Patented Medicine Prices Review Board

PMPRB NEWSletter

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October 2007

Inside...

Board Members

The PMPRB is an independent quasi-judicial body with a dual mandate.

Regulatory - To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive, thereby protecting consumers and contributing to Canadian health care.

Reporting - To report on pharmaceutical trends and on R&D spending by pharmaceutical patentees, thereby contributing to informed decisions and policy making.

Government of Canada Workplace Charitable Campaign 2007

"Building Bridges a Million Different Ways"

The federal government's charitable campaign 2007 runs from September 13 to November 21, 2007. This year's theme is: ***Be a Star in Someone's Life***.

Elaine McGillivray, team leader, and Staff members have embarked with their usual enthusiasm. Activities have already been set forth to guarantee a successful campaign again this year. ■

Since our last issue...

Here are some of the key events that occurred since the end of July 2007.

August 13:	The Board heard closing arguments in the matter of Teva Neuroscience G.P.-S.E.N.C. and the medicine Copaxone.
August 21:	Marie-Sophie Jobin gave a presentation: *Going a Lung Way*, at the 23rd International Conference on Pharmacoepidemiology & Therapeutic Risk Management – *Clinical Impact of an integrated Care Program in Asthma, The Respire Study*, in Québec City.
August 22:	The Board held meetings with representatives of Rx&D's Board of Directors and with representatives of the Canadian Generic Pharmaceutical Association.
August: 23:	The Board heard parties (video-conference) on its jurisdiction in the matter of Celgene Corporation and the medicine Thalomid.
August 29:	The Board heard closing arguments in the matter of Janssen-Ortho Inc. and the medicine Concerta.
September 10:	The HDAP held its quarterly teleconference.
September 10-12:	The Board held a series of bilateral meetings with stakeholders on the review of its Excessive Price Guidelines.
September 14:	Barbara Ouellet, Ginette Tognet and Sylvie Dupont briefed officials of the Taiwanese Bureau of National Health Insurance on the role of the PMPRB.
September 19:	The Board held its third quarterly meeting. A summary of the Minutes are available on page 6.
September 26:	Dr. Benoit, Ginette Tognet, Ron Corvari and Sylvie Dupont met with New Zealand officials, including the Honourable Peter Dunne, Minister of Revenue and Associate Minister of Health, to discuss the role and responsibilities of the PMPRB.
October 3-4:	Barbara Ouellet and Ginette Tognet made presentations on the price review process and on the review of the Board's Excessive Price Guidelines at the Brogan Advanced PMPRB Training Seminars held in Montréal and in Toronto.

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

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Senior Staff

Executive Director:
Barbara Ouellet

Secretary of the Board:
Sylvie Dupont

Director of Policy and Economic Analysis:
Ron Corvari

Director of Compliance and Enforcement:
Ginette Tognet

Director of Corporate Services:
Ravinder Dhillon

Senior Counsel:
Martine Richard

October 14-17:	Martine Richard gave a presentation on the PMPRB at the *2e Congrès international sur la Chaîne des médicaments : Regards interdisciplinaires sur la diversité et la complexité*, in Montréal.
October 17-18:	Barbara Ouellet gave a presentation, *Catching Up on the Latest Developments at the PMPRB*, at the 6th Annual Forum on Pharma Patents, in Toronto.
October 18:	The Board issued a Communiqué to all patentees further to its April 2007 NEWSletter article on the Federal Court decision in *LEO Pharma* and the calculation of the Average Transaction Price.
October 30:	Barbara Ouellet gave a presentation on the role and responsibilities of the PMPRB at the 2007 Canadian Drug Information Association Conference – *Blueprint for an Evolving Regulatory Environment*, in Ottawa.
October 31:	The Board held a pre-hearing conference (video conference) in the matter of sanofi pasteur Limited and the medicines Quadracel and Pentacel. The hearing on the merits will be held November 28-30, 2007.
October 31:	The Working Group on Therapeutic Improvement, as established by the Board in the context of the revision of its Excessive Price Guidelines, held its first meeting. ■

Comings and Goings

- Elena Lungu joined the Policy and Economic Analysis Branch as a Senior Economist with the NPDUIS team.
- Delia Melissa Lewis, formerly from the Patent Policy Branch at Industry Canada, has joined the PMPRB on a secondment with Legal Services as Legal Counsel.
- Renée Bergeron, formerly from Health Canada, has joined the Secretariat as Communications Officer. ■

Congratulations

- Congratulations to Tim Armstrong on his re-appointment to the Board for a five-year mandate. ■

News from the Chairperson

Review of the Board's Excessive Price Guidelines – Next Steps

To view stakeholders' submissions, please consult our Web site under: Consultations; Board's Excessive Price Guidelines.

The review of the Board's *Excessive Price Guidelines* (Guidelines) was undertaken to ensure that the Guidelines remain effective both in facilitating Board Staff's review of patented drug prices and in promoting voluntary compliance on the part of the patentee, in order to ensure that prices of patented medicines sold in Canada are not excessive.

On September 10-12, 2007, the Board held a series of bilateral consultation meetings with stakeholder groups, representing sectors of the pharmaceutical industry (innovative, biotechnology and generic), federal/provincial/territorial (F/P/T) governments and consumers. The purpose of these meetings was to provide participating stakeholders with an opportunity to raise their comments directly with Board Members in relation to issues discussed in the *Stakeholder Communiqué* of May 31, 2007, along with any other concerns they may, or may not, have raised in previous consultations.

We would like to thank those who took the time to participate in the bilateral meetings. The time and effort contributed by the participants was greatly appreciated, and has provided the Board with a better understanding of the issues that truly matter to our stakeholders.

In keeping with our commitment to openness and transparency, participants of the bilateral meetings were requested to make a written submission to the Board outlining the key concerns and messages raised during the discussions. To date, we received 12 submissions, which are posted on our Web site.

There is still much work to be done before the issues under review can be addressed. The Board expects to begin to issue requests for Notice and Comments in the spring of 2008 on strategies and guideline change proposals in regard to categorization of medicines, international therapeutic

class comparison (ITCC), price review in "any market", potential modifications to the Consumer Price Index (CPI) methodology, scenarios when a price may be "re-benched," and how "principles" might be applied in the Guidelines. Through the summer, further requests for Notice and Comments will focus on: price tests and definitins of "making and marketing".

Last May, we announced the creation of three working groups on: ITCC, definitions of making and marketing, and therapeutic improvement. The working groups will include representatives from F/P/T governments, consumers and the pharmaceutical industry, as well as appropriate key experts.

We recognize that there may be a certain degree of uncertainty for patentees and other stakeholders regarding the future price review process. To alleviate this uncertainty, we are committed to ongoing open communication through the NEWSletter, the Web site and other means as appropriate. We encourage all stakeholders to avail themselves of the various additional opportunities to provide comment and input on any proposed changes to the Guidelines; your views are extremely important to the Board as we take decisions on how to modernize the Guidelines so that they are relevant and appropriate in light of the current and evolving pharmaceutical environment. ■

Brien G. Benoit, MD

Brien G. Benoit, MD
Chairperson of the PMPRB

Amendments to the *Patented Medicines Regulations, 1994* – Update

The Board is pleased to report that its proposed regulatory amendments to the *Patented Medicines Regulations, 1994* (Regulations) were pre-published in the *Canada Gazette*, Part 1, on October 6, 2007.

This follows a lengthy consultation process which began in January 2005 with the publication of a Notice and Comment proposal to amend the Regulations, followed by the pre-publication of the proposed regulatory amendments in the *Canada Gazette*, Part I, on December 31, 2005 and which culminated in several meetings with stakeholders in the spring of this year.

Ten submissions were received which the Board is currently considering. These submissions are posted on our Web site for the information of all interested parties.

The Board intends to forward a regulatory package to the Minister of Health for submission to Treasury Board Cabinet Committee recommending publication of the proposed amendments in the *Canada Gazette*, Part II, prior to year end.

The Board is also aware that education and assistance for patentees on how to fully comply with the regulatory amendments will be important. To this end, Board Staff will be communicating with all patentees and will be offering various information sessions. ■

For further information on the proposed amendments to the *Patented Medicines Regulations, 1994*, please consult our Web site under Legislation, Regulations and Guidelines; *Patented Medicines Regulations, 1994*; Proposed Amendments.

Implications of the Federal Court decision in *LEO Pharma* and the calculation of the Average Transaction Price of patented medicines

The Board is continuing its work with stakeholders on resolving the issues arising from of the *LEO Pharma* decision of the Federal Court of Canada, including assessing possible options for further amendments to the *Patented Medicines Regulations*, and the Board's Excessive Price Guidelines.

Given the work will take some time to complete, the Board will not require any change in the manner in which average transaction prices for the periods of July 2007 to December 2008 are calculated. Accordingly, for the three periods (July-December 2007; January-June 2008; July-December 2008), patentees may elect to include or exclude all benefits and reductions in the calculations of average transaction prices, as long as consistency with previous reporting periods is maintained.

The Board will be communicating further with patentees in the near future as to the next steps it intends to take in this regard. The Board's priorities include the maintenance of compassionate access to needed medicines by consumers, as long as the program parameters remain consistent with the law. ■

Board's Quasi-Judicial Activities

Since 2002, there has been an increase, relative to prior years, in the number of Notices of Hearing issued by the Chairperson. Thirteen Notices of Hearing have been issued in the past five years. It is notable that six of the 13 matters were resolved without a hearing but by way of Voluntary Compliance Undertakings (VCUs).

In the last decade, the pharmaceutical environment has evolved while the regulatory mandate of the PMPRB remains to ensure that prices of patented medicines sold in Canada are not excessive. There has, however, been no change in the Board's enabling legislation or its Excessive Price Guidelines or in the Board's approach to the enforcement of its Guidelines.

Board Staff administer the price review and investigation processes as laid out in the Board's Guidelines on Excessive Prices. In the cases where there is a disagreement, in principle, between Board Staff and a patentee, there is often extensive dialogue and opportunity for information exchange in an effort to resolve the issue. The patentee may provide the evidence that sustains its position, and a price is determined to be within the Guidelines. In other cases, the patentee and Board Staff agree on a VCU. In cases where the efforts of both parties to resolve the issue are unsuccessful, the matter is referred to the Chairperson, who determines whether it is in the public interest to hold a hearing into the matter.

Finally, other issues, pertaining to the Board's jurisdiction, may arise where a hearing is required.

It is both the statutory responsibility of the Board and the right of patentees to have a fair hearing before the Board in order to determine whether the price of a patented medicine sold in Canada is, or was, excessive.

Status of Proceedings before the Board

Year Notice of Hearing	Drug	Patentee	Resolution
2002	Remicade	Schering Canada Inc.	VCU (2004)
2004	Fasturtec	Sanofi-Synthelabo Canada Inc.	VCU (2005)
	Evra	Janssen-Ortho Inc.	VCU (2004)
	Dovobet	LEO Pharma Inc.	Board Order (2007)
2006	Adderall XR	Shire BioChem Inc.	Decision pending
	Concerta	Janssen-Ortho Inc.	Decision pending
	Copaxone	Teva Neuroscience G.P.-S.E.N.C.	Decision pending
	Airomir	3M Canada Company	VCU (2007)
	Risperdal Consta	Janssen-Ortho Inc.	VCU (2007)
	Strattera	Eli Lilly Canada Inc.	Ongoing
2007	Penlac	sanofi-aventis Canada Inc.	Ongoing
	Quadracel & Pentacel	sanofi pasteur Limited	Ongoing
	Zemplar	Abbott Laboratories Limited	VCU (2007)

For more information on the Board's Hearings and a complete list of all VCUs, please consult our Web site or contact the Secretary of the Board at (613) 954-8299 or at sdupont@pmprb-cepmb.gc.ca. ■

Hearings – Update

The PMPRB's regulatory mandate is to ensure that patentees' prices of patented medicines are not excessive, thereby protecting consumer interests and contributing to Canadian health care. In the event that the price of a patented medicine appears to be excessive, the Board can hold a public hearing and, if it finds that the price is excessive, it may issue an Order to reduce the price and to offset revenues received as a result of excessive prices.

Completed Hearings

Dovobet, LEO Pharma Inc.

On September 7, 2007, the PMPRB ("Board") issued an Order in the matter of LEO Pharma Inc. and the medicine Dovobet on the maximum non-excessive (MNE) prices for the introductory period and subsequent periods and on the amount of excess revenues payable to the Crown.

The Board Order required LEO Pharma to offset the excess revenues derived from the sale of Dovobet in Canada from 2002 through to December 2005, by making a payment to the Government of Canada in the amount of $3,736,398.71. LEO complied with the Order.

LEO Pharma shall ensure that the average transaction price of Dovobet remains below the maximum non-excessive price, as calculated pursuant to the Order, for all future periods in which Dovobet remains under the Board's jurisdiction.

The Board had issued a Notice of Hearing in November 2004 pertaining to the allegations of Board Staff that Dovobet had been, and was being, sold by LEO Pharma at prices exceeding the Excessive Price Guidelines.

Zemplar, Abbott Laboratories Limited

On September 19, 2007, the Board approved a VCU agreed to by Abbott Laboratories Limited and Board Staff regarding the price of the medicine Zemplar and issued a Board Order concluding the proceedings initiated by the Board on July 24, 2007.

Abbott Laboratories has agreed to ensure that the average transaction price of Zemplar IV does not exceed the alleged 2007 MNE price, to offset alleged excess revenues in the amount of $58,741.67 and to ensure that the price of Zemplar IV is within the Guidelines in all future reporting periods in which Zemplar IV remains under the PMPRB's jurisdiction.

The Board had issued a Notice of Hearing on July 24, 2007, pertaining to the allegations of Board Staff that Zemplar IV had been, and was being, sold by Abbott Laboratories at prices exceeding those indicated by the Board's Excessive Price Guidelines.

The Board's Order is a public document and is available on the PMPRB Web site under Regulatory; Hearings; **Zemplar**, and under Voluntary Compliance Undertakings, or by contacting the Secretary of the Board.

Ongoing Hearings

On October 31, the Board held a pre-hearing conference (video conference) in the matter of **sanofi pasteur Limited** and the medicines **Quadracel** and **Pentacel**. The hearing on the merits will be held November 28-30, 2007.

Also, the hearing into the matter of **sanofi-aventis Canada Inc.** and the medicine **Penlac** is scheduled to commence on January 16, 2008. The matter of **Eli Lilly Canada Inc.** and the medicine **Strattera** remains to be scheduled.

Decisions Pending

Over the last quarter, the Board heard closing arguments in the matters of Adderall XR, Shire BioChem Inc.; Concerta, Janssen-Ortho Inc.; and Copaxone, Teva Neuroscience G.P.-S.E.N.C.

Upon issuance of the Board's decisions in these respective matters, they will be posted on the Board's Web site and the Board Orders will be filed with the Federal Court of Canada. ■

Dovobet is a dermatological drug administered for bringing psoriasis under control.

Zemplar is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure.

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

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

Adderall XR and **Concerta** are medicines indicated for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD").

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

Further information on hearings is available on our Web site under Regulatory; Hearings.

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

Sylvie Dupont
Secretary of the Patented Medicine Prices Review Board
Toll-free number: 1 877 861-2350
Direct line: (613) 954-8299
Fax: (613) 952-7626
E-mail: sdupont@pmprb-cepmb.gc.ca

Voluntary Compliance Undertakings

OctreoScan, Bristol-Myers Squibb Canada Inc.

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

Under the Compliance and Enforcement Policy, patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price set forth by the patentee for a patented medicine sold in Canada appears to have exceeded the Board's Excessive Price Guidelines (Guidelines).

VCUs are public documents and are available on the PMPRB Web site under Regulatory; Voluntary Compliance Undertakings; or by contacting the Secretary of the Board: Sylvie Dupont, at (613) 954-8299 or at: sdupont@pmprb-cepmb.gc.ca.

On September 19, 2007, the Chairperson of the Board accepted the Voluntary Compliance Undertaking (VCU) for OctreoScan submitted by Bristol-Myers Squibb Medical Imaging, a Division of Bristol-Myers Squibb Canada Inc. (Bristol-Myers Squibb).

In addition to reducing the price of OctreoScan to a non-excessive level, Bristol-Myers Squibb will offset the excessive revenues accrued, in the amount of $387,181.87, by mayking payments to hospitals that purchased OctreoScan and by making a payment to the crown for the remaining excess revenues in the amount of $7,439.82.

Bristol-Myers Squibb is to ensure that the price of OctreoScan remains within the Excessive Price Guidelines in all future reporting periods in which the medicine remains under the PMPRB's jurisdiction. For more details concerning the VCU for OctreoScan, please consult our Web site under Regulatory; Voluntary Compliance Undertakings; OctreoScan. ■

NPDUIS – Update

For more information on NPDUIS, please consult our Web site under Reporting; National Prescription Drug Utilization Information System.

Two new NPDUIS reports are underway.

- The *Pharmaceutical Trends Overview Report* will provide an overview of prescription drug expenditures and cost drivers. Aggregated DIN-level data, up to 2005-06, has been provided by nine provincial drug plans (British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island and Newfoundland & Labrador) and the Pharmacy Program of the Non-Insured Health Benefits, Health Canada.
- The second edition of the *New Drug Pipeline Monitor* (NDPM) will track the clinical development of the drugs identified in the first edition, and will provide information on additional pipeline drugs that are in the latter phases of research and could have a significant impact in terms of therapeutic value.

The PMPRB is also undertaking a costing analysis of Catastrophic Drug Coverage (CDC) for, and at the direction of, the National Pharmaceuticals Strategy Task Group.

Development and implementation of the claims-level NPDUIS database at the Canadian Institute for Health Information (CIHI) is well underway. The PMPRB is looking forward to undertaking more complex analyses relative to key policy questions and program trends. The PMPRB will be consulting with the F/P/T Steering Committee and the participating public drug plans to identify analytical priorities for 2008-09. ■

Patented Medicine Prices Review Board – September 2007 Meeting

For additional information, please contact the Secretary of the Board at: 1-877-861-2350, or (613) 954-8299, or at sdupont@pmprb-cepmb.gc.ca.

Summary of Board Meetings are available on our Web site under About the PMPRB.

At its meeting, the Board:

- Approved:
  - The work plan for the review of the Board's Excessive Price Guidelines

The next Board meeting is scheduled for December 12-13, 2007. ■

Questions and Comments

Please forward all subscriptions to the PMPRB mailing list and requests for publications to Elaine McGillivray at Elaine@pmprb-cepmb.gc.ca. For more information on our Web site, please contact our Communications Officer, Lyne Bélisle, at lbelisle@pmprb-cepmb.gc.ca.

PMPRB E-bulletin

Readers who wish to receive the PMPRB's Electronic News bulletins are required to register by forwarding their E-mail address to pmprb@pmprb-cepmb.gc.ca.

Your cooperation in submitting changes to your E-mail and/or mailing addresses is also appreciated. ■

Monitoring and Reporting of Non-Patented Prescription Drug Prices

The PMPRB is pleased to announce the forthcoming release of its fourth report on Non-Patented Prescription Drug Prices (NPPDP). *Non-Patented Single-Source Drugs in Canada* is available on the PMPRB Web site under Reporting; Non-Patented Prescription Drug Prices.

The report covers those drugs which are sold in Canada by only one manufacturer, and looks at manufacturers' sales and prices with particular emphasis on comparing Canadian and foreign prices.

The key finding is clear evidence that Canadian prices for non-patented single-source (NPSS) drugs are generally higher than most prices in other countries, with the exception of the United States. International comparisons of average prices are not always definitive, although the results can be interesting. Prices in Canada typically fall into the range of prices for the 11 comparator countries used in the study. Some broad measures suggest that Canadian prices are below the median and average international prices, but more direct comparisons show Canadian prices to be higher than most. Efforts to resolve these differences include alternative comparisons, one of which excludes the U.S. and which provides strong support for the conclusion that Canadian prices for NPSS drugs are generally higher than those of most other countries.

Six of the seven countries used for PMPRB price comparisons are also used in this report: France, Germany, Italy, Switzerland, the U.S., and the U.K. – with Sweden excluded for lack of data. In addition, Australia, Finland, the Netherlands, New Zealand, and Spain are included, having been added to the NPPDP project by the F/P/T governments.

Previous reports in the series are also available from the PMPRB Web site: Canadian and Foreign Price Trends Report (June 2006), Trends in Canadian Sales and Market Structure (October 2006), and Market for New Off-Patent Drugs (June 2007).

With the completion of the first series of four reports, experience gained will be taken into account before embarking upon further work on generic drug products. ■

In October 2005, the federal, provincial and territorial (F/P/T) Ministers of Health announced the endorsement of the PMPRB to monitor and report on the prices of non-patented prescription drugs. In November 2005, the PMPRB received direction from the federal Minister of Health, on behalf of himself and his P/T colleagues, to undertake this monitoring and reporting.

List of New Drugs Introduced since the publication of the July 2007 NEWSletter

Since the publication of the July 2007 NEWSlettter, 17 new DINs for human use (representing 13 medicines) were added to the list of New Patented Medicines reported to the PMPRB for the period ending September 30, 2007. Five of these new medicines are new active substances, representing six DINs.

The following table presents the new active substances reported to the PMPRB during the period July to September 2007.

As of September 30th, 2007

Brand Name	Generic Name	Company
Orencia (250 mg/vial)	*abatacept*	Bristol-Myers Squibb Canada Inc.
Thelin (100 mg/tablet)	*sitaxsentan sodium*	Encysive Pharmaceuticals Inc.
Champix (0.5 mg/tablet, 1 mg/tablet)	*varenicline tartrate*	Pfizer Canada Inc.
Spriafil (40 mg/ml)	*posaconazole*	Schering-Plough Canada Inc.
Replagal (3.5 mg/vial)	*agalsidase alfa*	Shire Human Genetic Therapies ■

Maintaining information regarding the identity and price of the medicines up-to-date

Form 1 is available on our Web site under Legislation, Regulations and Guidelines; Patentees' Guide to Reporting.

The *Patented Medicines Regulations, 1994* (Regulations) set out the obligations of the patentees in terms of filing requirements and maintaining the information regarding the identity of medicine up-to-date. Subsection 3(4) of the Regulations provides that the **Form 1** information shall be up-to-date and that any modification of that information shall be reported within 30 days after the modification.

Patentees are reminded that they are required to file an amended **Form 1** when there are any changes to the information that is required to be filed regarding the identity of the medicine, such as change of name of patentee, change of address or issuance of a new patent which pertains to the medicine. In order to ensure continuous communication, patentees are also encouraged to let the PMPRB know of changes in contact officer, president of company, phone and fax numbers. ■

Report on New Patented Drug – Enablex

(Novartis Pharmaceuticals Canada Inc.)

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

Brand Name:	Enablex
Generic Name:	*(darifenacin hydrobromide)*
DIN:	02273217 (7.5 mg/tablet) 02273225 (15 mg/tablet)
Patentee:	Novartis Pharmaceuticals Canada Inc.
Indication – as per product monograph:	For the treatment of overactive bladder
Date of Issuance of First Patent(s) Pertaining to the Medicine:	November 12, 1996
Notice of Compliance:	November 14, 2005
Date of First Sale:	April 6, 2006 (7.5 mg/tablet) April 11, 2006 (15 mg/tablet)
ATC Class:	G04BD10 *Genito Urinary System and Sex Hormones; Urologicals; Other Urologicals, including Antispasmodics; Urinary Antispasmodics*

Application of the Guidelines

Summary

The introductory prices of Enablex 7.5 mg/tablet and 15 mg/tablet were found to be within the Guidelines because the daily cost of therapy did not exceed the daily cost of therapy of existing drugs in the therapeutic class comparison and the prices did not exceed the range of prices in the other comparator countries listed in the *Patented Medicines Regulations, 1994* (Regulations) where Enablex 7.5 mg and 15 mg/tablets were sold.

See the PMPRB's Compendium of Guidelines, Policies and Procedures for a more complete description of the Guidelines and the policies on TCCs.

Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Enablex be reviewed as a category 3 new medicine (provides moderate, little or no therapeutic advantage).

The Therapeutic Class Comparison (TCC) test of the Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drugs that treat 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) System that are clinically equivalent in addressing the approved indication.

The HDAP identified flavoxate (Urispas), oxybutynin (Ditropan XL, Ditropan Syrup, PMS-Oxybutynin) and tolteridine (Detrol/Detrol LA) as the most appropriate comparators for Enablex (darifenacin). All these agents are administered orally, are indicated for the treatment of overactive bladder in adults and share the same 4th level ATC classification.

The 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 Enablex and the comparators are based on their respective product monographs, available comparative clinical trial information as well as guidelines relevant to the subject matter.

Price Review

Under the Guidelines, the introductory price of a new category 3 drug product will be presumed to be excessive if it exceeds the prices of all of the comparable drug products based on a TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the Regulations. The prices of Enablex 7.5 mg/tablet and 15 mg/tablet were within the Guidelines as the daily cost of treatment did not exceed the daily cost of treatment of the comparator medicines. Furthermore, the Canadian prices of Enablex were the lowest of the four comparator countries in which they were sold.

The comparator countries, as listed in the *Patented Medicines Regulations, 1994*, are France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S.

Introductory Period (April to June 2006)

Name Enablex	Strength 7.5 mg/tablet	Dosage Regimen 1 tablet	Unit Price $1.6671[1]	Cost Per Day $1.6671
Urispas	200 mg	3 tablets	$0.4940[2]	$1.4820
PMS-Oxybutynin	5 mg	2 tablets	$0.2485[3]	$0.4970
Ditropan Syrup	1 mg/mL	10 mL	$0.0888[3]	$0.8880
Ditropan XL + Ditropan XL	5 mg 10 mg	1 tablet 1 tablet	$1.7500[2] $1.7500[2]	$3.5000
Detrol	2 mg	2 tablets	$0.8750[3]	$1.7500
Detrol LA	4 mg	1 tablet	$1.7500[3]	$1.7500

Introductory Period (April to June 2006)

Name Enablex	Strength 15 mg/tablet	Dosage Regimen 1 tablet	Unit Price $1.6671[1]	Cost Per Day $1.6671
Urispas	200 mg	6 tablets	$0.4940[2]	$2.9640
PMS-Oxybutynin	5 mg	4 tablets	$0.2485[3]	$0.9940
Ditropan Syrup	1 mg/mL	20 mL	$0.0888[3]	$1.7760
Ditropan XL	10 mg	3 tablets	$1.7500[2]	$5.2500
Detrol	2 mg	2 tablets	$0.8750[3]	$1.7500
Detrol LA	4 mg	1 tablet	$1.7500[3]	$1.7500

1. MEDIS McKesseon Canada, May – July 2007
2. Liste de médicaments, Régie de l'assurance maladie du Québec, 15th Ed., Update 13, February 2006
3. Ontario Drug Benefit Formulary, No. 39, September 2005

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by the HDAP for the purpose of carrying out the PMPRB's regulatory mandate, which is to review the prices of patented medicines sold in Canada to ensure that such prices are not excessive. The publication of these reports is also part of the PMPRB's commitment to make its price review process more transparent.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than its stated purpose and is not to be interpreted as an endorsement, recommendation or approval of any drug, nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner. ■

Upcoming Events

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

November

14-16
Annual Senior Financial Officers' (SFO) Conference, Montebello

28-30
Hearing – Quadracel and Pentacel

December

3-4
Life Sciences Forum, Montebello

4-5
Market Access Conference, Toronto

5
HDAP Teleconference

12-13
Board Meeting

2008
January

16-18
Hearing – Penlac

29
University of Ottawa Healthcare System Management Seminar Series

February

27-28
Drug Patent Law and Patent Litigation

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