Patented Medicine Prices Review Board

Since 1987

PMPRB

NEWSletter

Volume 12, Issue No. 3, July 2008

Inside...

Consultation on the Board's Revised Excessive Price Guidelines

The Board has been consulting with all interested stakeholders on its current patented drug price regulatory regime in order to determine where and how the regime may be updated to be more appropriate, relevant and effective in today's modern pharmaceutical environment. The Board has given careful consideration to the views expressed and comments received from stakeholders throughout its consultation process and wishes to update readers on its work in regard to the *Patented Medicines Regulations* and its Excessive Price Guidelines.

The Board will be issuing a Communiqué to clarify what information patentees will be required to report pursuant to the *Patented Medicines Regulations* beginning in January 2009, in terms of the average transaction price. A Notice and Comment package, including draft revised Excessive Price Guidelines, will be released on August 20, 2008. The deadline for submitting comments on the draft revised Guidelines will be October 6, 2008.

The Communiqué and draft revised Guidelines will be available on our Web site under Consultations; Consultations on the Board's Excessive Price Guidelines; Notice & Comment.

Once again, the Board thanks all stakeholders who have participated in this process to date and looks forward to their continued active involvement in the completion of this important exercise. ■

Timetable

Deadlines	Products
August 18, 2008	Stakeholder Communiqué
August 20	Draft revised Guidelines posted on the PMPRB Web site for consultation
October 6	Deadline for stakeholders' submissions on the draft revised Guidelines
October 22	Board Meeting
November 17	Release of the amended Compendium of Policies, Guidelines and Procedures, and transition and implementation plans
November-December	Board Staff outreach to assist patentees in the implementation of the revised Guidelines

Brien G. Benoit, MD
Chairperson

Message from the Chairperson

Our Annual Report for 2007 was tabled in the House of Commons on June 18, 2008.

The Report provides detailed information on sales and price trends of medicines in Canada, including: international comparisons; patentees' compliance with the Board's Excessive Price Guidelines; enforcement activities and hearings; and patentees' R&D spending, to name a few.

We reported an increase of 3% in sales of patented drugs in Canada to $12.3 billion, representing 66.0% of total sales of drugs in 2007, a slight decrease from 2006. Patentees' prices of patented drugs, as measured by the Patented Medicine Price Index (PMPI), decreased on average by 0.1%, while the Consumer Price Index (CPI) was at 2.1% over the same period. Canadian prices ranked second highest of the seven comparator countries, second highest only to the U.S. This is based on currency conversion using market exchange rates and likely reflects the impact of the recent appreciation of the Canadian dollar.

Patentees reported sixty-four new patented drug products for human use in 2007 of which 20 medicines, representing 34 drug products, were new active substances. As of March 31, 2008, 53 new patented drug products had been reviewed. Of those, 47 were considered to be within the Guidelines, while 6 are subject to investigations. A total of 1178 patented drug products for human use were under the PMPRB's jurisdiction in 2007. There were nine Voluntary Compliance Undertakings approved by the Board. Currently, seven hearings are ongoing as are 103 investigations.

R&D expenditures rose in 2007. All patentees reported total R&D expenditures of $1,325 million, while those who were members of Rx&D reported R&D expenditures of $1,184 million over the same period. For all patentees, the R&D-to-sales ratio increased slightly to 8.3% from 8.1% in 2006, as did the R&D-to-sales ratio for members of Rx&D to 8.9% compared to 8.5% in the previous year.

We also reported on our extensive consultations on the review of our Excessive Price Guidelines. Indeed, we continue to provide stakeholders with the opportunity to participate in our ongoing consultation activities, which is a critically important part of the Board's efforts to reach decisions that are balanced and fair, and which will serve all Canadians effectively. To that end, we will be publishing a Notice and Comment package, including draft revised Guidelines, on August 20, 2008 and expect stakeholders' comments by October 6, 2008.

The Board is making all efforts to ensure transparency, accountability and good management of the price review process in its role of ensuring prices of patented medicines sold in Canada are not excessive. ■

Since our last issue...

Our recent key events

May 14-16	The Board held its second quarterly meeting. A summary of the Minutes is available on page 9. Minutes of Board meetings are also available on our Web site under: About the PMPRB; Summary of Board Meetings.
May 15	The Human Drug Advisory Panel (HDAP) held a face-to-face meeting in Ottawa.
May 22	Ginette Tognet gave a presentation on the *Price Review Process for Patented Medicines* at the Post Market Drug Safety and Effectiveness Workshop, University of Ottawa.

May 27-28	Béatrice Mullington and Ginette Tognet conducted information sessions with patentees on *How to Report according to the New Regulations*, in Montréal. Their presentation is available on our Web site under Regulatory; Filing Requirements Clarification; Patentee's Guide to Reporting; Presentation on How to Report according to New Regulations (May 2008).
May 30	The PMPRB submitted its Annual Report for the year 2007 to the Minister of Health.
June 3-6	Béatrice Mullington and Marc Legault conducted information sessions with patentees on *How to Report according to the New Regulations*, in Toronto.
June 9	Sylvie Dupont gave a presentation on the *Role and Responsibilities of the PMPRB (The Patented Medicine Prices Review Board and Pharmaceutical Price Regulation in Canada)*, at the MEDIUM Workshop, organized by the Ontario Pharmacists Association, in Toronto.
June 12	The Board met to discuss the review of its Excessive Price Guidelines.
June 13	The Board resumed its hearing in the matter of sanofi pasteur Limited and the medicines Quadracel and Pentacel.
June 24	Barbara Ouellet gave a presentation at the Canadian Institute – *Drug Pricing and Reimbursement in Canada* Conference, in Toronto.
June 26	The Board met with representatives of Rx&D and BIOTECanada to discuss issues related to the *Patented Medicines Regulations* and the review of the Board's Excessive Price Guidelines.
June 27	The Board heard the parties in the matter of Shire BioChem Inc. and its medicine Adderall XR, on Shire's motion to introduce further evidence in the proceeding for the purpose of determining the maximum non-excessive price of the medicine. The Board's decision is available on our Web site under Regulatory; Hearings.
July 3	The Board, in the matter of Hoechst Marion Roussel Canada and the medicine Nicoderm, heard the parties on their joint submission with regard to concluding these proceedings. The Board's decision is available on our Web site under Regulatory; Hearings.
July 4	Barbara Ouellet, Ginette Tognet and Sylvie Dupont met with representatives of the Brazilian National Health Surveillance Agency to discuss the role of the PMPRB in pharmaceutical price regulation in Canada.
July 8	The Board issued a Notice of Hearing in the matter of Apotex Inc. and the medicine Apo-Salvent CFC Free. The hearing is scheduled to start on December 8, 2008.
July 10-11	Barbara Ouellet attended Health Canada's invitational International Working-Level Meeting – *Pharmaceutical Innovation*, in Montréal.
July 14-15	The Board resumed its hearing in the matter of sanofi-aventis Canada Inc. and the medicine Penlac Nail Lacquer. The next session is scheduled for August 20.
July 16	The Board completed the review of its Excessive Price Guidelines for consultation with stakeholders.
July 18	The Board issued a Notice of Hearing in the matter of ratiopharm Inc. and the medicine ratio-Salbutamol HFA. The hearing is set to commence on January 12, 2009.

The PMPRB's speeches and presentations are available under Publications; Speech Series.

Hearings

The PMPRB's regulatory mandate is to ensure that patentees' prices of patented medicines are not excessive, thereby protecting consumer interests and contributing to Canadian health care. 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 revenues received as a result of excessive prices. The Board's decisions are subject to judicial review in the Federal Court (FC).

Adderall XR, Shire BioChem Inc.

On June 27, the Board heard the parties in the matter of Shire BioChem Inc. and its medicine Adderall XR on Shire's motion to introduce further evidence in this proceeding and to have the Hearing Panel establish the price of Dexedrine 5 mg tablets for the purpose of determining the maximum non-excessive (MNE) price for Adderall XR. The Panel admitted the evidence tendered by both Shire and Board staff regarding the price of Dexedrine and the relevance of that price to the appropriate MNE of Adderall XR. The Panel also considers appropriate for the Saskatchewan price of Dexedrine 5 mg tablets to be used in the calculation of the MNE of Adderall XR.

The full text of the Panel's decision is available on our Web site.

Apotex Inc.

The Board will hear the parties in this matter on October 6, 2008 as to the status of Apotex as a patentee under the jurisdiction of the PMPRB.

Apo-Salvent

On July 8, 2008, the Chairperson issued a Notice of Hearing in the matter of Apotex Inc. and the price of the medicine Apo-Salvent CFC Free. The hearing is to commence on December 8. A pre-hearing conference has also been scheduled for September 29, 2008.

Copaxone, Teva Neuroscience G.P.-S.E.N.C.

On May 12, 2008, the Board issued an Order and reasons in the matter of Teva Neuroscience G.P.-S.E.N.C. and its medicine Copaxone. Teva has filed applications for judicial review of the Board's decision and of the Board's Order in this matter with the FC. No hearing date has yet been scheduled.

Nicoderm

The Board held a hearing on July 3rd into the matter of Hoechst Marion Roussel Canada and its medicine Nicoderm, and heard the parties' joint submission regarding the conclusion of this proceeding.

Penlac, sanofi-aventis Canada Inc.

The hearing in this matter resumed on July 14 and 15. The next session of this hearing is scheduled for August 20.

Quadracel – Pentacel, sanofi pasteur Limited

The Board resumed its hearing in the matter of sanofi pasteur Limited and the medicines Quadracel and Pentacel on June 13. Two additional sessions have been scheduled to complete this matter: November 25-27, 2008 and January 5-7, 2009.

ratio-Salbutamol, ratiopharm Inc.

The Chairperson issued a Notice of Hearing in this matter on July 18, 2008. The hearing has been scheduled for January 12, 2009 and a pre-hearing will be held on October 27, 2008. ■

Adderall XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD").

Apo-Salvent CFC Free is a new DIN of an existing dosage form of an existing bronchodilator medicine (salbutamol sulphate) which relieves chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs.

Copaxone 20 mg/1.0 mL syringe is a new formulation of an existing compound (glatiramer acetate) indicated for use in ambulatory patients with Relapsing-Remitting Multiple Sclerosis to reduce the frequency of relapses.

Nicoderm is a transdermal smoking cessation patch.

Penlac is indicated as part of a comprehensive nail management program in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement.

Pentacel is indicated for the routine immunization of all children between 2 and 59 months of age against diphtheria, tetanus, whooping cough (pertussis), poliomyelitis and haemophilus influenzae type b disease. It is sold in Canada in the form of a reconstituted product for injection combining one single dose vial of Act HIB (Lyophilized powder for injection) and one single (0.5 mL) dose ampoule of Quadracel (suspension for injection).

Quadracel is indicated for the primary immunization of infants, at or above the age of 2 months, and as a booster in children up to their 7th birthday against diphtheria, tetanus, whooping cough (pertussis) and poliomyelitis.

ratio-Salbutamol is a new DIN of an existing dosage form of an existing bronchodilator medicine (salbutamol sulphate) which relieves chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs.

Further information on hearings, including Board decisions and orders, is available on our Web site under Regulatory; Hearings.

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

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Voluntary Compliance Undertaking

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust its price to conform to the Excessive Price Guidelines (Guidelines) and offset excess revenues obtained by selling a medicine at an excessive price.

Under the Compliance and Enforcement Policy, patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price of a patented medicine sold in Canada appears to have exceeded the Board's Guidelines.

Denavir, Barrier Therapeutics Canada Inc.

Denavir (*penciclovir*), a new active substance, is indicated for the treatment of recurrent herpes labialis (cold sores) in adults.

On May 20, 2008, the Chairperson of the Board accepted a VCU for Denavir submitted by Barrier Therapeutics Canada Inc.

The terms of the VCU require that, among others, Barrier Therapeutics offset cumulative excess revenues received from April 15, 2006 to December 31, 2007 in the amount of $61,021.80, by making a payment to Her Majesty in Right of Canada. Barrier Therapeutics fulfilled its undertaking.

Denavir is no longer sold in Canada. Barrier Therapeutics is to notify the PMPRB in the event that it sells Denavir in any future period in which Denavir remains under the PMPRB's jurisdiction.

AndroGel, Solvay Pharma Inc.

AndroGel 1% topical gel (*testosterone*) is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone.

On June 24, 2008, the Chairperson of the Board accepted a VCU for AndroGel submitted by Solvay Pharma Inc. (Solvay Pharma).

The terms of the VCU require that Solvay Pharma reduce the price of AndroGel 2.5 g/pouch to the 2008 MNE price of $2.1263 and offset cumulative excess revenues received from May 2002 to December 31, 2007 by making a payment of $3,327,180.61 to her Majesty in Right of Canada. Solvay Pharma fulfilled its undertaking.

Also, in order to offset the remaining excess revenues received from January 1, 2008 to the date of acceptance of the VCU, the average transaction price of AndroGel 2.5 g/pouch for 2008 is to be at or below the 2008 MNE price of $2.1263. In the event that any excess revenues remain as at December 31, 2008, Solvay Pharma shall make a further payment in the amount of any remaining excess revenues, as calculated by Board Staff. ■

VCUs are public documents and as such are posted on the PMPRB Web site under Regulatory; Voluntary Compliance Undertakings.

National Public Service Week 2008

The National Public Service Week is an important annual event, an opportunity to recognize and celebrate the work of federal public service employees and the contribution they make to Canada and to Canadians.

This year's theme was *Recognizing our history while building our tomorrow*. The PMPRB celebrated its history in December when it commemorated its 20th Anniversary. During the National Public Service Week, the PMPRB recognized its employees by holding events in recognition of their dedication to the PMPRB and to the federal public service.

NPDUIS Update

The National Prescription Drug Utilization Information System (NPDUIS) is a research initiative jointly conducted by the PMPRB and the Canadian Institute for Health Information. NPDUIS seeks to provide policy-makers with information and insights on trends in prices, utilization and costs of interest to participating public drug plans (all federal and provincial drug plans participate in NPDUIS except Québec).

The NPDUIS Steering Committee held a conference call on July 22. This meeting focused on identifying new research projects and prioritizing projects not yet initiated.

The second edition of the New Drug Pipeline Monitor report (NDPM) is being finalized for publication. A key part of the NPDM involves developing a list of drugs currently in development and expected to have substantial therapeutic and financial impacts when sold in Canada. An online version of this report is also being developed.

The first phase of a major research project, examining potential impacts of long-term demographic change on public drug plans, is nearing completion. A second phase of this project will provide more detailed results (e.g., by therapeutic class).

Another important research project, examining recent trends in the dispensing fees reimbursed by public drug plans is also underway.

Finally, a project examining methodological alternatives for measuring volumes of treatment in utilization analysis is being finalized. Research on new methodologies for decomposing program expenditure growth and constructing treatment cost indices has also been initiated.

The PMPRB's previous work on reporting on Non-Patented Prescription Drug Prices was folded under the umbrella of NPDUIS effective April 1, 2008. Two trend reports will be published this summer. In future, selected NPDUIS studies will highlight trends related to both patented and non-patented drug products. ■

NPDUIS studies and reports are posted on our Web site under Reporting; NPDUIS

Patented Medicines Regulations – *Information Sessions to Patentees*

Board Staff conducted workshops in Montréal on May 27-28, 2008 and in Toronto on June 3-6, 2008, to bring patentees up-to-date with the reporting requirements resulting from the amendments to the *Patented Medicines Regulations* which came into force in March 2008.

The workshops included two parts: a plenary session on the main changes in reporting Form 1 (Medicine Identification Sheet) and Form 2 (Information on the Identity of Prices of the Medicine), and individual sessions for patentees interested in discussing further the required format and layout of their own semi-annual report. About 70 persons representing 35 pharmaceutical companies participated in the sessions.

Although the requirement to file electronically in the specified format and layout did not come into force until July 1, 2008 (i.e., for the July to December 2008 reporting period which is filed on January 30, 2009), patentees are encouraged to file their January to June 2008 data using the Form 2 format and layout that can be downloaded from the PMPRB Web site. ■

The presentation is available on our Web site under Regulatory; Filing Requirements Clarification; Patentee's Guide to Reporting; Presentation on How to Report according to New Regulations (May 2008).

Comings and Goings

Gerry Taylor, PMPRB's Chief of Management Services since 1997, retired from the Public Service after 34 years. Thank you Gerry for your valuable contribution to the PMPRB! All the very best for a well deserved retirement.

Congratulations Gerry!

We welcome Karen Arial, formerly of Health Canada, as Chief, Corporate Planning and Reporting.

Also, we welcome two students, Nicholas Corvari and Karan Landge who have joined the NPDUIS Team for the summer.

We bid farewell to three colleagues! Ria Mykoo, from Legal Services, who is taking on new challenges in Toronto. Larissa Lefebvre left the Compliance and Enforcement Branch to join Health Canada. Also, Aaron Baillie returned to Industry Canada after working on a two-year assignment with the Compliance and Enforcement Branch. We wish them success in their new endeavours. ■

List of New Drugs Introduced Since the Publication of the April 2008 NEWSletter

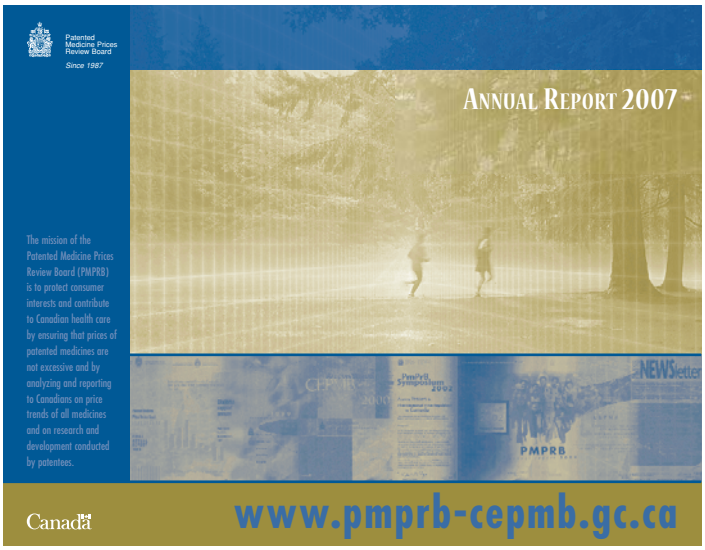
As of June 30, 2008, there were 42 new DINs for human use (representing 24 medicines) reported to the PMPRB for the year 2008. Of these 42 DINs, 13 DINs (representing 9 medicines) are new active substances.

The following table presents the new active substances reported to the PMPRB during the period January to June 2008. ■

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 just sold during the patent pending period (after the date when the product 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, 2008

Brand Name	Generic Name	Company	Therapeutic Use
Cymbalta (30 mg/capsule, 60 mg/capsule)	*duloxetine hydrochloride*	Eli Lilly Canada Inc.	Antidepressant/Analgesic
Eraxis (100 mg/vial)	*anidulafungin*	Pfizer Canada Inc.	Antifungal
Frova (2.5 mg/tablet)	*frovatriptan succinate*	Teva Neuroscience	Migraine
Intelence (100 mg/tablet)	*etravirine*	Janssen-Ortho Inc.	HIV treatment
Januvia (100 mg/tablet)	*sitagliptin phosphate monohydrate*	Merck Frosst Canada Ltd.	Diabetes
Natrecor (1.5 mg/vial)	*nesiritide*	Janssen-Ortho Inc.	Acute decompensated congestive heart failure
Relistor (20 mg/mL)	*methylnaltrexone bromide*	Wyeth Pharmaceuticals	Constipation due to epioid therapy
Torisel (25 mg/vial)	*temsirolimus*	Wyeth Pharmaceuticals	Renal cell cancer
Zeldox (20 mg/capsule, 40 mg/capsule, 60 mg/capsule, 80 mg/capsule)	*ziprasidone hydrochloride*	Pfizer Canada Inc.	Antipsychotic



JUNE 18, 2008

The PMPRB's 2007 Annual Report was tabled before Parliament

We invite readers to read our 2007 Annual Report and send us their comments and/or questions at pmprb@pmprb-cepmb.gc.ca.

Report on New Patented Drug – Aldurazyme

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 after January 1, 2002.

Brand Name: Aldurazyme

Generic Name: *(laronidase)*

DIN: 02254506 (0.58 mg mL)

Patentee: Genzyme Canada Inc.

Indication – as per product monograph:

Long-term enzyme replacement therapy in patients with Mucopolysaccharidosis I (MPSI; α-L-iduronidase deficiency) to treat the non-central nervous system manifestations of the disease

Date of Issuance of First Patent Pertaining to the Medicine: October 23, 2007

Notice of Compliance: May 31, 2004

Date of First Sale: July 8, 2004

ATC Class: A16AB
Alimentary Tract and Metabolism; Other Alimentary Tract and Metabolism Products; Enzymes

Application of the Guidelines

Summary

The introductory price (July to December 2004) of Aldurazyme was found to exceed the Guidelines but not by an amount sufficient to trigger any of the investigation criteria under the Board's Compliance & Enforcement Policy. It is currently within the Guidelines.

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

Scientific Review

Aldurazyme is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Aldurazyme be classified as a Category 2 new medicine (a breakthrough or provides a substantial improvement over comparable existing medicines). The HDAP did not recommend any comparators.

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 highest of the price of all the comparable drug products based on the Therapeutic Class Comparison (TCC) test and the median of the international prices identified in an International Price Comparison (IPC) test. See the PMPRB's Compendium for a more complete description of the Guidelines.

It was not possible to conduct a TCC test as the HDAP did not identify any comparable drug products. At introduction (July-December 2004), the price of Aldurazyme of $209.0000 per mL* exceeded the median of the international prices of $202.9845 per mL* but by an amount that did not trigger the investigation criteria. Aldurazyme was sold in five of the seven countries listed in the *Patented Medicines Regulations*. When Aldurazyme came under the PMPRB's jurisdiction in 2007, the price was within the Guidelines and there were no excess revenues. ■

*Publicly available price as per the 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 also refers to the publicly available prices of comparators provided such prices are not more than 10% above the maximum 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 that 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.

Board Meetings over the last quarter

May 14-16

At its May meeting, the Board dealt mainly with the review of its Excessive Price Guidelines and the 2007 Annual Report.

In the context of the review of its Guidelines, the Board:

- Received the recommendations of the Working Groups on Patented Generic Drugs; Price Tests; and Cost of Making and Marketing;
- Discussed options for revisions to the Guidelines.

The Board approved the text of its 2007 Annual Report for submission to the Minister of Health on May 30, 2008.

June 12

The Board prepared to discuss the recommendations of the various Working Groups with the innovative pharmaceutical and biotechnology industry on June 26, 2008.

July 16

The Board discussed the text of a Communiqué to stakeholders, which will be released on August 18, 2008, and of its Notice and Comment on draft revised Guidelines to be released on August 20, 2008.

The Board will be seeking stakeholder comments on its draft revised Guidelines by October 6, 2008. The Notice and Comment package will be posted on our Web site under Consultations; Consultations on the Board's Excessive Price Guidelines; Notice and Comment.

The next Board meeting is scheduled for October 22, 2008. ■

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.

What's New @ PMPRB

Readers are invited to check our Web site under **What's New @ PMPRB** for the latest information on the PMPRB's activities.

Questions and Comments

PMPRB E-bulletin

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Upcoming Events

August

August 18: Release of Board's Stakeholder Communiqué

August 20: Notice and Comment on Board's Excessive Price Guidelines

August 20: Hearing: Penlac Nail Lacquer, sanofi-aventis Canada Inc.

September

September 15: HDAP Teleconference

September 29: Pre-Hearing Conference: Apo-Salvent CFC Free, Apotex Inc.

October

October 6: Hearing: Apotex Inc. (jurisdiction)

October 6: Deadline for submissions on the Board's draft revised Excessive Price Guidelines

October 22: Board Meeting

October 27: Pre-Hearing Conference: ratio-Salbutamol, ratiopharm Inc.

October 28: (Montréal) Brogan Advanced Training Seminar

October 29: (Toronto) Brogan Advanced Training Seminar

October 31: Release of the October 2008 NEWSletter

November

November 17: Release of the Board's Revised Excessive Price Guidelines

November 24: HDAP Teleconference

November 20: First session of Board Staff's outreach to patentees on the Board's revised Excessive Price Guidelines

November 25-27: Hearing: Quadracel and Pentacel, sanofi pasteur Limited

December

December 8: Hearing: Apo-Salvent CFC Free, Apotex Inc.

December 11-12: Board Meeting, Ottawa

January 2009

January 5-7: Hearing: Quadracel and Pentacel, sanofi pasteur Limited

January 12: Hearing: ratio-Salbutamol HFA, ratiopharm Inc.

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

Readers' Corner

This segment "Readers' Corner" is dedicated to comments received from our readers. We will ensure that your comments are addressed and published.

We encourage you to submit your suggestions on topics you wish to see discussed in the NEWSletter.

We look forward to hearing from you.

Electronic PMPRB NEWSletter

Readers who wish to receive the NEWSletter electronically, please register by forwarding your E-mail address to pmprb@pmprb-cepmb.gc.ca.

To order our publications, call our toll-free number 1 877 861-2350 or e-mail us at elaine@pmprb-cepmb.gc.ca

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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