Patented Medicine Prices Review Board

*Since 1987*

# PMPRB NEWSletter

Volume 13, Issue No. 3, July 2009

## Inside...



## Since our last issue...

### Our recent key events

| | |
|---|---|
| May 5 | The Board met on the draft revised Excessive Price Guidelines. |
| May 12 | Brien G. Benoit and Barbara Ouellet, along with the Heads of the Health Portfolio agencies, appeared before the Standing Committee on Health relating to the Main Estimates. |
| May 15 | The HDAP held its quarterly conference call. |
| May 19 | The Board met on its 2008 Annual Report. |
| May 21-22 | The NPDUIS Steering Committee held its semi-annual meeting. More details are available on page 5, under NPDUIS.<br><br>Béatrice Mullington and Catherine Lombardo did a presentation on the price review process and regulatory filings at the Brogan Seminars, held in Montréal and Toronto. |
| May 28 | Barbara Ouellet did a presentation, *Canada's Patented Medicine Prices Review Board – Moving Forward on the Guidelines Review*, at the Drug Patent and Legal Forum Conference, in Toronto. |
| May 29 | The PMPRB submitted its Annual Report for 2008 to the Minister of Health. |
| June 3 | The Hearing Panel in the matter of Amgen Canada Inc. and the medicine Neulasta held a pre-hearing conference on June 3, 2009. The matter will resume in November. |
| June 9 | The Board released its revised Compendium of Policies, Guidelines and Procedures and the Results of its March 2009 Consultation. The revised Excessive Price Guidelines will be implemented as of January 1, 2010. |
| June 16 | Brien G. Benoit did a presentation, *Canada's Patented Medicine Prices Review Board – Moving Forward with the Board's Policies and Excessive Price Guidelines*, at the Drug Pricing and Reimbursement in Canada Conference in Toronto.<br><br>The Federal Court (FC) heard the Applications for Judicial Review on the Board's 2008 Stakeholder Communiqué on mandatory reporting of benefits, as filed by Rx&D *et al* and Pfizer Canada Inc. on September 17, 2008. The FC issued its decision on July 10, 2009, setting aside the Board's Communiqué. |
| June 17-18 | Ginette Tognet, Catherine Lombardo and Béatrice Mullington conducted outreach sessions with patentees on the revised Excessive Price Guidelines, in Toronto and Montréal. |



If you wish to know more about the PMPRB, please contact us at our toll-free number, 1 877 861-2350, or consult our Web site.

The PMPRB is an independent quasi-judicial body with a dual mandate.
**Regulatory:** to ensure that prices of patented drug products sold in Canada are not excessive; and
**Reporting:** to report annually to Parliament on pharmaceutical trends of all drug products and on R&D spending by patentees.

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|---|---|
| June 23 | Barbara Ouellet did a presentation, *Patented Medicine Prices Review Board – Moving Forward with the Board's Policies, Guidelines and Procedures*, at the du Canadian Summit on Biologics, in Toronto. |
| July 1 | Barbara Ouellet participated in a conference, New Drugs and Technologies: innovation, transferability and sustainability, organized by the Italian National Academy of Medicine (*Accademia Nazional di Medicina*) and held in Genoa, Italy. As part of a panel, Learning by different systems in pricing and reimbursement, Ms. Ouellet did a presentation, *Price Regulation in Canada: the Patented Medicine Prices Review Board.* |
| July 8-10 | The Hearing Panel in the matter of ratiopharm Inc. and the medicine ratio-Salbutamol HFA held a session on preliminary matters. More information on this matter is available on page 4, under Hearings. |
| July 9 | Barbara Ouellet made a presentation on the revised Excessive Price Price Guidelines to provincial and territorial officials. |
| July 29 | Barbara Ouellet, Gregory Gillespie and Sylvie Dupont met with representatives of Johnson and Johnson's Government Affairs Group from Japan, China and Asia Pacific on the role and mandate of the PMPRB. ■ |

PMPRB speeches and presentations are available on our Web site under Publications; Speech Series.

**Senior Staff**

Executive Director:
**Barbara Ouellet**

Director, Regulatory Affairs and Outreach:
**Ginette Tognet**

Director, Policy and Economic Analysis:
**Gregory Gillespie**

Director, Corporate Services:
**Marian Eagen**

Director, Board Secretariat and Communications:
**Sylvie Dupont**

General Counsel:
**Martine Richard**

# Comings and Goings

Delia Lewis has recently returned to the PMPRB in the Legal Services Branch. Welcome back!

Over the last quarter, new employees have joined our ranks: John Raasch (Legal Services), Dan Acton (Corporate Services, as Chief of IT) and Jesslyn Mullaney (Regulatory Affairs and Outreach). As well, on August 4, Tingyi Weng, from Health Canada, will be joining the Corporate Services Branch as a Financial Officer Recruitment and Development (FORD) trainee.

Our best wishes of success also go to Gary MacDonald who left the PMPRB in June to take on new challenges at Transport Canada, and to Nadia Persaud, on her return to Health Canada following her stay at the PMPRB as FORD trainee.

We take this opportunity to congratulate Patricia Hum on the new addition to her family! ■

# The National Public Service Week

National Public Service Week (NPSW) is an opportunity to celebrate the work and achievements of the individuals who make up the Public Service of Canada. It is a special occasion to recognize public servants and the important role we play in Canadian society. This year, from June 14 to 20, the NPSW celebrated the theme "It starts with you."

The PMPRB celebrated NPSW by distributing small mementos, including PMPRB lanyards, to all employees. On June 19, we held a BBQ. The weather turned out perfect. Everyone enjoyed a delicious meal outdoors and the opportunity for informal exchanges.

A highlight of the week was the inauguration of the new NPDUIS facilities on the ground floor of the Standard Life Building. A ribbon-cutting ceremony was held and employees were invited to tour the offices.

The NPSW was enjoyed by all and many employees commented that they appreciated the recognition received during the Week.

The Board thanks everyone for their hard work and commitment to the PMPRB throughout the year and offers its best wishes of success to all in the coming months. ■

## What's New @ PMPRB

**Readers are invited to check our Web site for the latest information on our activities!**

# News from the Chairman – The Board releases its revised Excessive Price Guidelines

On June 9, 2009, the PMPRB released the new Compendium of Policies, Guidelines and Procedures (Compendium) and the Results of the March 2009 Consultation.

The release of these documents marks the culmination of the Board's review of its Excessive Price Guidelines (Guidelines), which included an extensive series of consultations with all interested stakeholders to ensure that the Guidelines remain relevant and appropriate in the modern pharmaceutical environment.

**The revised Guidelines will be implemented on January 1, 2010**. In order to help prepare patentees for implementation, Board Staff held outreach sessions in Toronto on June 17th and in Montreal on June 18th. Additional outreach sessions are being planned for the fall of 2009, and stakeholders will be notified as soon as details become available.

Following implementation, Board Staff will be monitoring and evaluating the application and impact of the changes to the Excessive Price Guidelines on an ongoing basis.

Here are highlights of the most significant changes:

- Four new levels of therapeutic improvement that replace the categories previously used by the PMPRB;
- New price tests that align with the levels of therapeutic improvement;
- A new methodology for selecting the public prices of drug products used for comparison purposes;

These changes, among others made to the Compendium, are outlined in greater detail in the document entitled "Results of the March 2009 Consultation and the Board's Revised Excessive Price Guidelines", available on the PMPRB Web site under Consultations; Consultations on the Board's Excessive Price Guidelines.

- New terminology replacing the "Maximum Non-Excessive (MNE) Price";
- A change to the Highest International Price Comparison (HIPC) test providing an exception for the wholesaler class of customer;
- New Guidelines on how the International Therapeutic Class Comparison (ITCC) test should be conducted;
- Additional guidance regarding how any market price reviews will be undertaken;
- Clarity on circumstances for re-setting the Non-Excessive Average Price after introduction taking into consideration the cost of making and marketing;
- Additional guidance on the implementation of the DIP Methodology when benefits to customers are reduced or end; and
- A new policy on the offset of excess revenues.

The Board appreciates the valuable input provided by stakeholders over the course of the past four years. ■

*Brien G. Benoit, MD, Chairman*


# 2008 Annual Report

The PMPRB Annual Report for the year ending December 31, 2008, was tabled by the Minister of Health with the Clerks of the House of Commons and Senate on July 22, 2009.

Among other information, the Report provides: detailed information on sales and price trends of patented drugs sold in Canada, including international comparisons; patentees' R&D spending; patentees' compliance with the Board's Excessive Price Guidelines; and enforcement activities and hearings.

In 2008, sales of patented drugs in Canada increased by 5.0% to $13.0 billion, representing 64.9% of total sales of drugs by companies under the Board's jurisdiction, a slight decrease from 2007. Prices of patented drugs, as measured by the Patented Medicine Price Index (PMPI), increased on average by 0.1%, while the Consumer Price Index (CPI) was at 2.3% over the same period. Canadian prices ranked third highest of the seven comparator countries, after the U.S. and Germany.

Patentees reported 78 new patented drug products (DINs) for human use in 2008, including 19 new active substances (26 DINs). A total of 1,260 new and existing patented drug products for human use were under the PMPRB's jurisdiction in 2008. There were nine Voluntary Compliance Undertakings approved by the Board. Currently, eight hearings are ongoing as are 125 investigations.

R&D expenditures declined slightly in 2008, by 1.1% from 2007. Patentees reported total R&D expenditures of $1.3 billion. Members of Rx&D reported R&D expenditures of $1.2 billion over the same period, a decrease of 1%. For all patentees, the R&D-to-sales ratio declined to 8.1% from 8.3% in 2007, while the ratio for Rx&D members remained at 8.9%, as in the previous year.

The Annual Report is available on the PMPRB Web site, on the Home page. ■

# Hearings

The PMPRB's regulatory mandate is to ensure that patentees' prices of patented medicines sold in Canada are not excessive. 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 for the reduction of the price and the offsetting of revenues received by the patentee as a result of excessive prices. The Board's decisions are subject to judicial review in the Federal Court (FC).

## Amgen Canada Inc. and the medicine Neulasta

On March 16, 2009, the Board issued a Notice of Hearing into the price of the patented medicine Neulasta to determine whether Amgen Canada Inc. is selling or has sold Neulasta 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 in this matter was held on June 3, 2009. The hearing is scheduled to resume in November.

Neulasta is a new active substance (pegfilgrastim) indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with cancer receiving myelosuppressive chemotherapy.

## ratiopharm Inc. and the medicine ratio-Salbutamol HFA

On July 8, 9 and 10, the Hearing Panel heard the parties on Board Staff's Motions: to add GlaxoSmithKline Inc. as a party to the hearing on the merits; and for the issuance of an Inspection and Production Order to ratiopharm. The Panel's decisions on these Motions are pending.

ratio-Salbutamol HFA is indicated for the relief of chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs. ■

# Human Drug Advisory Panel (HDAP) 2010 Schedule

| HDAP Meeting/ Conference Call | Information | Deadline |
|---|---|---|
| February 17, 2010 | 1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada) | November 17, 2009 |
| | 10 copies of company submission | December 17, 2009 |
| May 10, 2010 | 1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada) | February 10, 2010 |
| | 10 copies of company submission | March 10, 2010 |
| September 15, 2010 | 1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada) | June 15, 2010 |
| | 10 copies of company submission | July 15, 2010 |
| November 17, 2010 | 1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada) | August 17, 2010 |
| | 10 copies of company submission | September 17, 2010 ■ |

# Electronic PMPRB NEWSletter

**If you wish to receive the NEWSletter electronically, please register by forwarding your e-mail address to: pmprb@pmprb-cepmb.gc.ca.**

**Readers who have changed e-mail address recently are invited to send us their new coordinates if they wish to keep receiving the NEWSletter.**

# New Drugs introduced since the publication of the April 2009 NEWSletter

As of June 30, 2009, there were 29 new DINs for human use (representing 20 medicines) reported to the PMPRB for the year 2009. Of these 29 DINs, 9 DINs (representing 4 medicines) are new active substances.

The following table presents the new active substances reported to the PMPRB during the period April to June 2009. ■

New patented drug products come under the PMPRB's jurisdiction once they are both patented and sold in Canada. If a patented drug product was first sold during the patent pending period (after the date when the patent was laid open for public inspection and before patent grant), the PMPRB's policy is to review the price of the product back to the date of first sale.

**As of June 30, 2009**

| Brand Name | Generic Name | Company | Indication |
|---|---|---|---|
| Metvix – 168 mg/g | methyl aminolevulinate hydrochloride | Galderma Canada Inc. | Antineoplastic |
| Olmetec – 20 mg/tablet | olmesartan medoxomil | Schering-Plough Canada Inc. | Antihypertensive |
| Olmetec – 40 mg/tablet | olmesartan medoxomil | Schering-Plough Canada Inc. | Antihypertensive |
| Olmetec Plus 20/12.5 – 32.5 mg/tablet | olmesartan medoxomil / hydrochlorothiazide | Schering-Plough Canada Inc. | Antihypertensive |
| Olmetec Plus 40/12.5 – 52.5 mg/tablet | olmesartan medoxomil / hydrochlorothiazide | Schering-Plough Canada Inc. | Antihypertensive |
| Olmetec Plus 40/25 – 65 mg/tablet | olmesartan medoxomil / hydrochlorothiazide | Schering-Plough Canada Inc. | Antihypertensive |
| Pristiq – 50 mg/tablet | desvenlafaxine succinate | Wyeth Pharmaceuticals | Antidepressant |
| Pristiq – 100 mg/tablet | desvenlafaxine succinate | Wyeth Pharmaceuticals | Antidepressant |
| Zeftera – 500 mg/vial | Ceftobiprole medocaril | Janssen-Ortho Inc. | Antibacterial |

# NPDUIS Update

The National Prescription Drug Utilization Information System (NPDUIS) initiative is a partnership between the PMPRB and the Canadian Institute for Health Information (CIHI). NPDUIS provides critical analyses of price, utilization, and cost trends in Canada to support drug plan policy decision-making for participating federal, provincial, and territorial governments.

The NPDUIS Steering Committee met in Ottawa on May 21-22, 2009. PMPRB Staff presented the preliminary findings of three studies currently underway, pertaining to professional fee expenditures in public drug plans, the impact of a generic entry on the utilization of the ingredient, and an analysis of estimated Canadian generic drug expenditures at international price levels. Steering Committee members also discussed priorities for future research.

The NPDUIS Steering Committee is composed of representatives of all provincial and territorial drug plans (except Quebec), as well as representatives from Health Canada, CIHI, and the PMPRB.

The NPDUIS Steering Committee held a teleconference call on July 16, 2009. PMPRB Staff provided a status update on current research projects, and Steering Committee members discussed the possibility of holding their fall meeting in conjunction with a meeting of CIHI's NPDUIS Data Advisory Group and a group of academic researchers with funding from the Canadian Institutes of Health Research. ■

*From left to right: Gregory Gillespie (Director, Policy and Economic Analysis), Greg McComb (Senior Economist), Elena Lungu (Acting Manager, NPDUIS), Gary Warwick (Economist), and Barbara Ouellet (PMPRB Executive Director).*

On June 19, 2009, PMPRB Staff working on the NPDUIS initiative moved into new offices located on the ground floor of the building in which the PMPRB is located at 333 Laurier Avenue West in Ottawa. The event was celebrated with a ribbon cutting ceremony, coinciding with the annual celebration of National Public Service Week.

# Report on a New Patented Drug — Myozyme

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drugs by Board Staff, for purposes of applying the Board's Excessive Price Guidelines (Guidelines) for all new active substances introduced in Canada after January 1, 2002.

**Brand Name:** Myozyme (50 mg/vial)

**Generic Name:** alglucosidase alfa

**DIN:** 02284863

**Patentee:** Genzyme Canada Inc.

**Indication – as per product monograph:** For use in patients with Pompe disease (GAA deficiency)

**Date of Issuance of First Patent(s) Pertaining to the Medicine:** April 29, 2008

**Notice of Compliance:** August 14, 2006

**Date of First Sale:** January 9, 2007

**ATC Class:** A16AB07
*Alimentary Tract and Metabolism; Other Alimentary Tract and Metabolism products; Other Alimentary Tract and Metabolism products; Enzymes*

## Application of the Guidelines

### Summary

The introductory price of Myozyme exceeded the Excessive Price Guidelines (Guidelines) because the price in Canada slightly exceeded the median of the prices of the same drug product sold in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) in which Myozyme was sold. However, the investigation criteria were not triggered and excess revenues were offset in the following year.

### Scientific Review

Myozyme is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Myozyme be classified as a category 2 new medicine (breakthrough or substantial improvement). The HDAP did not recommend any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

### Price Review

Under the Guidelines, the introductory price of a category 2 new drug product will be presumed to be excessive if it exceeds the higher of the prices of all comparable drug products based on the TCC test or the median of the international prices identified in an International Price Comparison (IPC) test. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines: http://www.pmprb-cepmb.gc.ca/CMFiles/comp08-e38NBY-3182008-1638.pdf.

No comparators were identified for purposes of conducting a TCC test. The introductory price of Myozyme was just slightly above the median of the international prices identified in an IPC test. Myozyme was sold in five country listed in the Regulations.

### Introductory Period (January to June 2007)

| Country and Median | Price (in Canadian dollars) |
|---|---|
| Canada | $840.3100 per vial |
| France | Not sold |
| Germany | $840.3099 per vial |
| Italy | $840.3099 per vial |
| Sweden | $856.2828 per vial |
| Switzerland | Not sold |
| United Kingdom | $823.5171 per vial |
| United States | $734.9248 per vial |
| Median | $840.3099 per vial |

**Sources:**
Canada, Germany, Italy, Sweden, United Kingdom and United States: Publicly available price as per Regulations.

The publication of Summary Reports is part of the PMPRB's commitment to make its price review process more transparent.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by 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 PMPRB reserves the right to exclude from the therapeutic class comparison test any drug product it has reason to believe is being sold at an excessive price.

In its Summary Reports, the PMPRB will also refer to the publicly available prices of comparators provided such prices are not more than 10% above a non-excessive price in which case no price will be made available. As a result, the publication of these prices is for information purposes only and should not be relied upon as being considered within the Guidelines.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than stated 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.

This report, including the references, is available on our Web site under Regulatory; Patented Medicines; Reports on New Patented Drugs for Human Use; Myozyme. ■

# Summary of Board Meetings – May 5 and May 19, 2009

The Board met on May 5, 2009 to complete its review of the stakeholders' submissions on the March 2009 Notice and Comment on the final draft revised Excessive Price Guidelines and to finalize the review of the Guidelines. The revised Guidelines were released on June 9, 2009 with an implementation date of January 1, 2010.

The Board also met on May 19, 2009, to review and approve the 2008 Annual Report. The Report was submitted to the Minister of Health on May 29, 2009 and was released following tabling with the Clerks of the House of Commons and Senate on July 22, 2009.

For additional information, please contact the Director, Board Secretariat and Communications, at: 1 877 861-2350, or (613) 954-8299, or at sylvie.dupont@pmprb-cepmb.gc.ca.

Summary of Board meetings are available on our Web site under About PMPRB. ■

# Upcoming Events

## September

**September 16-17:**
Board meeting

**September 17:**
HDAP meeting

**September 23:**
NPDUIS Steering Committee teleconference

**September 30 – October 1:**
International Generic Pharmaceutical Alliance, Montreal

## October

**October 5-9:**
NICODERM Hearing

**October 13-15:**
ratiopharm Inc. Hearing

**October 28-29:**
Advanced Administrative Law and Practice, Ottawa

**October 29-30:**
Forum on Pharma Patents, Toronto

**October 30:**
October 2009 NEWSletter

## November

**November 3:**
PMPRB NPDUIS Steering Committee meeting, Ottawa

**November 3-4:**
PMPRB/HC/PT/CIHR meeting on Pharmaceutical Policy Research, Ottawa

**November 2-4:**
DIA's 7th Canadian Annual Meeting: "Time to Act", Ottawa

**November 4-5:**
8th Annual Market Access Summit, Toronto

**November 10-11:**
Market Access Canada for Pharma, Toronto

**November 16-18:**
NEULASTA Hearing

**November 19:**
HDAP meeting

**November 24-25:**
Brogan Advanced Seminars, Montreal, Toronto

## December

**December 10-11:**
Board meeting

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

# Questions and Comments

## PMPRB E-bulletin

Readers who wish to receive PMPRB Electronic News bulletins are required to register by forwarding their e-mail address to pmprb@pmprb-cepmb.gc.ca. Your cooperation in submitting changes to your e-mail and/or mailing address is also appreciated. Please forward all **subscriptions** to the PMPRB mailing lists, and requests for publications to Elaine McGillivray at Elaine@pmprb-cepmb.gc.ca.

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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.

## Mailing List

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