Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 15, Issue No. 2, April 2011

Inside...

Since our last issue...

Our recent key events

February 7:	The HDAP held its quarterly meeting.
February 9–11:	Michelle Boudreau spoke at the Canadian Healthcare Licensing Association Winter Meeting in Mont Tremblant.
February 15:	The Vice-Chairperson of the Board accepted a Voluntary Compliance Undertaking (VCU) submitted by Bristol-Myers Squibb Canada Co. regarding the price of the patented medicine Abilify.
February 16–17:	The Federal Court of Canada heard the Application for Judicial Review on the Board's decision in the matter of sanofi pasteur Limited and the medicines Pentacel and Quadracel.
March 2:	The Regulatory Affairs and Outreach Branch made a presentation to patentees in Montreal.
March 3:	The Regulatory Affairs and Outreach Branch made a presentation to patentees in Toronto.
March 4:	The Board held its quarterly meeting.
March 8:	The Minister of Health announced the appointment of Mary Catherine Lindberg as Chairperson and Dr. Mitchell Levine as Vice-Chairperson of the PMPRB.
March 9–11:	The redetermination hearing into the matter of Teva Neuroscience G.P. –S.E.N.C. and the medicine Copaxone was completed. The Panel's decision is pending.
March 23–24:	Michelle Boudreau spoke at the 5th Annual Pharmaceutical Pricing, Reimbursement and Market Access Summit in London, UK.
March 24:	The Chairperson, Mary Catherine Lindberg, appeared before the Standing Committee on Health (HESA), along with the Minister and Health and Portfolio members, on Main Estimates.
March 29:	The final report of the DIP Methodology Technical Working Group on the Recommendations on the Implementation of the DIP Methodology was released.
April 11:	The Chairperson of the Board accepted a Voluntary Compliance Undertaking (VCU) submitted by Baxter Corporation regarding the price of the patented medicine Suprane.
April 11–12:	The hearing on the merits in the matter of Sandoz Canada Inc. was completed. The Panel's decision is pending.
April 13:	Michelle Boudreau spoke at the Pharma Continuous Legal Education (CLE) Session Life Sciences and Pharmaceutical Law hosted by Ogilvy Renault LLP. ■

PMPRB speeches and presentations are available on the website at Publications/Speech Series.

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

The PMPRB is an independent quasi-judicial body with a dual mandate.
Regulatory: to ensure that prices at which patentees sell their patented medicines in Canada are not excessive; and
Reporting: to report on pharmaceutical trends of all medicines and on R&D spending by patentees.

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News from the Chairperson

I am thrilled to have been named to the position of Chairperson of the Board. It is a privilege to continue my association with my fellow Board Members and with the Staff of the PMPRB. I strongly believe in the work of the PMPRB and its mandate to protect consumers, and I look forward to working closely with the industry and stakeholders for the benefit of all Canadians.

I am also delighted that Dr. Mitchell Levine has agreed to take on the job of Vice-Chair. Dr. Levine's extensive experience and expertise in pharmacology and medicine make him an extremely valuable addition to the Board.

As we move ahead, we will strive to uphold transparency and fairness in our regulatory responsibilities. We continue to evaluate the impact of the new Guidelines. Already we have been able to work with industry to find practical solutions to some issues identified early in the implementation phase.

We are particularly pleased with the recent results from the DIP Methodology Technical Working Group. This group, a collaboration of PMPRB Staff and industry representatives, was established in January 2011 to identify challenges in applying the DIP Methodology. Their final report has been posted on the PMPRB website, and we have established a pilot project that will be implemented until December 31, 2011, with an evaluation to follow.

Once again, I look forward to the challenges of this rewarding position and would like to take this opportunity to underline the Board's commitment to our stakeholders and to the Canadian public. ■

Mary Catherine Lindberg

Mary Catherine Lindberg, Chairperson

Senior Staff

Executive Director:
Michelle Boudreau

Director, Regulatory Affairs and Outreach:
Ginette Tognet

Acting Director, Policy and Economic Analysis:
Karen Reynolds

Director, Corporate Services:
Marian Eagen

Director, Board Secretariat and Communications:
Sylvie Dupont

General Counsel:
Martine Richard

New Board Members: Appointment of Chairperson and Vice-Chairperson

Dr. Mitchell Levine, Vice-Chairperson

The Minister of Health recently announced the appointments of Mary Catherine Lindberg as Chairperson of the Board and Dr. Mitchell Levine as Vice-Chairperson.

Ms. Lindberg had been assuming the powers and functions of the Chairperson since May 19, 2010, while the office was vacant. She was first appointed Member and Vice-Chair of the Board in June 2006. From 2002 to 2009, Ms. Lindberg was Executive Director of the Council of Academic Hospitals of Ontario. Previously she was Assistant Deputy Minister, Health Services, with the Ontario Ministry of Health and Long-Term Care.

Dr. Levine is a professor in the departments of Medicine and Clinical Epidemiology and Biostatistics in the Faculty of Health Sciences at McMaster University in Hamilton, Ontario. He is also director of the Centre for Evaluation of Medicines at St. Joseph's Healthcare in Hamilton. Dr. Levine has a medical degree from the University of Calgary. He studied internal medicine and clinical pharmacology at the University of Toronto and he has an MSc in clinical epidemiology from McMaster University. Dr. Levine was a member of the PMPRB's Human Drug Advisory Panel until his recent appointment to the Board.

For additional information, see the PMPRB website at About the PMPRB/Membership. ■

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Comings and Goings

We are pleased to welcome two new employees to the PMPRB. Karen Reynolds joined the PMPRB for four months as Acting Director, Policy and Economic Analysis Branch. Karen comes to the PMPRB from Health Canada's Pest Management Regulatory Agency where she was the Director of Submission and Information Management. Jek-Hui Sim joined the PMPRB as a lawyer with the Legal Services Branch on a 6 month secondment from Industry Canada.

We extend our best wishes to Karen Arial, who retired from Federal Public Service in February following many years of dedicated service. Karen had been at the PMPRB since early 2008. We also wish good luck to Matthew Bondy, who recently left the PMPRB to continue his career with the Privy Council Office. ■

Congratulations to Dr. Fred Aoki

On behalf of the Board Members and Staff of the PMPRB, we wish to congratulate Dr. Fred Aoki and his coauthors on winning the Lancet Paper of the Year 2010.

Each year, the Lancet invites readers to submit their nominations for the most significant paper of the previous year in any journal. Dr. Fred Aoki's paper *Effect of Influenza Vaccination of Children on Infection Rates in Hutterite Communities*, published in JAMA (Journal of the American Medical Association), was this year's winner.

Dr. Aoki is Professor of Medicine, Medical Microbiology, Pharmacology and Therapeutics at the University of Manitoba. He joined the Human Drug Advisory Panel of the PMPRB in 2010. ■

CPI-Adjustment Factors for 2012

The *Patent Act* specifies the factors to be used by the PMPRB in determining whether the price of a patented drug product sold in Canada is excessive. One of these factors is the Consumer Price Index (CPI). The Board's *Compendium of Policies, Guidelines and Procedures* requires the cumulative increase in a product's price over any three-year period be no more than the increase in the CPI over the same period. The Guidelines also set a cap on year-over-year price increases equal to one and one-half times the CPI-inflation rate for the year in question.

To allow patentees to set prices in advance, the Board's CPI-Adjustment Methodology provides for the calculation of the CPI-adjustment factors based on forecast changes in the CPI. The Board informs patentees of these CPI-adjustment factors each year through its *NEWSletter*.

The following table provides CPI-adjustment factors for 2012. These factors were based on forecasts of annual CPI-inflation rates of 2.4% and 2.1% for 2011 and 2012, respectively, as well as the actual 2010 CPI-inflation rate of 1.8%. CPI-inflation rates are provided by Finance Canada (see Government of Canada, *Budget 2011: A Low-Tax Plan For Jobs and Growth*, March 22, 2011, Table 2.1).

Forecast 2012 Price-Adjustment Factors for Patented Drug Products

Benchmark Year	(1) 2009	(2) 2010	(3) 2011
Price-Adjustment Factor	1.064	1.046	1.021

These figures imply: (1) a maximum allowable cumulative price increase between 2009 and 2012 of 6.4% for patented drug products with Canadian sales in 2009 (that is, products whose "benchmark year" is 2009); (2) a maximum allowable cumulative price increase between 2010 and 2012 of 4.6% for products whose first Canadian sales occurred in 2010; and (3) a maximum allowable cumulative price increase between 2011 and 2012 of 2.1% for products whose first Canadian sales occurred in 2011.

In addition, the forecast inflation rate of 2.1% for 2012 implies a year-over-year price increase cap (applicable to all drug products, regardless of benchmark year) of 3.2% (= 1.5 x 2.1%) for 2012. ■

New Patented Medicines Reported to the PMPRB

New drug products first sold in 2011 will be reviewed based on the Guidelines implemented on January 1, 2010. As of March 31, 2011, a total of 16 new drug products (DINs) were reported to the PMPRB (representing 11 medicines). Information on these patented drug products can be found on the PMPRB website at Regulatory/Patented Medicines/New Medicines Introduced in/2011.

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 drug product back to the date of first sale. ■

The Guidelines – Observations to Date (DIP Methodology)

In the revised Guidelines that came into effect on January 1, 2010, the Board adopted the DIP Methodology. It was intended as an alternative to the application of the CPI-Adjustment Methodology in certain circumstances in order to avoid creating disincentives to offering "benefits" to customers.

When the revised Guidelines were implemented, the PMPRB noted that it would monitor and evaluate their application on an ongoing basis and would assess the need for further changes. Since the review of prices of existing patented drug products is based on full-year data, there were no cases where the DIP Methodology was applied in 2010. However, the DIP Methodology was discussed with some patentees in the context of ongoing existing investigations. Based on these discussions, the PMPRB acquired some early insights into the application of the DIP Methodology. In a December 2010 communiqué to patentees, the PMPRB noted that the DIP Methodology would not be applied until its application and impact had been assessed by Board Staff and proposed adjustments had been brought to the Board for approval.

The PMPRB established the DIP Methodology Technical Working Group (DIP-WG) to identify the challenges in applying the DIP Methodology and to develop workable solutions. The DIP-WG met four times between January 20, 2011, and February 23, 2011. It comprised three representatives of the innovative pharmaceutical industry, two representatives of the biotechnology industry, one representative of the generic pharmaceutical industry and four members of Board Staff, including the group Chairperson. The DIP-WG produced a report that identified current challenges in implementing the DIP Methodology and outlined options to address them. The report was presented to the Board on March 4, 2011.

The Board agreed to the proposed recommendations outlined in the report. However, in order to ensure that the objectives of adopting the DIP Methodology are met, the Board decided to implement the recommendations of the DIP-WG on a pilot basis for the next two reporting periods: January to June 2011 and July to December 2011.

The DIP Methodology will consist of two processes: (1) the Simplified DIP Methodology, and (2) the Regular DIP Methodology. Effectively, the Simplified DIP Methodology is a streamlined approach requiring minimal evidence for situations in which the National Average Transaction Price is less than or equal to the Introductory Benchmark Price. Conversely, the Regular DIP Methodology is an expanded version of the Simplified DIP Methodology requiring additional evidence from patentees. It is to be applied in cases where the DIP is invoked and the Simplified DIP Methodology does not apply.

A webinar was hosted on Wednesday, April 20, 2011, to provide patentees with more information on the Simplified and Regular DIP Methodologies.

The PMPRB will continue to monitor and analyze the impacts of the changes to the DIP Methodology and will provide further guidance as necessary. A copy of the final report of the DIP Methodology Technical Working Group can be found on the PMPRB website under Consultations.

The Board's new Guidelines were released in June 2009 and implemented on January 1, 2010. As the PMPRB and patentees continue to gain experience with the revised Guidelines, more additions, amendments and/or clarifications may be made. These changes will be published in the quarterly *NEWSletter*, as required, and incorporated into the Guidelines. The *Compendium of Policies, Guidelines and Procedures* will be updated annually in June.

The Guidelines are available on the PMPRB website under Legislation, Regulations and Guidelines (http://www.pmprb-cepmb.gc.ca/cmfiles/Compendium-June09-E.pdf). ■

Consultation on the Board's Rules of Practice and Procedure for Hearings

The Board is amending its current Rules of Practice and Procedure for Hearings and is seeking comments from interested parties through its Notice and Comment process.

The Rules constitute a published standard set of procedures for all participants to follow in proceedings before the Board. The Rules set out the Board's procedures in accordance with the requirement under the *Patent Act* to resolve matters before it as informally and expeditiously as the circumstances and considerations of fairness permit. They provide a fair opportunity for interested parties to participate in the Board's hearings.

The current Rules have generally fulfilled their intended purpose. However, the Board is of the view that the Rules should be amended to better reflect current practices in recent proceedings and facilitate case management. The proposed amendments to the current set of Rules relate mainly to the areas of procedure and evidence, filing, preservation of electronic evidence, expert witnesses, service, confidentiality, as well as document and case management. The proposed Rules have been drafted to codify the Board's practices and procedures. They also take into consideration relevant current practices in other federal administrative tribunals and courts.

In December 2010, the Board held a first round of pre-consultation with selected lawyers based on their expertise in administrative law and their experience before administrative tribunals such as the PMPRB. The Board wishes to take this opportunity to thank Counsel for their thoughtful submissions.

The proposed Rules will be available for comments on the Board's website under Consultations/Notice and Comments on May 16, 2011. Interested parties are asked to file their submissions with the Director of the Board Secretariat, no later than June 30, 2011, by email at sylvie.dupont@pmprb-cepmb.gc.ca.

The Board is looking forward to receiving submissions on its proposed revised Rules. ■

March 4, 2011, Board Meeting

The Board held its first quarterly meeting of 2011 on March 4.

The Board received the report of the Technical Working Group on the DIP Methodology. The Working Group was established in January 2011 to identify challenges in applying the DIP Methodology under the Guidelines and to develop workable solutions to ensure that the Board's objective in adopting this methodology is met. The DIP Methodology is being implemented as a pilot project until December 31, 2011, at which time it will be evaluated.

The Board approved the draft of its revised Rules of Practice and Procedure for Hearings. The draft revised Rules are being put to consultation through the Board's Notice and Comment process. The Notice and Comment and draft revised Rules will be available on the PMPRB's website under Consultations/Notice and Comments. Board Members also approved the outline of a non-industry stakeholder engagement policy. The Board wishes to ensure ongoing and effective exchanges with all stakeholders.

The Board discussed the preliminary results of the 2010 Annual Report, Board direction and governance principles, and the upcoming 2012 program evaluation of the PMPRB.

The Board's next meeting is scheduled for May 12–13, 2011.

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 website at About PMPRB. ■

Voluntary Compliance Undertakings

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust its price to conform to the Board's Guidelines. 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.

In the first quarter, two VCUs were accepted for the patented medicines Abilify and Suprane.

Abilify, Bristol-Myers Squibb Canada Co.

On February 15, 2011, the Vice-Chairperson of the Board approved a VCU submitted by Bristol-Myers Squibb Canada Co. (BMS) regarding the price of Abilify. Under the terms of the VCU, BMS was to ensure that no customer paid a price exceeding $4.5000 per tablet of Abilify 15 mg in 2010. In the event that the full amount of cumulative excess revenues, $1,043,311.33, had not been offset through price reduction by December 31, 2010, BMS was to make a payment to the Government of Canada following the filing of the July to December 2010 price and sales data in accordance with the *Patented Medicines Regulations*, of such amount as calculated by Board Staff. BMS offset the full amount of cumulative excess revenues through price reduction.

Abilify is currently indicated for the treatment of schizophrenia and related psychotic disorders and for the acute treatment of manic or mixed episodes in Bipolar I Disorder.

Suprane, Baxter Corporation

On April 11, 2011, the Chairperson of the Board approved a VCU submitted by Baxter Corporation regarding the price of Suprane. Under the terms of the VCU, Baxter is to offset excess revenues in the amount $43,659.43 by making a payment to the Government of Canada on or before May 16, 2011.

Suprane is indicated as an inhalation agent for maintenance of general anesthesia. ■

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For any other questions or comments on our publications, call our toll-free number 1-877-861-2350 or send an email message to pmprb@pmprb-cepmb.gc.ca. ■

Hearings – Update

The PMPRB's regulatory mandate is to ensure that prices charged by patentees for their 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	Date of Notice of Hearing	Status
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 – Redetermination	Use in ambulatory patients with relapsing-remitting multiple sclerosis to reduce the frequency of relapses	Teva Neuroscience G.P.-S.E.N.C.	New panel struck February 2010	**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 issued Jan. 31, 2011 Payment of excess revenues: $9,409,074.36**
Pentacel and Quadracel	Pentacel is a co-marketing of two licensed vaccines: Act-HIB (the lyophilized Haemophilus b Conjugate Vaccine (Tetanus Protein-Conjugate) to be reconstituted with Quadracel. It 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. Quadracel is a Component Pertussis Vaccine and Diphtheria and Tetanus Toxoids Adsorbed combined with Inactivated Poliomyelitis Vaccine. It 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.	sanofi pasteur Limited	Board Decision: December 21, 2009 Board Order: March 16, 2010	**Federal Court of Canada hearing: Feb. 16 & 17, 2011 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	**Board decision pending**

Patentee	Issue	Date of Notice of Application	Status
Apotex Inc.	Failure to file (jurisdiction)	March 3, 2008	**Ongoing**
Celgene Corporation	Failure to file (jurisdiction)	Board decision: January 21, 2008	**Supreme Court of Canada: Decision issued Jan. 20, 2011, dismissing appeal**
ratiopharm Inc.	Failure to file (jurisdiction)	August 28, 2008	**Board decision pending**
Sandoz Canada Inc.	Failure to file (jurisdiction)	March 8, 2010	**Board decision pending**

Report on New Patented Drugs – Olmetec and Olmetec Plus

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drug products conducted by Board Staff for purposes of applying the Board's pre-2010 Guidelines for all new active substances introduced in Canada after January 1, 2002.

Olmetec

Brand Name: Olmetec

Generic Name: olmesartan medoxomil

DIN: 02318660 (20 mg per tablet)
02318679 (40 mg per tablet)

Patentee: Schering-Plough Canada Inc.

Indication – as per product monograph: Indicated for the treatment of mild to moderate essential hypertension.

Date of Issuance of First Patent Pertaining to the Medicine: January 19, 1999

Notice of Compliance: October 28, 2008

Date of First Sale: December 22, 2008

ATC Class: C09CA08
Cardiovascular System; Agents Acting on the Renin-Angiotensin System; Angiotensin II Antagonists, Plain; Angiotensin II antagonists, plain

Application of the Guidelines

Summary

The introductory prices of Olmetec were found to be within the pre-2010 Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison and the prices did not exceed the range of prices in other comparator countries where Olmetec is sold.

Scientific Review

Olmetec is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Olmetec be classified as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable existing drug products in the treatment of essential hypertension).

The Therapeutic Class Comparison (TCC) test of the pre-2010 Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drug products that are clinically equivalent in treating the same disease or condition. Comparators are generally selected from among existing drug products in the same 4th level of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system. See the PMPRB's then *Compendium of Guidelines, Policies and Procedures "up to 2009"* for a more complete description of the Guidelines and the policies on TCCs.

The HDAP recommended losartan (Cozaar), eprosartan (Teveten), valsartan (Diovan), irbesartan (Avapro), candesartan (Atacand) and telmisartan (Micardis) as the most appropriate comparators to olmesartan medoxomil (Olmetec). All these agents share the same 4th level ATC classification, share the same indication and are clinically equivalent in addressing the approved indication of Olmetec.

The pre-2010 Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The recommended comparable dosage regimens for Olmetec and its comparable drug products have been selected based on their respective product monographs as well as the available clinical trials and reviews relevant to Olmetec.

Price Review

Under the pre-2010 Guidelines, the introductory price of a category 3 new drug product will be presumed to be excessive if it exceeds the price of all the comparable drug products based on the Therapeutic Class Comparison (TCC) test or if it exceeds the range of prices of the same drug product sold in the seven countries listed in the *Patented Medicines Regulations* (Regulations). At introduction, the costs of treatment of Olmetec were within the Guidelines, as the daily cost of therapy did not exceed the cost of therapy of the comparator medicines.

Name	DIN	Strength	Dosage Regimen/Day	Cost per Day
Olmetec (olmesartan medoxomil)	02318660	20 mg/tablet	1 tablet	$0.9900[1]
Cozaar (losartan)	02182882	100 mg/tablet	1 tablet	$1.1628[1]
Teveten (eprosartan)	02240432	400 mg/tablet	1/2 tablet	$0.3502[1]
Diovan (valsartan)	02244781	80 mg/tablet	1 tablet	$1.1000[1]
Avapro (irbesartan)	02237924	150 mg/tablet	1 tablet	$1.1416[1]
Atacand (candesartan)	02239091	8 mg/tablet	1 tablet	$1.1400[1]
Micardis (telmisartan)	02240769	40 mg/tablet	1 tablet	$1.1296[1]
Olmetec (olmesartan medoxomil)	02318679	40 mg/tablet	1 tablet	$0.9900[1]
Teveten (eprosartan)	02240432	400 mg/tablet	1 tablet	$0.7004[1]
Diovan (valsartan)	02244782	160 mg/tablet	1 tablet	$1.1000[1]
Avapro (irbesartan)	02237925	300 mg/tablet	1 tablet	$1.1416[1]
Atacand (candesartan)	02239092	16 mg/tablet	1 tablet	$1.1400[1]
Micardis (telmisartan)	02240770	80 mg/tablet	1 tablet	$1.1296[1]

Source:
1 La Régie de l'assurance maladie du Québec, June 2009.

At the time of introduction, Olmetec 20 mg and 40 mg were sold in six of the seven countries (i.e., France, Germany, Italy, Switzerland, United Kingdom and United States) listed in the Regulations. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in these countries. The price of Olmetec 20 mg was second highest of the six countries in which it was sold, above the median international price. Olmetec 40 mg was third lowest of the six countries in which it was sold, below the median international price.

Olmetec Plus

Brand Name: Olmetec Plus

Generic Name: olmesartan medoxomil/hydrochlorothiazide

DIN: 02319616 (20 mg/12.5 mg per tablet)
02319624 (40 mg/12.5 mg per tablet)
02319632 (40 mg/25 mg per tablet)

Patentee: Schering-Plough Canada Inc.

Indication – as per product monograph: Indicated for the treatment of mild to moderate essential hypertension in patients for whom combination therapy is appropriate.

Date of Issuance of First Patent Pertaining to the Medicine: January 19, 1999

Notice of Compliance: November 21, 2008

Date of First Sale: December 22, 2008

ATC Class: C09DA08
Cardiovascular System; Agents Acting on the Renin-Angiotensin System; Angiotensin II Antagonist, Combinations; Angiotensin II antagonists and diuretics

Application of the Guidelines

Summary

The introductory prices of Olmetec Plus were found to be within the pre-2010 Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison and the prices did not exceed the range of prices in other comparator countries where Olmetec Plus is sold.

Scientific Review

Olmetec Plus is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Olmetec be classified as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable existing drug products in the treatment of essential hypertension).

The Therapeutic Class Comparison (TCC) test of the pre-2010 Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drug products that are clinically equivalent in treating the same disease or condition. Comparators are generally selected from among existing drug products in the same 4th level of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system. See the PMPRB's then *Compendium of Guidelines, Policies and Procedures "up to 2009"* for a more complete description of the Guidelines and the policies on TCCs.

The HDAP recommended losartan/hydrochlorothiazide (Hyzaar), valsartan/hydrochlorothiazide (Diovan-HCT), irbesartan/hydrochlorothiazide (Avalide), candesartan/hydrochlothiazide (Atacand Plus) and telmisartan/hydrochlorothiazide (Micardis Plus) as the most appropriate comparators to Olmetec Plus. The HDAP had also recommended eprosartan/hydrochlorothiazide (Teveten Plus) as a comparator. However, a dosage regimen could not be derived for this agent. All these agents share the same 4th level ATC classification, share the same indication and are clinically equivalent in addressing the approved indication of Olmetec Plus.

The pre-2010 Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The recommended comparable dosage regimens for Olmetec Plus and its comparable drug products have been selected based on their respective product monographs as well as the available clinical trials and reviews relevant to Olmetec Plus.

Price Review

Under the pre-2010 Guidelines, the introductory price of a category 3 new drug product will be presumed to be excessive if it exceeds the price of all the comparable drug products based on the Therapeutic Class Comparison (TCC) test or it exceeds the range of prices of the same drug product sold in the seven countries listed in the *Patented Medicines Regulations* (Regulations). At introduction, the costs of treatment of Olmetec Plus were within the Guidelines as the daily cost of therapy did not exceed the cost of therapy with the comparator medicines.

Name	DIN	Strength	Dosage Regimen/Day	Cost per Day
Olmetec Plus (olmesartan medoxomil/hydrochlorothiazide)	02319616	20/12.5 mg tablet	1 tablet	$0.9900[1]
Hyzaar (losartan potassium/hydrochlorothiazide)	02297841	100/12.5 mg tablet	1 tablet	$1.1490[2]
Diovan-HCT (valsartan/hydrochlorothiazide)	02241900	80/12.5 mg tablet	1 tablet	$1.1100[2]
Avalide (irbesartan/hydrochlorothiazide)	02241818	150/12.5 mg tablet	1 tablet	$1.1416[2]
Olmetec Plus (olmesartan medoxomil/hydrochlorothiazide)	02319624	40/12.5 mg tablet	1 tablet	$0.9900[1]
Diovan-HCT (valsartan/hydrochlorothiazide)	02241901	160/12.5 mg tablet	1 tablet	$1.1000[2]
Avalide (irbesartan/hydrochlorothiazide)	02241819	300/12.5 mg tablet	1 tablet	$1.1416[2]
Atacand Plus (candesartan cilexetil/hydrochlorothiazide)	02244021	16/12.5 mg tablet	1 tablet	$1.1400[2]
Micardis Plus (telmisartan/hydrochlorothiazide)	02244344	80/12.5 mg tablet	1 tablet	$1.1296[2]
Olmetec Plus (olmesartan medoxomil/hydrochlorothiazide)	02319632	40/25 mg tablet	1 tablet	$0.9900[1]
Diovan-HCT (valsartan/hydrochlorothiazide)	02246955	160/25 mg tablet	1 tablet	$1.1100[2]
Avalide (irbesartan/hydrochlorothiazide)	02280213	300/25 mg tablet	1 tablet	$1.1279[2]

Sources:

1 Publicly available price as per the *Patented Medicines Regulations*

2 La Régie de l'assurance maladie du Québec, June 2009.

At the time of introduction, Olmetec Plus 20 mg/12.5 mg tablet was sold in four of the seven countries (i.e., Germany, Switzerland, United Kingdom and United States) listed in the Regulations. Olmetec Plus 40 mg/12.5 mg and Olmetec Plus 40 mg/25 mg were sold in the United States only. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in these countries. The price of Olmetec 20 mg/12.5 mg was second highest of the four countries in which it was sold, above the median international price. Olmetec Plus 40 mg/12.5mg and 40 mg/25 mg were lower than the United States price.

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 Summary Reports under the pre-2010 Guidelines, the PMPRB refers to the publicly available prices of comparators, provided that such prices are not more than 10% above a non-excessive price, in which case no price will be made available. Publication of these prices is for information only and should not be construed as indicating that the public prices are considered to be within the pre-2010 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.

These reports, including the references, are available on the PMPRB website at PMPRB/Regulatory/Patented Medicines/Reports on New Patented Drugs for Human Use ■

Upcoming Events

May

May 9–12:
Canadian Association for Health Services and Policy Research (CAHSPR) 2011 Annual Conference, Halifax

May 12–13:
Quarterly Board Meeting

May 16:
HDAP Meeting

May 25–27:
Life Sciences Invitational Forum, Cambridge, Ont.

May 31:
2010 PMPRB Annual Report submitted to the Minister of Health

June

June 5–7:
27th Annual Council of Canadian Administrative Tribunals (CCAT) Conference, Ottawa

June 14–15:
5th Annual Conference on Drug Pricing and Reimbursement in Canada, Toronto

June 14–20:
National Public Service Week

June 30:
Submissions on the Board's proposed revised Rules of Practice and Procedure for Hearings

August

August 2:
Deadline for patentees' Form 2 filings

September

September 8:
HDAP Meeting

September 15–16:
Quarterly Board Meeting

September 21:
Canadian Association for Healthcare Reimbursement (CAHR) – Ottawa Federal Day

October

October 3–6:
Market Access World USA 2011 Conference, Washington, DC

November

November 7:
HDAP Meeting

December

December 8–9:
Quarterly Board Meeting

Upcoming Events are available on the PMPRB Web site at Consultations/Events ■