Patented
Medicine Prices
Review Board

PMPRB NEWSletter

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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 July 2003.

July 31:	Sylvie Dupont gave a presentation at the Rx&D Industrial Pharmacy Studentship Seminar, in Montréal.
September 18-19:	The Board held its third quarterly meeting for 2003. A summary of the Minutes appear on page 7.
September 23:	Dr. Robert Elgie, Réal Sureau and Wayne Critchley appeared before the Standing Committee on Health. The Committee is currently studying various issues relative to prescription drugs in Canada. More information is available in the *Message from the Chair*.
October 21:	The Chairperson approved a Voluntary Compliance Undertaking by Pfizer Canada Inc., regarding the medicine Dostinex. More information is available on page 6.
October 30:	Wayne Critchley addressed private insurers on the role of the PMPRB at a Brogan Seminar.
October 31:	Wayne Critchley and Sylvie Dupont met with a delegation from the department of The Ministry of State Development Price Committee and Price Inspection Division of the People's Republic of China on the role of the PMPRB in drug price regulation in Canada.

Congratulations!

Robert Sauvé, Director of Corporate Services, was appointed to the Board of the Public Service Dental Care Plan (National Joint Council Part). ■

Comings and Goings!

Over the past few months, new employees have joined the PMPRB. We are happy to welcome ***Dan Roumelis*** back among our midst after a few years at the Department of National Defence. We also welcome new members to the team: ***Suzanne Paré***, from Health Canada, ***Marc Legault***, from the Competition Bureau, Industry Canada, and ***Brigitte Boulet***, from the Canadian Intellectual Property Office.

We bid farewell to Jennifer-Anne McNeill, Communications Advisor, who accepted a promotion with Health Canada and to Angela Pinchero, statistician, who joined a humanitarian group in Sri Lanka. We wish them both success in their new endeavours.

On November 10, Ron Corvari, Director of Policy and Economic Analysis, joined Health Canada as Executive Advisor, Pharmaceuticals Policy,

Health Policy and Communications Branch, where he will be responsible for selected policy initiatives, in particular non-patented drug price policy work. Ron has had a profound impact on a professional and personal level within the PMPRB in pursuing our strategic objectives to strengthen our economic analysis capacity and appropriate relationships with stakeholders, including F/P/T governments. We wish him continued success in his new challenges. ■

Senior Staff

Executive Director:
Wayne Critchley

Secretary of the Board:
Sylvie Dupont

Director of Policy and Economic Analysis:
Vacant

Director of Compliance and Enforcement:
Ginette Tognet

Director of Corporate Services:
Robert Sauvé

Senior Counsel:
Martine Richard

Message from the Chair

The Standing Committee on Health announced last June that it would be conducting a study on prescription drugs.

This Fall, the Committee held hearings in Ottawa and across the country to gather information on the health aspects of various issues relative to prescription drugs, patented and non-patented, in Canada, such as rising costs, price controls, and approval of new drugs, to name a few.

Robert G. Elgie, Chairperson

The PMPRB was invited to appear before the Committee to brief the members on its role and responsibilities and to discuss the current regulatory framework on pricing of pharmaceuticals in Canada.

Pharmaceuticals management is of great interest to Canadians while representing a central part of our health care system. We reiterated to the Committee the PMPRB's commitment to playing its part in carrying out its mandate and in supporting a collaborative process based on the goal of serving the health care needs of all Canadians.

For those of you interested in reading the transcript of the Committee's deliberations on this important issue, they are available on the Parliament's website at www.parl.gc.ca. ■

Robert G. Elgie,
Chairperson

The Chairperson's introductory remarks to the Standing Committee on Health are available on our website under Other Publications; Speech Series; 2003.

Compendium of Guidelines, Policies and Procedures

The PMPRB first published the *Compendium of Guidelines, Policies and Procedures* in 1994 as a consolidation of its Guidelines, policies and procedures which had previously been published in various issues of its now defunct publication, the Bulletin.

From time to time since then, we have published clarifications of the Guidelines in the NEWSletter and consulted on amendments through our Notice and Comment process. Recently, we have updated the Compendium to incorporate amendments as well as other revisions of a technical nature.

In order to assist our readers in identifying the changes, strikeout and highlight features have been used to draw attention to these changes. This updated version of the Compendium will be posted on our website on December 1 and replaced with a clean copy at the beginning of the new year.

The Compendium is available on our website under Legislation, Regulations and Guidelines. ■

Price Increases – Monitoring Compliance with the Guidelines

As a result of recent reports of possible price increases for some patented medicines, the PMPRB has received enquiries regarding the application of the Guidelines.

The mission of the PMPRB is to protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive. 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.

Consistent with section 85 of the *Patent Act*, the Guidelines limit increases in the prices of patented medicines to increases in the Consumer Price Index (CPI). The method for forecasting changes in the CPI and the calculation of allowable increases is set out in Schedule 4 of the Compendium of Guidelines Policies and Procedures. With respect to existing drugs, the PMPRB reviews the price of the drug to determine if it exceeded its benchmark price adjusted for the cumulative change in the CPI from the benchmark year to the year under review. The usual practice is to calculate the average of the prices at which drug product was sold to all classes of customers in all provinces during the period under review.

In 2002, the prices of all patented medicines declined, on average, by 1.2% from the previous year. This result continued the trend of average increases below the increases in the CPI that has been reported over the past decade.

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

In addition, the policies of the PMPRB provide that Board Staff may conduct an investigation upon receipt of a substantiated complaint. If it receives information that a manufacturer has increased a price by more than the allowable amount, Board Staff will conduct an investigation to determine the facts.

An investigation may result in a hearing by the Board. In the event that the Board finds 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*** (emphasis added). 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. ■

Top-Selling Multiple Source Study – Data Correction

Last June, the PMPRB released a study on prices of the top-selling multiple source medicines, conducted on behalf of the Federal/Provincial/Territorial Working Group on Drug Prices, *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*. In Table 7, page 29, the figures reported for the Generic Market Share (by volume) for the U.S. are incorrect; it has been estimated that the generic U.S. market share based on prescription volume accounted for approximately 45% in 2000. The market share reported for the U.K. was based on prescriptions under the National Health Services; it is reported that generics accounted for 53% of the prescriptions dispensed in the U.K. as a whole.

These corrections will be made to the copy of the *Study of the Prices of the Top Selling Multiple Source Medicines in Canada* available on our website under Other Publications; Study Series; F/P/T Reports. ■

PMPRB

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.

Report on New Patented Drugs – Aranesp

Brand Name:	Aranesp
Generic Name:	darbepoetin alfa
DIN:	02246354 10 mcg/syr 02246355 20 mcg/syr 02246357 30, 40, 50 mcg/syr 02246358 60, 80, 100 mcg/syr 02246360 150 mcg/syr
Patentee:	Amgen Canada Inc.
Indication (as per product monograph):	For the treatment of anaemia associated with chronic renal failure (CRF), including patients on dialysis and patients not on dialysis.
Notice of Compliance:	August 2, 2002
Date of First Sale:	August 2002 In most cases, patents are issued before the drugs come to market. In this case, the first patent pertaining to Aranesp was issued November 5, 2002 and it came under the PMPRB's jurisdiction at that time.
ATC Class:	B03XA02 *Antianemic Preparations, Other Antianemic Preparations*

Application of the Guidelines

Summary:

The introductory prices of Aranesp at date of first sale were found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison or did not do so by an amount sufficient to trigger the investigation criteria and the prices did not exceed the range of prices in other comparator countries where Aranesp was sold. These prices continued to be within the Guidelines when Aranesp came under the PMPRB's jurisdiction in November 2002.

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.

Scientific Review:

Aranesp 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).

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 only other agent that falls within the same 4th level ATC class as Aranesp is Eprex (epoetin alfa). Eprex also shares the same indication as Aranesp and is used in Canada for treating anaemia in patients with chronic renal failure. Consequently, the HDAP recommended that Eprex be the sole comparator for purposes of a TCC for Aranesp.

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 Aranesp and the comparator are based on the respective product monographs and supported by clinical literature. See the following table.

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 prices 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*.

As shown in the table below, the prices of Aranesp were considered within the Guidelines relative to the TCC test as they did not exceed the prices of the other drugs in the therapeutic class or did not do so by an amount that triggered the investigation criteria.

Name	Strength	Dosage Regimen	Unit Price/Syringe[1]	Cost Per Day
Aranesp	10 mcg/0.4 ml	1 syringe	$26.80	$26.80
Eprex	1000 IU/0.5 ml	2 syringes	$14.25	$28.50
Eprex	2000 IU/0.5 ml	1 syringe	$28.50	$28.50
Aranesp	20 mcg/0.5 ml	1 syringe	$53.60	$53.60
Eprex	2000 IU/0.5 ml	2 syringes	$28.50	$57.00
Eprex	4000 IU/0.4 ml	1 syringe	$57.00	$57.00
Aranesp	30 mcg/0.3 ml	1 syringe	$80.40	$80.40
Eprex	2000 IU/0.5 ml	3 syringes	$28.50	$85.50
Eprex	6000 IU/0.6 ml	1 syringe	$85.50	$85.50
Aranesp	40 mcg/0.4 ml	1 syringe	$107.20	$107.20
Eprex	4000 IU/0.4 ml	2 syringes	$57.00	$114.00
Eprex	8000 IU/0.8 ml	1 syringe	$114.00	$114.00
Aranesp	50 mcg/0.5 ml	1 syringe	$134.00	$134.00
Eprex	3000 IU/0.3 ml	3 syringes	$42.75	$128.25
Eprex	10000 IU/1.0 ml	1 syringe	$133.95	$133.95
Aranesp	60 mcg/0.3 ml	1 syringe	$160.80	$160.80
Eprex	4000 IU/0.4 ml	3 syringes	$57.00	$171.00
Eprex	6000 IU/0.6 ml	2 syringes	$85.50	$171.00
Aranesp	80 mcg/0.4 ml	1 syringe	$214.40	$214.40
Eprex	8000 IU/0.8 ml	2 syringes	$114.00	$228.00
Aranesp	100 mcg/0.5 ml	1 syringe	$268.00	$268.00
Eprex	10000 IU/1.0 ml	2 syringes	$133.95	$267.90
Aranesp	150 mcg/0.3 ml	1 syringe	$402.00	$402.00
Eprex	10000 IU/1.0 ml	3 syringes	$133.95	$401.85

1 Liste des médicaments, Régie de l'assurance maladie du Québec, 2003

Aranesp was also sold in France, Germany, Italy, Sweden, Switzerland, and the United Kingdom in 2002. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in those countries; the prices in Canada were lower than the prices in those 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. ■

Evidence/ References:

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

NPDUIS Update

The PMPRB has added a project to its list of deliverables under the National Prescription Drug Utilization Information System with the **Pharmaceutical Trends Overview Report**. Under a previous Memorandum of Understanding with the Minister of Health, the PMPRB, on behalf of the Federal/Provincial/Territorial Working Group on Drug Prices, conducted research and produced several reports, including detailed reports on price and expenditure trends, price levels and cost drivers in six participating provincial drug plans. Key findings of these studies were summarized in an overview report. The **Pharmaceutical Trends Overview Report** will be an update and extension of this cost-driver overview report, making it a regular NPDUIS publication. This report will cover all public drug plans. The **Pharmaceutical Trends Overview Report** has been added to the PMPRB's Research Agenda and is expected to be released next Spring.

The Steering Committee of the National Prescription Drug Utilization Information System will be holding its next meeting in Ottawa on November 26-27.

For more information on the NPDUIS, please visit our website. ■

Voluntary Compliance Undertaking – Dostinex

On October 21, 2003, the Chairperson approved a VCU from Pfizer Canada Inc. for Dostinex (cabergoline).

Dostinex was introduced in Canada by Pharmacia Canada Inc. (now Pfizer Canada Inc.) on June 30, 2000 and is used for the treatment of hyperprolactinaemia, inhibition of physiological lactation and suppression of established lactation. On November 8, 2000 the patent pertaining to Dostinex expired and the manufacturer submitted that it was not subject to the jurisdiction of the PMPRB after that date. There are four patent applications which pertain to Dostinex, but none of the patents have issued. Dostinex continues to be available on the Canadian market. It is listed in the June 2003 edition of the *Liste de médicaments du Québec* at $12.65 per tablet.

For the purposes of the PMPRB's Guidelines, Dostinex was classified as a category 2 new medicine in that it represented a substantial improvement in therapeutic effects. The median of international prices identified in an International Price Comparison Test was applied; the introductory price of Dostinex exceeded the maximum non-excessive (MNE) price with resulting excess revenues of $42,116.31 during the period June 30 to November 8, 2000.

The terms and conditions of the VCU were agreed to between Board Staff and the patentee. Having considered the evidence before it, the Chairperson approved the VCU submitted by Pfizer. Under the terms of the VCU, Pfizer has undertaken to offset excess revenues received for the sales of Dostinex for the period June 30 to November 8, 2000 by making a payment to Her Majesty the Queen in right of Canada, within 30 days of the acceptance of the undertaking, in the amount of $42,116.31.

Pursuant to section 103 of the *Patent Act*, the Minister of Health may enter into agreements with any province respecting the distribution of amounts collected as a result of orders made under the Act. ■

PMPRB's Research Agenda

Our Research Agenda outlines our current and upcoming projects. Recently, we have added a fifth project to our NPDUIS activities, under Analysis of expenditures of publicly funded drug plans – the Pharmaceutical Trends Overview Report. It is expected that the Report will be published next Spring.

The Research Agenda is available on our website under Other Publications; Research Agenda. ■

New Patented Medicines Reported to the PMPRB

Since the publication of the July 2003 NEWSletter, 26 new DINs for human use were added to the list of New Patented Medicines Reported to the PMPRB for the period ending September 30, 2003. These new medicines included six new active substances.

The following table presents the six new active substances reported to the PMPRB during the period July to September 2003. ■

Brand Name	Generic Name	Company
Ketek (400 mg/tab)	telithromycin	Aventis Pharma Inc.
TNKase (50 mg/vial)	tenecteplase	Hoffmann La-Roche Canada
Pegasys (180 mcg/syr; 180 mg/vial)	peginterferon alfa-2a	Hoffmann La-Roche Canada
Keppra (250 mg/tab; 500 mg/tab; 750 mg/tab)	levetiracetam	Lundbeck Canada Inc.
Ezetrol (10 mg/tab)	ezetimibe	Merck Frosst Canada Inc.
Angiomax (250 mg/vial)	bivalirudin	Oryx Pharmaceuticals Inc.

The list of New Patented Medicines Reported to the PMPRB is updated regularly and posted on our website under Other Publications; Patented Medicines; 2003 as are the Reports on New Medicines.

Questions and Comments

Contact Us!

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

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

We look forward to hearing from you! ■

You can contact us at:

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or e-mail us at:
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or write to us at:

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

At its meeting, the Board:

- Approved:
  - the updated Terms of Reference of the Human Drug Advisory Panel; and
  - editorial revisions to the Compendium of Guidelines, Policies and Procedures;
- Received:
  - the report by Professor David Mullan, Queen's University, on the status of the PMPRB and Board Staff in judicial review proceedings;
- Received Board Staff's briefings on:
  - ongoing initiatives under the National Prescription Drug Utilization Information System (NPDUIS);
  - internet Pharmacies;
  - the Therapeutic Access Strategy and the timelines project;
  - 2003-2004 Communications Plan ■

The next Board meeting is scheduled for December 18 & 19, 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

November
17-18
HDAP, Ottawa

November
26-27
NPDUIS Steering Committee, Ottawa

November
27
Group Insurance and Pharmaceutical Committee, GlaxoSmithKline, Toronto

December
18-19
Board Meeting, Ottawa

To order our publications, call our toll-free number 1 877 861-2350

Comments

We want to hear from you. If you have any comments, ideas or suggestions on topics you wish to see covered in the NEWSletter, please let us know.

Mailing List

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

Name:

Title/Organization:

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Please return the completed form to the PMPRB, at:

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