg/ml)	treprostinil sodium	Northern Therapeutics Inc.

Patented Medicine Prices Review Board – December 16-17, 2004 Meeting

At its meeting, the Board:

- had a presentation on:
  - CIHI's Report – National Health Care Expenditure Trends – 1975-2004
- received briefings on:
  - results of the price review of Iressa;
  - dual pricing; and
  - ongoing activities under the NPDUIS and the following projects:
    - Impact Upon Drug Plans of Changes in Drug Distribution Channels
    - Pharmaceutical Trends Overview
    - Budget Impact Analysis
  - Common Drug Review Program. ■

The next Board meeting is scheduled for February 25, 2005.

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.

VCU accepted during the last quarter: Busulfex

The PMPRB concluded an investigation into the price of the drug product Busulfex, resulting in a price reduction of over 7%.

On November 16, the Chairperson accepted a VCU by ESP Pharma. The terms of this VCU required that, for the purposes of complying with the Board's Price Guidelines, ESP lower the average selling price of Busulfex to the 2004 maximum non-excessive price (MNE) of $359.89 per ampoule.

To offset excess revenues received, ESP made payments totaling $150,646.99 to the Government of Canada.

Busulfex has been sold in Canada since April 1999. The patent pertaining to Busulfex was granted in July 2002. Although Busulfex came under the PMPRB's jurisdiction in July 2002, the PMPRB's price review jurisdiction extends retroactively to include pre-grant patent infringement period, which in this instance is April 1999. The price of Busulfex will remain under the PMPRB's jurisdiction until the expiry of the patent in August 2014. ■

Busulfex is an antineoplastic agent indicated for use in combination with other chemotherapeutic agents and/or radiotherapy as a conditioning regimen prior to hematopoietic progenitor cell transplantation (HPCT), or bone marrow transplant.

National Health Expenditure Trends, 1975-2004

On December 8, 2004, the Canadian Institute for Health Information (CIHI) released its annual report on Canada's health expenditure.

CIHI reports that:

- Health care expenditure is expected to reach $130.3 billion in 2004 – a 5.9% increase over 2003, and the lowest annual growth rate since 1997.
- Health care expenditure per person is expected to reach $4,077 in 2004 – a 5% increase from 2003.
- The public and private sector shares of health expenditure are expected to remain at 69.9% and 30.1% in both 2003 and 2004.

Canada remains among the heaviest health care spenders in the industrialized world. Health care took up 9.6% of GDP in 2002, which gave Canada the fifth highest ratio of OECD countries reported – following the United States, Switzerland, Germany and France.

Spending on hospitals accounted for the largest share (29.9%) of total health care expenditure in 2004. Spending on drugs outside hospitals remains the second largest component (16.7%) of total health expenditure, ahead of physicians (12.9%), other professionals (11.2%) and other institutions (9.6%).

The report also includes estimates of total drug spending by prescription status and by source of funds. Included as drugs are prescribed medications, over-the-counter drugs and personal health supplies. Excluded from the estimates are drugs dispensed in hospitals and in other institutions.

CIHI estimates spending on drugs to rise by 8.7% in 2003 (to $20 billion) and by another 8.8% in 2004 (to $21.8 billion). Spending on prescription drugs is estimated to have increased by 10% in 2003 and by 10.2% in 2004.

The public sector is estimated to account for 39% of all drug spending in 2004. This estimate rises to 47.2% when we consider only prescription drugs.

The public share of drug expenditure varies significantly among provinces and territories – with lows ranging from 26 to 30% in Prince Edward Island, Nova Scotia and New Brunswick and highs of 41 to 45% in Saskatchewan, Manitoba and Quebec. Public sector shares of drug spending are even higher in the territories – at 42%, 53% and 68%, respectively for Nunavut, Yukon and the Northwest Territories.

The PMPRB is collaborating with CIHI on the assessment of drug utilization and expenditures within the public sector as part of the National Prescription Drug Utilization Information System (NPDUIS). The data from the *National Health Expenditure Trends, 1975-2004* provides a valuable reference for this collaboration.

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

Values reported for 2003 and 2004 are estimates based on provincial/territorial government budgets and forecasts of spending by private and public sectors. ■

Consult the Canadian Institute for Health Information website at www.cihi.ca to obtain the *National Health Expenditure Trends, 1975-2004*.

Upcoming Events

February
17
HDAP Meeting

February
24
Pre-hearing conference in the Evra matter

February
25
Board Meeting

March
9
Hearing in the Dovobet matter

April
4-5
Canadian Institute conference – *Understanding the National Pharma Strategy: Balancing Canadian Price Controls with a Global Free Trade Environment*

April
29
April NEWSletter

May
11
Hearing in the Evra matter

May
17-18
Board Meeting

May
18
HDAP Meeting

May
31
2004 Annual Report to the Minister of Health

June
19-21
Canadian Council of Administrative Tribunals (CCAT)

July
30
July NEWSletter

August
15
HDAP Meeting

September
22-23
Board Meeting

October
31
October NEWSletter

November
17
HDAP Meeting

December
15-16
Board Meeting

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