Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 14, Issue No. 1, January 2010

Inside...

Since our last issue...

Our recent key events

November 2:	The Hearing Panel in the matter of ratiopharm Inc. and the medicine ratio-Salbutamol HFA, held a pre-hearing conference.
November 3:	Barbara Ouellet gave a presentation – Overview of the PMPRB – at the Drug Information Association's (DIA) 7th Canadian Annual Meeting: *Time to Act*, in Ottawa.
November 3:	The PMPRB NPDUIS Steering Committee meeting was held in Ottawa.
November 3-4:	The PMPRB NPDUIS Steering Committee and Staff took part in the Pharmaceutical Policy Research Collaboration (PPRC) meeting in Ottawa.
November 4:	Barbara Ouellet gave a presentation – PMPRB: Revised Excessive Price Guidelines – at the 8th Annual Market Access Summit, in Toronto.
November 11:	Barbara Ouellet gave a presentation on the Board's revised Guidelines at the Market Access Canada for Pharma conference in Toronto.
November 12:	The Federal Court issued its decision on Teva Neuroscience's application for Judicial Review, which was heard October 27-28.
November 12:	The PMPRB Staff met with Rx&D's Sub-Committee on the PMPRB on the Board's revised Excessive Price Guidelines.
November 19:	The HDAP held its quarterly meeting.
November 24:	Barbara Ouellet and Ginette Tognet gave a presentation on the Board's revised Excessive Price Guidelines to Bristol-Myers Squibb in Montreal.
November 24-25:	The PMPRB Staff gave a presentation on the Board's revised Excessive Price Guidelines at the Brogan Advanced Seminars in Montreal and Toronto.
November 26:	Barbara Ouellet gave a presentation on the Board's revised Excessive Price Guidelines to the Federal-Provincial-Territorial Advisory Committee on Pharmaceuticals.
December 1:	The Federal Court of Appeal heard the parties on the Celgene Corporation matter regarding Thalomid and issued its decision on December 21.
December 4:	The Board held its last quarterly meeting of the year. A summary of the Minutes is available on page 9.

Continued on page 2

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.

ISSN 1920-3713

2010

January 1:	The Board's revised Excessive Price Guidelines came into effect.
January 25-26:	The Hearing Panel in the ratiopharm Inc. and ratio-Salbutamol HFA matter held the first session of its hearing on the merits. ■

PMPRB speeches and presentations are available on the 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

News from the Chairman

Brien G. Benoit, MD, Chairman

In June 2009, the Board completed a four-year- long consultation with stakeholders on the modernization of its Excessive Price Guidelines. Outreach sessions were held for patentees and presentations were given to other interested parties in an effort to assist them in better understanding the application of the revised Guidelines.

After the implementation of our revised Guidelines on January 1, 2010, we are shifting our priorities and focusing our resources on the day-to-day application of the Guidelines. The impact of the main changes to the Guidelines have resulted in, among other things, an increase in the membership of our Human Drug Advisory Panel, from three to six, so that the HDAP may continue to provide expertise and timely advice to Board Staff in conducting the scientific reviews. As well, through the implementation of our integrated business and human resources planning framework, we have addressed our capacity gaps, more particularly in our Regulatory Affairs and Outreach Branch, and Policy and Economic Analysis Branch, as is evident from the highlighted "Comings and Goings". Our Information Technology Programs have been updated to reflect and accommodate the revised Guidelines so that we continue to support efficient and timely price reviews.

The Board remains committed to providing predictability, fairness and transparency in the fulfillment of its regulatory responsibilities. To that end, the Board will monitor and evaluate the application and impact of key revisions to Guidelines to ensure that its overall objectives of relevance and appropriateness to the current pharmaceutical environment are met. ■

Brien G. Benoit, MD, Chairman

Comings and Goings

Several new employees have joined us over the past few months. Kevin Crombie joined the Board Secretariat and Communications Branch as Communications Manager and Natalie Lowe is the Senior Hearing Officer. New in the Policy and Economic Analysis Branch are Mélanie Leroux, Assistant to the Director, and Senior Economic Analyst with the NPDUIS team Derek Jones, on secondment from the Ontario Public Drug Programs of the Ministry of Health and Long Term Care. George Botulynsky is the new Manager, Investigations Unit, in the Regulatory Affairs and Outreach Branch. John Cook and Theresa Traynor also joined the Branch as Senior Regulatory Officers and Kirk Stanley was appointed to the same position.

Martin Szumski returned to Regulatory Affairs and Outreach after a secondment at Health Canada, and Jill Dunlap has returned from maternity leave. Ria Mykoo returns to the PMPRB as counsel in the Legal Services Branch. Cecile Lachance joined the Corporate Services Branch, as Assistant to the Director.

Jesslyn Mullaney completed an assignment with the Board and returned to the Canadian Radio-television and Telecommunications Commission (CRTC) in January 2010. Paul McKenzie retired from the Public Service in December 2009. We wish him the very best for a well deserved retirement.

Best of luck to all! ■

Human Drug Advisory Panel

As part of the implementation of the new Compendium of Policies, Guidelines and Procedures, the membership of the Human Drug Advisory Panel (HDAP) has been increased from three to six members.

We welcome Dr. Fred Y. Aoki, Professor of Medicine, Medical Microbiology and Pharmacology and Therapeutics at the University of Manitoba, Dr. Jacques LeLorier, Professor in the Departments of Medicine and Pharmacology at the Université de Montréal and Adjunct Professor in the Department of Epidemiology and Biostatistics at McGill University, and Dr. Muhammad Mamdani who is Director of the Applied Health Research Centre, Li Ka Shing Knowledge Institute at St. Michael's Hospital, Toronto and Associate Professor in the Department of Health Policy, Management, and Evaluation at the University of Toronto.

They join the current members: Dr. Jean Gray, Professor Emeritus of Medical Education, Medicine, and Pharmacology at Dalhousie University, Dr. Mitchell A.H. Levine, Professor in the Department of Clinical Epidemiology and Biostatistics at McMaster University and Director of the Centre for Evaluation of Medicines, St. Joseph's Healthcare in Hamilton, and Dr. Adil Virani, who is Director of Pharmacy Services at the Fraser Health Authority and Associate Professor in the Faculty of Pharmaceutical Sciences at the University of British Columbia.

We look forward to the participation of the new members in the scientific review process. ■

Report on PMPRB's contribution to the Workplace Charitable Campaign 2009

Thanks to our dedicated team of volunteers – and our generous contributors – the PMPRB has once again surpassed its goal for the Government of Canada Workplace Charitable Campaign. This year, Health Canada (on belalf of the Health Portfolio) was awarded the Chair's Cup, the highest honour of the 2009 Government of Canada campaign. The Chair's Cup will spend a week at PMPRB in February.

Thank you all for your generosity! ■

2009 CPI-Based Price-Adjustment Factors

Preliminary Price-Adjustment Factors (Based on Forecast Inflation Rates)

Table 1 reproduces preliminary price-adjustment factors for 2009 published in the April 2008 NEWSletter. These factors were based on annual forecast CPI-inflation rates of 2.2% and 2.0% for 2008 and 2009, respectively.

Table 1

Preliminary 2009 Price-Adjustment Factors for Patented Drug Products (Based on Forecast CPI-Inflation Rates)

	Benchmark Year		
	(1) 2006	(2) 2007	(3) 2008
Price-Adjustment Factor	1.065	1.042	1.020

These figures imply: (1) a maximum allowable cumulative price increase between 2006 and 2009 of 6.5% for patented drug products with Canadian sales in 2006; (2) a maximum allowable cumulative price increase between 2007 and 2009 of 4.2% for products whose first Canadian sales occurred in 2007; and (3) a maximum allowable cumulative price increase between 2008 and 2009 of 2.0% for products whose first Canadian sales occurred in 2008.

In addition, the forecast inflation rate of 2.0% for 2009 implies a year-over-year price increase cap of 3.0% (= 1.5 x 2.0%) for 2009.

Final Price-Adjustment Factors (Based on Actual Inflation Rates)

The actual rate of CPI inflation for 2008 of 2.4% was published in the January 2009 NEWSletter. The actual CPI inflation for 2009 is now available and was 0.3 %. These rates (along with the actual 2007 CPI-inflation rate of 2.1%) yield the following final price-adjustment factors.

Table 2

Final 2009 Price-Adjustment Factors for Patented Drug Products (Based on Actual CPI-Inflation Rates)

	Benchmark Year		
	(1) 2006	(2) 2007	(3) 2008
Price-Adjustment Factor	1.049	1.027	1.003

The final year-over-year price increase cap for 2009 is 0.5 % (= 1.5 x 0.3%). ■

Patentees' Reporting on Research and Development (R&D) and Sales

Under the *Patented Medicines Regulations* (Regulations), all patentees are required to file Form 3 information on revenues and R&D expenditures. Paragraph 5(1)(c) of the Regulations specifies that patentees shall indicate total gross revenues from all sales (i.e. of patented and non-patented drugs) in Canada during the year by the patentee. If a patentee has a license or other agreement with a person related to the sale of a drug in Canada, it must also report total revenues received from all licensees/others, including royalties or any other revenues as prescribed by the license/other agreement.

Paragraph 5(1)(d) of the Regulations requires that the patentee provide a summary of all expenditures made during the year by the patentee towards the cost of R&D relating to medicines for human or veterinary use carried out in Canada by or on behalf of the patentee. These expenditures are not limited to R&D related to patented drugs under the Board's jurisdiction.

Patentees are reminded that the deadline for filing Form 3 information on revenues and R&D expenditures is March 1, 2010.
The *Patent Act* (Act) defines a patentee as the person for the time being entitled to the benefit of a patent and includes both the patent holder and any other person with a license or other agreement that enables the rights under the patent to be exercised.

Form 3, the template created by the PMPRB to help patentees file this information, is available on our Web site, under Regulatory Filings.

Failure to File

If a patentee fails to file complete information by March 1, 2010, the patentee will be advised in writing that the information required to be filed under the Regulations has not been received by the PMPRB and will be given a further seven (7) days to provide the information. Should the patentee not file within the further period, Board Staff shall request that the Board issue an order pursuant to section 88 of the Act requiring that the patentee file the required information.

Orders issued by the Board are registered with the Federal Court and reported in the PMPRB's publications and posted on its Web site. ■

Report on November NPDUIS Meeting

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

The federal, provincial, territorial NPDUIS Steering Committee met in Ottawa on November 3, 2009. The meeting was attended by representatives of the public drug plans in Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Newfoundland and Labrador, and the Yukon, as well representatives from the PMPRB, CIHI, and Health Canada. During the morning session, PMPRB Staff presented preliminary results of research underway and brought forward new research proposals for consideration.

In the afternoon, the NPDUIS Steering Committee held a joint meeting with members of the Pharmaceutical Policy Research Collaboration (PPRC), a network of academic researchers funded by the Canadian Institutes of Health Research and led by Professor Steve Morgan of the University of British Columbia. The meeting provided policy makers and researchers with an excellent opportunity to share ideas and exchange information, leverage existing knowledge, and identify common priorities for future policy research.

The NPDUIS Steering Committee held a teleconference call on January 14, 2010, in which the PMPRB Staff provided a status update on current research projects. ■

What's New @ PMPRB

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

Hearings – Update

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 to reduce the price and to offset revenues received as a result of excessive prices. Board decisions are subject to judicial review in the Federal Court of Canada.

Status of Board Proceedings

Patented Drug Product	Indication / Use	Patentee	Issuance of Notice of Hearing – Date	Status
Apotex Inc.	Failure to File (jurisdiction)		March 3, 2008	**Ongoing**
Apo-Salvent CFC-Free	Relief of chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs	Apotex Inc.	July 8, 2008	**Ongoing**
Copaxone	Use in ambulatory patients with relapsing-remitting multitude sclerosis to reduce the frequency of relapses	Teva Neuroscience G.P.-S.E.N.C.	May 8, 2006	**Federal Court Decision – Nov 12, 2009**
Nicoderm	Smoking cessation	sanofi-aventis Canada Inc.	April 20, 1999	**Board decision pending**
Penlac	Part of a comprehensive nail management program in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement	sanofi-aventis Canada Inc.	March 26, 2007	**Board decision pending**
Pentacel	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)	sanofi pasteur Limited	March 27, 2007	**Board Decision – Dec 21, 2009 Order pending** **Application for Judicial Review – January 19, 2010**
Quadracel	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			**Board Decision – Dec 21, 2009 Order pending** **Application for Judicial Review – January 19, 2010**
ratiopharm Inc.	Failure to File (jurisdiction)		August 28, 2008	**Board decision pending**
ratio-Salbutamol HFA	Relief of chest tightness and wheezing caused by spasms or narrowing in the small air passages of the lungs	ratiopharm Inc.	July 18, 2008	**Hearing: Jan 25-26, 2010 March 4-5, 2010 April 12-16, 2010** ■

Questions and Comments

PMPRB E-bulletin

Readers who wish to receive PMPRB electronic news bulletins should forward their e-mail address to **pmprb@pmprb-cepmb.gc.ca**. Your cooperation in submitting updates 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**.

Voluntary Compliance Undertakings – Update

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to conform to the Board's Excessive Price Guidelines (Guidelines) including adjusting its price to a non-excessive level and offsetting excess revenues. Under the Guidelines, patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price set forth by the patentee for a patented drug product sold in Canada appears to have exceeded the Guidelines. A VCU can also be submitted by a patentee after a Notice of Hearing is issued.

Sinces the October NEWSletter, the Chairman of the Board accepted VCUs for: Andriol, Claritin Allergy and Sinus Extra Strength, Trinipatch, Voluven and Xarelto.

Andriol, Schering-Plough Canada Inc.

Schering-Plough offset excess revenues of $348,605.86, by making a payment to the Receiver General of Canada.

Under the terms of the VCU, Schering-Plough was to provide, among other things, a discount of 21.25% against the 2009 maximum non-excessive (MNE) price to all customers and to maintain the discount until December 31, 2010. In the event that the full amount of the excess revenues has not been offset by December 31, 2010, the patentee is to make a further payment to the Government of Canada.

The price of Andriol is to remain within the Guidelines during all periods in which it is under the PMPRB's jurisdiction (March 2020).

Andriol (testosterone undecanoate) is indicated for the replacement therapy in males in conditions associated with symptoms of deficiency or absence of endogenous testosterone: for the management of congenital or acquired primary hypogonadism and hypogonadotropic hypogonadism; to develop and maintain secondary sexual characteristics in males with testosterone deficiency; to stimulate puberty in carefully selected males with clearly delayed puberty not secondary to a pathological disorder. It is used as a replacement therapy in impotence or for male climacteric symptoms when the conditions are due to a measured or documented androgen deficiency.

Claritin Allergy & Sinus Extra Strength, Schering-Plough Canada Inc.

Schering-Plough will offset the cumulative excess revenues received from January 1, 2005 to June 30, 2009 by making a payment to the Government of Canada in the amount of $69,950.43, by no later than February 26, 2010.

Claritin Allergy & Sinus Extra Strength is to remain within the Guidelines in all future periods in which it is under the PMPRB's jurisdiction (October 2013).

Claritin Allergy & Sinus Extra Strength (10 mg loratadine / 240 mg pseudoephedrine sulphate) is indicated for the relief of symptoms associated with allergic rhinitis, including nasal and sinus congestion, sneezing, postnasal discharge and tearing and redness of the eyes.

Trinipatch, Novartis Pharmaceuticals Canada Inc.

Novartis offset excess revenues received from January 1, 2008 to January 13, 2009, by making a payment to the Government of Canada in the amount of $47,099.61.

Trinipatch is no longer sold in Canada.

Trinipatch® (nitroglycerin), a patented medicine sold in Canada from March 16, 2006 to January 13, 2009, was indicated for the prevention of anginal attacks in patients with stable angina pectoris associated with coronary artery disease.

Voluven, Fresenius Kabi Canada

Fresenius will offset cumulative excess revenues received from March 2, 2007 to August 7, 2008, in the amount of $1,448,002.25 by making a payment to the Government of Canada, by no later than March 2, 2010.

Voluven is no longer under the PMPRB's jurisdiction, its patent having lapsed on August 7, 2008.

Voluven (hydroxyethyl starch) is indicated for the treatment of hypovolemia when plasma volume is required.

Xarelto, Bayer Inc.

Bayer will reduce the price of Xarelto and offset excess revenues received from September 18, 2008 to June 30, 2009 by making a payment to the Government of Canada in the amount of $49,978.33, by no later than February 22, 2010. Bayer is also to offset any excess revenues received from July 1, 2009 to the date of the implementation of the price reduction, by making a further payment to the Government of Canada in an amount calculated by Board Staff after the regulatory filing of the price and sales data for that period.

Xarelto is to remain within the Guidelines in all future reporting periods in which it is under the PMPRB's jurisdiction (December 2020).

Xarelto (rivaroxaban) is indicated for the prevention of venous thromboembolic events in patients who have undergone elective hip or total knee replacement surgery.

VCUs are available on the PMPRB Web site under Regulatory; Voluntary Compliance Undertakings. ■

New Patented Medicines Reported to the PMPRB

Thirty five new DINs for human use (representing 19 medicines) were added to the list of Patented Medicines reported to the PMPRB for the period October to December 31, 2009. Nine of these new medicines are new active substances representing 10 DINs.

The following table presents the new active substances reported to the PMPRB during this period.

Brand Name	Generic Name	Company	Indication
Abilify – 15 mg/tablet	aripiprazole	Bristol-Myers Squibb Canada Co.	Schizophrenia
Doribax – 500 mg/vial	doripenem	Janssen-Ortho Inc.	Antibiotic
Firmagon – 80 mg, 120 mg vials	degarelix	Ferring Inc.	Prostate cancer
Multaq – 400 mg/tablet	dronedarone hydrochloride	Sanofi-Aventis Canada Inc.	Antiarrhythmic
Stelara – 45 mg/vial	ustekinumab	Janssen-Ortho Inc.	Psoriasis
Synflorix – 0.5 mL/dose	pneumococcal conjugate vaccine	GlaxoSmithKline Inc.	Vaccine
Tasigna – 200 mg/caplet	nilotinib	Novartis Pharma Canada Inc.	Leukemia
Tykerb – 250 mg/tablet	lapatinib ditosylate	GlaxoSmithKline Inc.	Breast Cancer
Zolinza – 100 mg/capsule	vorinostat	Merck Frosst Canada Ltd.	Anti-neoplastic

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 or the date the patent is laid open, which is more recent. ■

Report on New Patented Drugs

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drug products 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.

Sprycel

Brand Name: Sprycel

Generic Name: dasatinib

DINs: 02293129 (20 mg/tablet) 02293137 (50 mg/tablet) 02293145 (70 mg/tablet)

Patentee: Bristol-Myers Squibb Canada Co.

Indication – as per product monograph (as of date of first sale – 2007): For the treatment of adults with chronic, accelerated, or blast phase chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy including imatinib mesylate. Sprycel is also indicated for the treatment of adults with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukemia (ALL) and lymphoid blast chronic myeloid leukemia with resistance or intolerance to prior therapy.

Date of Issuance of First Patent(s) Pertaining to the Medicine: August 25, 2009

Notice of Compliance: March 26, 2007

Date of First Sale: April 13, 2007

ATC Class: L01XE06

Antineoplastic and Immunomodulating Agents; Antineoplastic Agents; Other Antineoplastic Agents; Protein Kinase Inhibitors.

Application of the Guidelines

Summary

The introductory prices of Sprycel were found to be within the Guidelines because the prices in Canada did not exceed the median of the prices of the same drug product sold in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) in which Sprycel was sold.

Scientific Review

Sprycel is a new active substance.

The Guidelines provide that new DINs with multiple approved indications will be categorized based on the approved indication for which the medicine offers the greatest therapeutic advantage in relation to alternative therapies for the same indication in a significant population.

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that the primary indication for Sprycel would be for the treatment of the chronic phase of CML in patients who are resistant or intolerant to prior therapy including imatinib mesylate, as it is during that phase that Sprycel is more likely to be initiated and this would offer the greatest therapeutic advantage.

The HDAP recommended that Sprycel be classified as a Category 2 new drug product (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 highest of the prices of all comparable drug products based on the TCC test and/or the median of the international prices identified in an International Price Comparison (IPC) test.

No comparators were identified for purposes of conducting a TCC test. The introductory prices of Sprycel were below the median of the international prices identified in an IPC test. Sprycel was sold in four of the seven countries listed in the Regulations.

Introductory Period (April to June 2007)

Country and Median	Sprycel 20 mg Price per tablet (in Canadian dollars)	Sprycel 50 mg Price per tablet (in Canadian dollars)	Sprycel 70 mg Price per tablet (in Canadian dollars)
Canada	$34.2162	$68.4322	$75.4672
France	Not sold	Not sold	Not sold
Germany	$55.7060	$111.3968	$111.3968
Italy	Not sold	Not sold	Not sold
Sweden	$55.7355	$111.4710	$111.4710
Switzerland	Not sold	Not sold	Not sold
United Kingdom	$48.3781	$96.7562	$96.7562
United States	$37.4023	$74.7984	$82.4828
Median	$52.0421	$104.0765	$104.0765

Source: Publicly available prices as per the Regulations.

When the IPC test is conducted to determine the median price, an interim median international price is used in cases when the medicine is sold in fewer than five countries at the time of introduction. Unless it is excessive, the introductory price will be treated as an interim benchmark price. The interim benchmark price may be reviewed at the end of the three years or when the medicine is sold in at least five countries, whichever comes first.

In 2008, all three strengths of Sprycel were sold in six of the seven countries listed in the Regulations and the Canadian prices continued to be below the median of the international prices identified in an IPC test.

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 drug products 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 a non-excessive price in which case no price will be made available. As a result, the publication of these prices is for information only and should not be construed as indicating the public prices are 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 product, 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 the PMPRB Web site under Patented Medicines; Reports on New Patented Drugs for Human Use; Sprycel. ■

Board Meeting

The Board met on December 4, 2009, to discuss, among other issues, the monitoring and evaluation of the new Excessive Price Guidelines and the Board's Draft Hearing Rules of Practice and Procedure.

The Board's next meeting is scheduled for March 11, 2010.

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.

Summaries of Board meetings are available on the PMPRB Web site under About PMPRB. ■

Upcoming Events

February

February 17:
HDAP meeting

February 26:
Presentation on the PMPRB – Faculty of Pharmacy and Pharmaceutical Sciences, University of Alberta

March

March 1:
Patentees' Form 3 filings

March 3:
Presentation on the Board's Excessive Price Guidelines – Faculty of Law, University of Ottawa

March 4-5:
Hearing in the matter of ratiopharm Inc. and the medicine ratio-Salbutamol HFA

March 11:
Board meeting

March 24-25:
Pharma Pricing & Market Access Outlook 2010, London, UK

April

April 12-16:
Hearing in the matter of ratiopharm Inc. and the medicine ratio-Salbutamol HFA

April 30:
April 2010 NEWSletter

May

May 6-7:
Drug Patents in Canada Conference, Toronto

May 10:
HDAP meeting

May 20:
Board meeting

May 28:
2009 PMPRB Annual Report submitted to the Minister of Health

May 30-June 2:
Canadian Council of Administrative Tribunals (CCAT) 26th Annual Conference, Montreal

June

June 14-20:
National Public Service Week

July

July 16:
NPDUIS Steering Committee teleconference

July 30:
Patentees' Form 2 filings

July 2010 NEWSletter

September

September 15:
HDAP meeting

September 16:
Board meeting

September 23:
NPDUIS Steering Committee teleconference

October

October 30:
October 2010 NEWSletter

November

November 17:
HDAP meeting

December

December 9:
Board meeting

Upcoming Events are available on the PMPRB Web site under Consultations; Events. ■

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.

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