Patented Medicine Prices Review Board

# PMPRB NEWSletter

Volume 10, Issue No. 4
October 2006

## Inside...



## Board Members



The PMPRB is an independent quasi-judicial body with a dual mandate.

**Regulatory** - To protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive.

**Reporting** - To contribute to informed decisions and policy making, by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.

## Since our last issue...

**Here are some of the key events that occurred since the end of July 2006.**

| | |
|---|---|
| August 21: | HDAP Teleconference |
| September 20: | The Board held a pre-hearing conference in the matter of Teva Neuroscience G.P.-S.E.N.C. and the medicine Copaxone. The hearing on the merits will be held February 5-7, 2007. For more information, please consult our Web site under Regulatory; Hearings. |
| September 27: | The Board held its quarterly meeting. A summary of the Board Minutes is available on page 7. |
| September 28-29: | The Board resumed its public hearing in the matter of Janssen-Ortho Inc. and its medicine Risperdal Consta. The next session of this hearing is scheduled for November 27 to 29. |
| October 14: | Maria Gutschi gave a presentation on the role of the PMPRB, at the National Oncology Pharmacy Symposium – *Dollars and Sense of Quality Cancer Care*, in Montréal. ■ |

## Government of Canada Workplace Charitable Campaign 2006 (United Way)

The United Way Campaign will run from September 7 to November 22, 2006. This year's theme is "***Federal employees and retirees – creating hope...changing lives***."

Once more, the PMPRB has embarked with its usual enthusiasm.

Elaine McGillivray who knows how to bring people together has once again accepted to represent the PMPRB. ■

If you wish to know more about the PMPRB, please contact us at our toll-free number or consult our Web site.

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Canada

**1 877 861-2350** **www.pmprb-cepmb.gc.ca**

## Senior Staff

Executive Director:
**Barbara Ouellet**

Secretary of the Board:
**Sylvie Dupont**

Director of Policy and Economic Analysis:
**Ron Corvari**

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

Director of Corporate Services:
**Ravinder Dhillon**

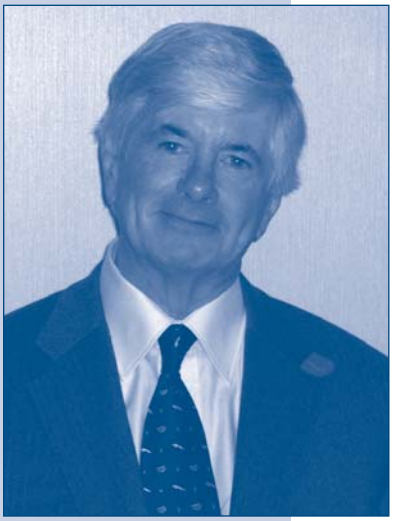
Senior Counsel:
**Martine Richard**

# Comings and Goings

- On September 18, the PMPRB welcomed Ravinder Dhillon as Director, Corporate Services Branch.
- Ron Corvari has successfully completed his French language training; thus re-assuming his position as Director, Policy and Economic Analysis Branch. Welcome back Ron!
- Paul De Civita who has been Acting Director, Policy and Economic Analysis Branch, will take on the position of Special Advisor to the Executive Director.
- Joanne Butler, Amanda Moir and Matthew Bondy all formerly from Health Canada, have joined the Policy and Economic Analysis Branch.
- Béatrice Mullington, formerly from International Affairs Directorate, Health Canada, joined the Compliance and Enforcement Branch as Manager of Compliance.
- Tara Watkinson, Jessica Fortin and Bradley Sernoskie, formerly from Statistics Canada, have joined the Compliance & Enforcement Branch, as a Statistical Research Assistants.
- Hans Lefebvre comes to the PMPRB from Defence Research and Development Canada. He is on a one-year assignment with the Information Systems Group.
- The PMPRB wishes best of luck and success to Bindu Islam and Andrew MacDonald. They both accepted positions with Health Canada. As well, best of luck to Murray Suchorab who left the PMPRB to join Defence Research and Development Canada. ■

# News from the Chairperson

## *Public Consultations on the Board's Excessive Price Guidelines*



Brien G. Benoit, M.D.
Chairperson of the PMPRB

The Board held its first meeting in a series of five taking place across Canada in November. We want to thank all of you who have taken part in the Edmonton and Montréal meetings and those of you who will join us at the discussion table in Toronto, Halifax and Ottawa over the next few weeks.

It is the Board's hope that these meetings will contribute to a better understanding of the issues and perspectives of key stakeholders concerning the Board's current Excessive Price Guidelines, particularly in relation to the review of introductory prices of patented medicines. These consultations are in no way about changing the *Patent Act*. We seek to identify potential areas and directions for change that would help ensure that the Board's Excessive Price Guidelines remain relevant and appropriate in the context of the current pharmaceutical environment. The Board has not determined that changes are needed – we want to listen closely to the stakeholders participating in these meeting as to whether and why changes may be appropriate.

These meeting are the second step in a multi-staged consultative process, the first having been the release, in May of this year, of a Discussion Guide for public comments. Over 40 stakeholders commented on the questions in the Guide. These submissions were thoughtful and reflective of the need to carry these consultations forward.

Following the November meetings, it is our expectation that, in the Spring of 2007, a further stakeholder meeting will be organized to discuss any potential changes to the Guidelines that the Board considers to be appropriate and necessary.

The Board is determined to ensure that the current process is as open and inclusive as possible. We are committed to seeing that the Guidelines provide both transparency and predictability in the patented drug price review process. This is clearly important in offering guidance to patentees. Of equal importance is maintaining the integrity and credibility of the price review process for all stakeholders who, quite rightly, have an interest in, and may ultimately be affected by, how the price review process works.

Again, I thank our stakeholders who have accepted our invitation to take part in the consultations. Also, I invite everyone to read the submissions we have received and the documents we have prepared in the context of these consultations, all of which are available on our Consultations Web page. ■

Brien G. Benoit, M.D.

# Hearings

## Schedule of On-Going Hearings

| Medicine | Patentee | Pre-hearing Conference Date | Hearing Date |
|---|---|---|---|
| **ADDERALL XR** | **Shire BioChem Inc.**<br>Interveners<br>Rx&D; Janssen-Ortho Inc. | March 8, 2006 | April 24-26<br>Aug 8-10<br>**Jan 17-18, 2007**<br>**Jan 24-25**<br>**Jan 31-Feb 1** |
| **AIROMIR** | **3M Canada Company Inc.** | May 19 | Oct 16-19<br>*(October 16-19 postponed – revised dates forthcoming)* |
| **CONCERTA** | **Janssen-Ortho Inc.** | September 15<br>*(Cancelled)* | **December 4-6** |
| **COPAXONE** | **Teva Neuroscience G.P.-S.E.N.C.** | September 20 | **February 5-7, 2007** |
| **DOVOBET** | **LEO Pharma Inc.** | | *date to be determined* |
| **RISPERDAL CONSTA** | **Janssen-Ortho Inc.** | April 21 | June 7-8-9<br>June 27-28<br>Sept. 28-29<br>**Nov 27-29**<br>*(Dates of additional sessions forthcoming)* |

All requests for information on hearings should be addressed to the Secretary of the Board:

Sylvie Dupont
Secretary of the Patented Medicine Prices Review Board
Standard Life Centre, 333 Laurier Avenue West, Suite 1400
Ottawa ON K1P 1C1
Toll-free number: 1 877 861-2350 Direct line: (613) 954-8299
Fax: (613) 952-7626 E-mail: sdupont@pmprb-cepmb.gc.ca ■

# Patentees' Reporting on R&D/Sales – Licensee Issues

## (Form 3 – Reporting requirements regarding licensees and revenues from sales of medicines for licensees)

Under section 88 of the *Patent Act*, a patentee of an invention pertaining to a medicine is required to provide to the PMPRB information on scientific research and experimental development.

One of the requirements is that a patentee must identify all licensees who, by means of a license or other formal arrangement, sell or distribute medicines for which the patentee holds a patent, and must provide the names and addresses of these licensees. In addition, a patentee must list total revenues from its own sales of medicines for human and veterinary use in Canada and total royalties license fees or any other revenue obtained from licensees. ■

The PMPRB's regulatory mandate is to ensure that manufacturers' prices of patented medicines are not excessive and hence protect consumer interests. In the event that the price of a patented medicine appears to be excessive, the Board can hold a public hearing and, if it finds that the price is excessive, it may issue an Order to reduce the price and to offset the excess revenues.

Detailed information on the reporting requirements for Form 3 are set out in **The Patentees' Guide to Reporting and the *Patented Medicines Regulations, 1994***. The Patentees' Guide is available on our Web site under Legislation, Regulations and Guidelines.

# Failure to File – January to June 2006 reporting period

Patentees are due to file pricing and sales information, for the July 1 to December 30, 2006 period **on or before January 30, 2007**.

The Form 2 information (price and sales data) for the January to June reporting period was due July 30, 2006. As of July 31, 2006, 43% of reporting patentees had failed to file all or part of the required information; 8% of reporting patentees had failed to file all the required information and 35% had failed to file some of the required information. In accordance with the practice set out in the April 2005 NEWSletter, patentees were provided a further seven days to provide the information. All but one patentee filed the required information within the additional period provided.

The Board issued an Order to Galderma Canada Inc. which had failed to file pricing and sales information for the January 1, 2006 to June 30, 2006, as required pursuant to the *Patent Act* and the *Patented Medicines Regulations*.

The Board is pleased to report that Galderma met its obligations and filed its regulatory data. ■

# Amendments to the *Patented Medicines Regulations, 1994* – Publication in the *Canada Gazette*, Part II

A revised regulatory package, including an updated Regulatory Impact Analysis Statement is presently with the Minister of Health for approval. Upon ministerial approval, Treasury Board Cabinet Committee approval is required for final publication in the *Canada Gazette*, Part II.

When the Regulations come into force, Board Staff will be advising patentees of all changes to the filing requirements and will be providing revised forms to ensure appropriate implementation of all amendments made to the Regulations. ■

# Public Consultations on the Board's Excessive Price Guidelines

## *To Invitees*

*The consultations include a series of targeted meetings taking place across Canada with key stakeholders this November 2006. Meetings are being held in Edmonton, Toronto, Montréal, Halifax and Ottawa. Their purpose is to further engage stakeholders both to better understand the issues with the current Guidelines and to explore potential options for change. A further meeting is likely planned in the spring of 2007, to discuss potential changes to the Guidelines.*

*The Board is looking forward to meeting stakeholders at its face-to-face meetings throughout the month of November. The Board also wishes to take this opportunity to thank the invited stakeholders who have already confirmed their participation.*

Discussion Guide and Comments received are posted on our Web site under Consultations; Consultations on the Board's Excessive Price Guidelines.

Earlier this year, the Board invited stakeholders to submit their views on key issues regarding the introductory prices of patented medicines specifically: the categorization of new drugs; introductory price tests of new drugs; and, how the Board addresses the "any market" clause of the *Patent Act*.

Invited stakeholders were provided with a Discussion Guide that outlined these subjects and posed specific questions. The process resulted in more than 40 submissions. Board members wish to thank all those who wrote in for the time and effort they put into their observations and suggestions.

The submissions reflected the wide-ranging perspectives of the individuals and groups affected by or interested in the Guidelines – patentees; patient and health care provider representatives; private and public insurance plans, members of the Human Drug Advisory Panel; academics and consultants. For instance, some commentators recommended eliminating the therapeutic category system, while others suggested enhancing the system with additional sub-categories. As another example, some people said the Board should continue to use the average transaction price for Canada as a whole to conduct the various price tests, while others suggested it may be time to look at average prices by jurisdiction, or customer class.

The commentary will help inform the five face-to-face meetings during the month of November. A member of the Board will chair each event.

The meetings, which will draw together a variety of stakeholders to further explore the issues, will complement the submission process with additional advice on how to ensure the Guidelines are as effective and relevant as possible.

Although not included in the Discussion Guide, the issue regarding the reassessment of a price was mentioned in some of the stakeholder submissions. It was also raised in the context of the National Pharmaceuticals Strategy. The Board has included a discussion of the re-benching issue in the November meetings. An overview of this issue is also available on our Consultations Web page.

We invite you to access our Consultations Web page and review the submissions we received on the Discussion Guide along with the meeting Participant's Kit which provides additional information on the issues for discussion. ■

## Invitational Face-to-Face Meetings

| | |
|---|---|
| November 2: | Edmonton |
| November 8: | Montréal |
| November 16: | Toronto |
| November 28: | Halifax |
| November 30 | Ottawa |

# Monitoring and Reporting of Non-Patented Prescription Drug Prices

The PMPRB has released its second report on Non-Patented Prescription Drug Prices (NPPDP), *Trends in Canadian Sales and Market Structure*. This report includes annual growth rates, sources of growth, market shares, sales concentration, and international price comparisons by level of concentration. Sales covered in the report are those of manufacturers and wholesalers to pharmacies. Price comparisons reported refer to prices paid by pharmacies through wholesalers or directly to manufacturers and not prices paid by consumers or drug plans.

The first report on NPPDP, released in July 2006, provided an overview of non-patented prescription drug sales and price trends, including international price comparisons and notable price changes. The report can be found on our Web site under Reporting; Non-Patented Prescription Drug Prices.

The third quarterly report is scheduled for publication in January of 2007. It will examine new off-patent products including leading products that have gone off-patent in the last five years and prices and market shares of non-patented branded and generic drugs that have entered markets of newly off-patent drugs. Results for Canada will be compared with other countries. ■

In October 2005, the federal, provincial and territorial (FPT) Ministers of Health announced the endorsement of the PMPRB to monitor and report on the prices of non-patented prescription drugs. In November 2005, the PMPRB received direction from the federal Minister of Health, on behalf of himself and his Provincial/Territorial colleagues, to monitor and report on the prices of non-patented prescription drugs.

The ***Trends in Canadian Sales and Market Structure*** report is available on our Web site under Reporting; Non-Patented Prescription Drug Prices. We invite readers to forward their comments and or questions to pmprb@pmprb-cepmb.gc.ca.

## Questions and Comments

Please forward all subscriptions to the PMPRB e-mail or mailing lists, and requests for publications to Elaine McGillivray at Elaine@pmprb-cepmb.gc.ca. For more information on our Web site, please contact our Communications Officer at pmprb@pmprb-cepmb.gc.ca. ■

# List of New Drugs introduced since the publication of the July 2006 NEWSletter

Since the publication of the July 2006 NEWSletter, 16 new DINs for human use (representing 12 medicines) were added to the list of New Patented Medicines reported to the PMPRB as of September 30, 2006. Three of these new medicines are new active substances, representing 4 DINS.

The following table presents the new active substances reported to the PMPRB during the period July to September 2006.

## As of September 30, 2006

| Brand Name | Generic Name | Company |
|---|---|---|
| Baraclude (0.5 mg/tablet, 0.05 mg/ml) | *entecavir* | Bristol-Myers Squibb Canada Co. |
| Fuzeon (108 mg/vial) | *enfuvirtide* | Hoffmann-La Roche Ltd. Canada |
| Phoslo (667 mg/tablet) | *calcium acetate* | Prempharm Inc. |

# Report on New Patented Drugs – Fuzeon

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 Excessive Price Guidelines (Guidelines) for all new active substances introduced after January 1, 2002.

**Brand Name:** Fuzeon

**Generic Name:** *(enfuvirtide)*

**DIN:** 02247725 3 mL/vial

**Patentee:** Hoffmann-LaRoche Ltd. Canada

**Indication - as per product monograph:** For the treatment of HIV-1 infection in antiretroviral experienced patients or patients with resistant virus.

**Notice of Compliance:** July 14, 2003

**Date of First Sale:** August 2003

**Date of Issuance of First Patent Pertaining to the Medicine:** March 14, 2006

**ATC Class:** J05AX07
*Antivirals for Systemic Use, Direct Acting Antivirals, Other Antivirals*

## Application of the Guidelines

### Summary

The introductory price of Fuzeon was found to be within the Guidelines in the introductory sale period (August to December 2003), as the price in Canada did not exceed the median of the prices of the same drug product in those countries listed in the *Patented Medicines Regulations, 1994* (Regulations) in which it was sold, by an amount sufficient to trigger the investigation criteria under the Compliance & Enforcement Policy.

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

### Scientific Review

Fuzeon is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Fuzeon be reviewed as a category 2 new medicine (provides a breakthrough or substantial

improvement). Enfuvirtide represented the first drug of a new class of antiretroviral agents (fusion inhibitors) to be marketed in Canada.

The HDAP did not identify any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

**Price Review**

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

As no comparable drug products could be identified for purposes of conducting a TCC test, the introductory price of Fuzeon was considered within the Guidelines as it did not exceed the median of the international prices identified in the IPC test by an amount that triggered the investigation criteria. Fuzeon was sold in six of the seven countries listed in the Regulations.

## Introductory period (August to December 2003)

| Country | Price per vial (CDN$) |
|---|---|
| Canada | $39.7600 |
| France | $37.1614 |
| Germany | $39.3053 |
| Sweden | $38.8904 |
| Switzerland | $38.3194 |
| United Kingdom | $45.5822 |
| United States | $37.6958 |
| International Median | $38.6049 |

**Source:** Publicly available prices as per the *Patented Medicines Regulations*

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. ■

Summary Reports are available on our Web site under Regulatory; Patented Medicines; Reports on New Patented Drugs for Human Use.

# Patented Medicine Prices Review Board – September 27, 2006 Meeting

At its meeting, the Board:

- Approved:
  - The second quarterly report on Non-Patented Prescription Drug Prices: *Trends in Canadian Sales and Market Structure*
  - The format and process for the November face-to-face meetings in the context of the Board's consultations on its Excessive Price Guidelines, to be held in Edmonton, Montréal, Toronto, Halifax and in Ottawa.
- Was briefed on:
  - Patented generic drugs
  - Ongoing PMPRB activities
    - NPDUIS
  - National Pharmaceuticals Strategy – Progress Report released on September 21, 2006. ■

The next Board meeting will be held December 13, 2006. For additional information, please contact the Secretary of the Board at: 1-877-861-2350, or (613) 954-8299, or at sdupont@pmprb-cepmb.gc.ca.

Summary of Board Meetings are available on our Web site under About the PMPRB.

# Upcoming Events

**Upcoming Events are available on our Web site under Consultations; Events.**

November

**2006**

Board's Consultations on its Excessive Price Guidelines
- **November 2:** Edmonton;
- **November 8:** Montréal;
- **November 16:** Toronto;
- **November 28:** Halifax;
- **November 30:** Ottawa

**15**
Meeting with Taiwan's Bureau of National Health Insurance

**20**
HDAP Teleconference

December

**4-6**
Public Hearing: Concerta

**13**
Board Meeting

**27-29**
Public Hearing: Risperdal Consta

January

**2007**

Public Hearing: Adderall XR
- **January 17-18**
- **January 24-25**
- **January 31-Feb 1**

**31**
Release of the January 2007 NEWSletter

February

**5-7**
Public Hearing: Copaxone

# PMPRB E-bulletin

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## Comments

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

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