Patented Medicine Prices Review Board

Since 1987

PMPRB NEWSletter

Volume 15, Issue No. 1, January 2011

Inside...

Since our last issue...

Our recent key events

November 2:	The PMPRB NPDUIS Steering Committee meeting was held in Ottawa.
November 10:	The Supreme Court of Canada heard the appeal of the Celgene Corporation regarding the sale of Thalomid and handed down its decision on January 20, 2011.
November 16–17:	Michelle Boudreau spoke at the 9th Annual Market Access Summit in Toronto.
November 17:	The HDAP held its quarterly meeting.
December 2–3:	Michelle Boudreau spoke at the Canadian Pharmaceutical Pricing and Reimbursement Conference in Toronto.
December 8:	The Hearing Panel in the matter of Sandoz Canada Inc. heard the motions of the parties. Decisions are pending.
December 9–10:	The Board held its final quarterly meeting of 2010.
December 15:	Four new NPDUIS reports were released.

2011

January 11:	Michelle Boudreau and Matthew Bondy met with the President of the Canadian Generic Pharmaceutical Association (CGPA) and the Director of Federal Government Relations.
January 18:	Michelle Boudreau, Ginette Tognet and Matthew Bondy met with representatives of the Canadian Treatment Action Council, Best Medicines Coalition, Canadian Health Coalition and Carleton University's School of Public Policy and Administration.
January 20:	The Supreme Court of Canada dismissed the appeal by the Celgene Corporation regarding the sale of Thalomid.
January 20:	The Working Group on the DIP Methodology held its first meeting. ■

PMPRB speeches and presentations are available on the Web site 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 Web site.

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 Vice-Chairperson

Mary Catherine Lindberg, Vice-Chairperson

In the year that has followed implementation of the new Guidelines, Board Staff has closely followed the application of the changes and begun examining the short- and long-term impacts.

While the bulk of the evaluation work can really only begin following the final filing by patentees for 2010, the monitoring efforts so far have allowed us to remark that some changes are already a success. Members of the Human Drug Advisory Panel have been working with the new levels of therapeutic improvement since late fall 2009 and report that they appreciate the opportunity to distinguish moderate from slight or no level of improvement.

Our monitoring efforts have also allowed us to make a number of adjustments rapidly in the field, such as clarifying the International Therapeutic Class Comparison Test and the policy on the Offset of Excess Revenues. This is part of our long-standing commitment to maintaining a regulatory regime that is relevant, responsive and appropriate.

We are also taking advantage of these adjustments as opportunities for dialogue with patentees. A working group has been established with industry representatives to look at the application of the DIP Methodology. More discussions of various aspects of the Guidelines are likely in the future.

The Board remains committed to providing fairness and transparency in carrying out its regulatory responsibilities. ■

Mary Catherine Lindberg

Senior Staff

Executive Director:
Michelle Boudreau

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Ginette Tognet

Acting Director, Policy and Economic Analysis:
Matthew Bondy

Director, Corporate Services:
Marian Eagen

Director, Board Secretariat and Communications:
Sylvie Dupont

General Counsel:
Martine Richard

Watch for Changes to Our Web Site!

The PMPRB is updating its Web site. You may have already noticed that access to Board decisions has been given a higher profile in the left-hand menu. More changes are planned over the next few months that are intended to make the information you are looking for easier to find.

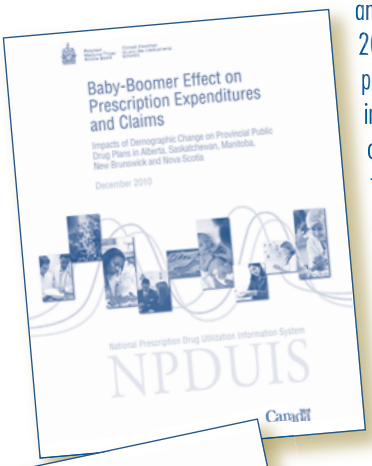
While the changes will make the site easier to navigate, some of the links you rely on to locate important documents may change. Check back regularly at www.pmprb-cepmb.gc.ca and do not hesitate to ask if you cannot find what you are looking for. ■

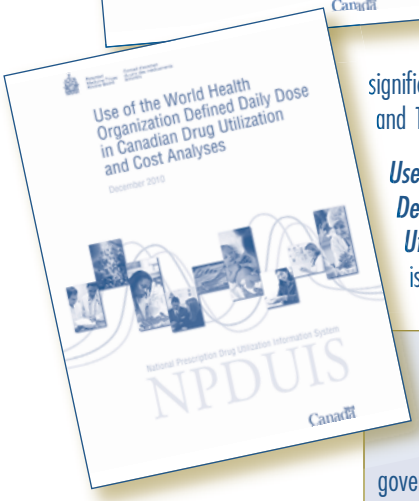
NPDUIS – Release of Analytical Reports

Four new analytical reports were published by the PMPRB on December 15, 2010. The topics covered in the reports relate to the cost implications of an aging population; the application of the World Health Organization's (WHO) Defined Daily Dose measure (ATC/DDD); and the price level and market structure of the Canadian generic drug industry.

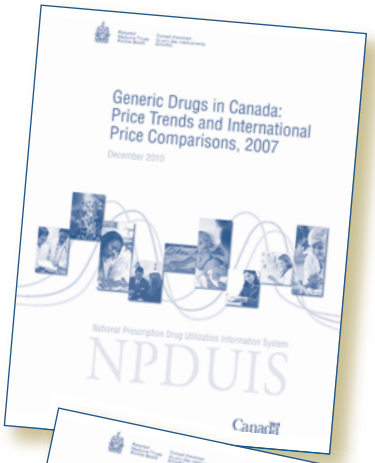
A brief description of each of the reports follows:

The Baby-Boomer Effect on Prescription Expenditures: Using the available NPDUIS data for five provinces (Alberta, Saskatchewan, Manitoba, New Brunswick and Nova Scotia) between 2002 and 2006 and Statistics Canada population projections, this report estimates the impact of Canada's aging population on public drug plan expenditures in these provinces. The findings of the report suggest that public drug plans have not yet felt the impact of an aging population. While annual increases in prescription drug expenditures due to an aging population are moderate, between 1.9% and 3.8% per year, by 2031 the predicted cumulative impact will be significant, with increases between 62% and 152%.

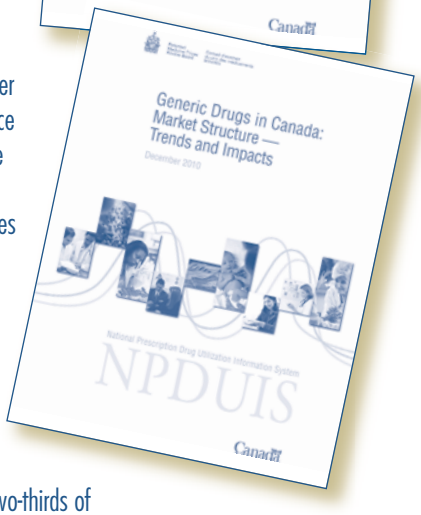




Use of the World Health Organization Defined Daily Dose in Canadian Drug Utilization and Cost Analyses: This report is a methodological review of issues related to the appropriate use of the Defined Daily Dose (DDD) measure when conducting drug utilization and costs analyses. The report identifies relevant considerations and provides recommendations for appropriate use of the DDD metric in the context of analyzing data from Canadian administrative databases.



Generic Drugs in Canada: Price Trends and International Price Comparisons and ***Generic Drugs in Canada: Market Structure — Trends and Impacts:*** These two reports are an update of earlier research looking at Canadian generic price levels relative to international levels. The updated analyses use IMS international data and compare Canadian generic prices for 2004–2007 for a basket of 298 leading generic drugs sold in Canada. The findings are consistent with those presented in previous analyses (for the period 2001–2005). The report on price trends and international price comparisons concludes that international prices were on average approximately two-thirds of corresponding Canadian prices. The market structure research shows that Canadian markets for generic drug products are highly concentrated with respect to sales, often dominated by two suppliers. The analysis examines whether the level of concentration is the source of the differences and concludes that other factors are more likely behind the price discrepancy.



NPDUIS reports can be downloaded from the PMPRB Web site at www.pmprb-cepmb.gc.ca

Through the NPDUIS initiative, the PMPRB provides critical analyses of price, utilization, and cost trends in Canada to support drug plan policy decision-making. NPDUIS is a partnership between the PMPRB and federal, provincial, territorial governments and the Canadian Institute for Health Information. ■

Comings and Goings

We extend our best wishes to Gail Kohlmeyer who recently retired from the Public Service. Gail worked at the PMPRB for the last 20 years of her professional career, most recently as a Senior Regulatory Officer with the Regulatory Affairs and Outreach Branch. We wish her much happiness in her retirement. ■

PMPRB's Contribution to the Workplace Charitable Campaign 2010

Thanks to our generous contributors, the PMPRB once again surpassed its goal for the Government of Canada Workplace Charitable Campaign by 50%. Staff enjoyed many fund-raising events including bake sales, book sales and raffles, as well as our annual PMPRB breakfast featuring the ever-popular "eggs McGillivray". Many thanks go to all of the volunteers for their hard work and creativity. A special thanks goes to Elaine McGillivray for her many years of dedication and leadership in the campaign (as well as for her superb culinary skills). ■

2010 CPI-Based Price-Adjustment Factors

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

Table 1 reproduces preliminary price-adjustment factors for 2010 published in the April 2009 *NEWSletter*. These factors were based on forecasted annual CPI-inflation rates of 0.7% and 1.9% for 2009 and 2010, respectively.

Table 1

Preliminary 2010 Price-Adjustment Factors for Patented Drug Products (Based on Forecast CPI-Inflation Rates for 2009 and 2010)

	Benchmark Year		
	(1) 2007	(2) 2008	(3) 2009
Price-Adjustment Factor	1.050	1.026	1.019

These figures imply: (1) a maximum allowable cumulative price increase between 2007 and 2010 of 5.0% for patented drug products with Canadian sales in 2007 (that is, products whose "benchmark year" is 2007); (2) a maximum allowable cumulative price increase between 2008 and 2010 of 2.6% for products whose first Canadian sales occurred in 2008; and (3) a maximum allowable cumulative price increase between 2009 and 2010 of 1.9% for products whose first Canadian sales occurred in 2009.

In addition, the forecast inflation rate of 1.9% for 2010 implies a year-over-year price increase cap of 2.9% (= 1.5 x 1.9%) for 2010.

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

The actual rate of CPI inflation for 2009 of 0.3% was published in the January 2010 *NEWSletter*. The actual rate of CPI inflation for 2010 is now available and was 1.8%. These rates (along with the actual 2008 CPI-inflation rate of 2.4%) yield the following final price-adjustment factors.

Table 2

Final 2010 Price-Adjustment Factors for Patented Drug Products (Based on Actual CPI-Inflation Rates for 2009 and 2010)

	Benchmark Year		
	(1) 2007	(2) 2008	(3) 2009
Price-Adjustment Factor	1.045	1.021	1.018

The final year-over-year price increase cap for 2010 is 2.7% (= 1.5 x 1.8%). ■

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, 2011. 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. Form 3 should be filed at: compliance@pmprb-cepmb.gc.ca

Failure to File

If a patentee fails to file complete information by March 1, 2011, 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 reported in the PMPRB's publications and posted on its Web site. ■

The Guidelines – Observations to Date

Since the new Guidelines came into effect on January 1, 2010, the PMPRB has been closely monitoring the effect of various changes. The result of that monitoring has already produced a number of clarifications on various aspects of the Guidelines:

- International Therapeutic Class Comparison (ITCC) Test (Schedule 7) — April 2010 *NEWSletter*
- Policy on the Use of Non-Patented Comparator Drug Products in Price Tests — October 2010 *NEWSletter*
- Offset of Excess Revenues (Schedule 13, Subsection 1.3.1) — October 2010 *NEWSletter*
- Existing Drug Products Subsequently Sold by Another Patentee — January 2011 *NEWSletter* (see next article)

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.

Some areas for discussion with patentees include:

- Application of the review of prices in any market and DIP Methodology for existing patented drug products — As a result of recent discussions with the Board, these measures in the Guidelines are not being implemented at this time. A DIP Methodology Working Group has been established in cooperation with industry representatives to assist Board Staff in developing recommendations for adjustments to the Guidelines. In the meantime, if the Average Transaction Price (ATP) of an existing patented drug product is found to exceed the Guidelines and the patentee believes it is as a result of the discontinuation of a benefit, the patentee should contact its Senior Regulatory Officer at the PMPRB.
- Making information about new "moderate improvement" drug products publicly available sooner — The PMPRB currently publishes the results of the price review for a drug product once it is patented and sold and the price is within the Guidelines. Potential changes to this practice will be discussed with the patentees.

The impact of other elements of the Guidelines, such as the thresholds for opening an investigation or the requirement for a Voluntary Compliance Undertaking (VCU) after three years of offset, will be assessed by Board Staff in the coming months.

The PMPRB is committed to ensuring transparency and accountability in the development and maintenance of an efficient and effective regulatory scheme. Stakeholder feedback continues to play an important role in this process.

The Board's new Guidelines were released in June 2009 and implemented on January 1, 2010. The Guidelines are available on the PMPRB Web site under Legislation, Regulations and Guidelines (http://www.pmprb-cepmb.gc.ca/cmfiles/Compendium-June09-E.pdf). ■

Existing Drug Products Subsequently Sold by Another Patentee

The application of the Guidelines to existing drug products subsequently sold by another patentee, in the case of a merger or an acquisition, has not changed. Specifically, where an existing drug product is sold in Canada by persons other than the initial patentee, the PMPRB's Guidelines will apply to the DINs sold by these persons as if they were the DINs of the initial patentee. For example, if as part of a merger and acquisition agreement, a patentee ceases to sell a patented drug product and the marketing rights to the product are transferred to another patentee, the DIN sold by the new patentee will be considered as a continuation of the original DIN for purposes of the application of the Guidelines and the CPI-Adjustment Methodology. ■

New Patented Medicines Reported to the PMPRB

New drug products first sold in 2010 will be reviewed based on the Guidelines implemented on January 1, 2010. As of December 31, 2010, a total of 68 new drug products (DINs) were reported to the PMPRB (representing 48 medicines). Information on these patented drug products can be found on the PMPRB Web site at Regulatory/Patented Medicines/New Medicines Introduced in/2010.

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. ■

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	**Next hearing session: March 9–11, 2011**
Penlac	Part of a comprehensive nail management program in patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement	sanofi-aventis Canada Inc.	March 26, 2007	**Board decision pending**
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 session: Feb. 16 & 17, 2011**
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 January 20, 2011**
ratiopharm Inc.	Failure to file (jurisdiction)	August 28, 2008	**Board decision pending**
Sandoz Canada Inc.	Failure to file (jurisdiction)	March 8, 2010	**Next hearing session: April 11–13, 2011**

Matter Before the Supreme Court of Canada

After a hearing in August 2007, the Board issued its decision in January 2008 asserting its jurisdiction over the price of Thalomid.

The Board's decision was subsequently quashed by the Federal Court and then upheld by the Federal Court of Appeal. Celgene Corporation was granted leave to appeal to the Supreme Court of Canada and the matter was heard on November 10, 2010.

The Supreme Court of Canada handed down its decision on January 20, 2011. The appeal was dismissed, confirming the Board's jurisdiction over the price of Thalomid. The decision recognizes that the purpose of the Board's legislative mandate is the protection of consumers. It also addresses standard of review, stating that in the Court's view, the standard should be that of reasonableness when the Board is interpreting its enabling legislation.

The decision is available on the PMPRB Web site under Hearings/Board Decisions/Thalomid. ■

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 last quarter, two VCUs were accepted for Miochol®-E and Tasigna®, respectively.

Miochol®-E, Novartis Pharmaceuticals Canada Inc.

On September 29, 2010, the Vice-Chairperson of the Board approved a VCU submitted by Novartis Pharmaceuticals Canada Inc. regarding the price of Miochol-E. Under the terms of the VCU, Novartis reduced the price of Miochol-E effective September 27, 2010, so that it did not exceed the 2010 national non-excessive average price (N-NEAP) of $16.4883 for the remainder of 2010. In addition, Novartis made payments to the Government of Canada in the amount of $328,870.70 to offset the cumulative excess revenues it received from July 1, 2000, to June 30, 2010; and made a second payment in the amount of $25,089.28 to offset the cumulative excess revenues it received from July 1, 2010, through September 26, 2010.

Miochol®-E (acetylcholine chloride) is indicated to obtain miosis of the iris in seconds after delivery of the lens in cataract surgery, in penetrating keratoplasty, iridectomy and other anterior segment surgery where rapid miosis may be required.

Tasigna®, Novartis Pharmaceuticals Canada Inc.

On October 12, 2010, the Vice-Chairperson approved a VCU submitted by Novartis Pharmaceuticals Canada Inc. regarding the price of Tasigna. Under the terms of the VCU, Novartis reduced the price of Tasigna so that it did not exceed the 2010 national non-excessive average price (N-NEAP) of $38.7147 for the remainder of 2010. In addition, Novartis offset the cumulative excess revenues it received from September 30, 2008, to December 31, 2009, by making a payment to the Receiver General of Canada in the amount of $196,069.26. Novartis will also offset any excess revenues it received from January 1, 2010, to the date of the implementation of the price reduction (no later than December 6, 2010) by making a further payment to the Receiver General of Canada on or before March 2, 2011, in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Tasigna at a price higher than the 2010 N-NEAP.

Tasigna® 200 mg, at the date of first sale, was indicated for the treatment of accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (CML) in adult patients resistant to or intolerant of at least one prior therapy including imatinib. ■

Subscription Information

E-bulletin alert: sign up for an email alert and you will be automatically notified as soon as the *NEWSletter* is published, with a link to the full electronic content. To subscribe, click on the link at the bottom of the PMPRB home page at www.pmprb-cepmb.gc.ca.

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. ■

Report on New Patented Drugs – Tysabri

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.

Brand Name: Tysabri

Generic Name: natalizumab

DIN: 02286386 (20 mg/mL)

Patentee: Biogen Idec Canada Inc.

Indication – as per product monograph: Indicated as monotherapy (i.e., single disease-modifying agent) for the treatment of patients with the relapsing–remitting form of multiple sclerosis (MS) to reduce the frequency of clinical exacerbations, to decrease the number and volume of active brain lesions identified on magnetic resonance imaging (MRI) scans and to delay the progression of physical disability. Tysabri is generally recommended in MS patients who have had an inadequate response to, or are unable to tolerate, other therapies for multiple sclerosis.

Date of Issuance of First Patent Pertaining to the Medicine: June 29, 2004

Notice of Compliance: September 28, 2006

Date of First Sale: November 21, 2006

ATC Class: L04AA23
Antineoplastic and Immunomodulating Agents; Immunosuppressants; Immunosuppressants; Selective immunosuppressants

Application of the Guidelines

Summary

The introductory price of the Tysabri was found to be within the pre-2010 Guidelines because the price 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 Tysabri was sold.

Scientific Review

Tysabri is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Tysabri be classified as a category 3 new medicine (provides moderate, little or no therapeutic over comparable drug products). The HDAP did not recommend any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

Price Review

The TCC 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. However, when it is inappropriate or impossible to conduct a TCC test, Board Staff will give primary weight to the median of the international prices identified in an International Price Comparison (IPC) test. See the Board's *Compendium of Guidelines, Policies and Procedures "up to 2009"* for a more complete description of the Guidelines and the policies on TCCs.

As no comparators were identified for purposes of conducting a TCC test, an IPC test was conducted. The introductory price of Tysabri was considered within the pre-2010 Guidelines as it did not exceed the median of the international prices identified in the IPC test. Tysabri was sold in six countries listed in the Regulations, namely, Germany, Italy, Sweden, Switzerland, United Kingdom and the United States.

Introductory Period (November to December 2006)

Country and Median	Price (in Canadian dollars)
Canada	(1)
France	Not sold
Germany	$185.7471 per mL(2)
Italy	$184.2120 per mL(2)
Sweden	$172.3649 per mL(2)
Switzerland	$178.2805 per mL(2)
United Kingdom	$168.8668 per mL(2)
United States	$179.1648 per mL(2)
Median	$178.7227 per mL

Sources:

1 No public price available until 2008. La Régie de l'assurance maladie du Québec, 2008, listed a price of $159.1876/mL.

2 Publicly available price as per the *Patented Medicines 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 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.

This report, including the references, is available on the PMPRB Web site at PMPRB/Regulatory/Patented Medicines/Reports on New Patented Drugs for Human Use/Tysabri ■

December 9–10, 2010, Board Meeting

The Board held its final quarterly meeting of 2010 on December 9 and 10.

Board Members reviewed four reports prepared under the National Prescription Drug Utilization Information System (NPDUIS) Initiative, which were published on December 15. The Board discussed the current environment of the organization and its future direction. Preliminary results of the application of the new Guidelines were discussed, and the Board decided that measures relevant to the application of the review of prices in any market and the DIP Methodology for existing patented drug products would not be implemented at this time. As a result, a DIP Methodology Working Group has been established in cooperation with industry representatives to assist Board Staff in developing recommendations for adjustments to the Guidelines. Also, the Board re-confirmed that the application of the Guidelines to existing drug products subsequently sold by another patentee, in the case of a merger or an acquisition, has not changed.

Board Members were also briefed on the upcoming 2012 program evaluation of the PMPRB.

The Board's next meeting is scheduled for March 4, 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 Web site at About PMPRB. ■

Foreign Price Verification

The PMPRB established a foreign price verification methodology to verify foreign price information as reported by patentees in each of the seven countries listed in the *Patented Medicines Regulations*.

Under the *Patent Act* and the Regulations, patentees are required to file information showing ex-factory prices for patented medicines sold in the seven comparator countries (France, Germany, Italy, Sweden, Switzerland, UK and the U.S.). "Ex-factory" prices are the prices charged by patentees to their customers, usually wholesalers, pharmacies and hospitals. Ex-factory prices are different from the prices paid by consumers because the retail price may include wholesale and retail mark-ups as well as dispensing fees. Information on retail prices in the comparator countries is publicly available.

In the six European comparator countries, retail and wholesale markups are fixed and it is possible to "back out" ex-factory prices. As a result the PMPRB is able to estimate the public ex-factory price by removing the legislated retail and wholesale markups from the retail prices set by national drug plans in the comparator countries. This approach allows the PMPRB to obtain independent estimates of foreign ex-factory prices and verify the accuracy of the publicly available ex-factory prices submitted by patentees.

Retail and wholesale markups are updated on a yearly basis. Starting in June 2011, the PMPRB will publish this information on its Web site. As well, the PMPRB will release an updated study on foreign price verification next June. ■

Upcoming Events

February

February 7:
HDAP meeting

February 9–11:
Canadian Healthcare Licensing Association Winter Meeting, Mont Tremblant

February 22–23:
UBC Centre for Health Services & Policy Research (CHSPR) Policy Conference, Vancouver — *BOOMERANGST: Myths and Realities about Health Care for an Aging Population*

March

March 2:
PMPRB Outreach Sessions with patentees, Montreal

March 3:
PMPRB Outreach Sessions with patentees, Toronto

March 4:
Quarterly Board Meeting

March 9–11:
Redetermination hearing in the matter of Teva Neuroscience G.P. – S.E.N.C. and the medicine Copaxone

March 23–24:
5th Annual Pharmaceutical Pricing, Reimbursement and Market Access Summit, London, UK

April

April 3–5:
CADTH Symposium, Vancouver

April 11–13:
Hearing in the matter of Sandoz Canada Inc.

May

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

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

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