Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

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PMPRB *NEWSletter*

Coming Soon: Public consultation on PMPRB framework modernization

In December 2015, the PMPRB released its *2015-2018 Strategic Plan*, the culmination of a year-long strategic planning process that identified a new vision, a revised mission statement, and four strategic objectives that will guide the organization over the next three years. One of these objectives, Framework Modernization, includes a commitment by the PMPRB to examine changes to its regulatory framework to ensure that it continues to fulfill its mandate of protecting consumers from excessively priced patented medicines in the face of recent and significant changes in its operating environment.

As the first step toward meeting this commitment, the PMPRB will publish *PMPRB Guidelines Modernization: Discussion Paper*. This document will examine in more depth the nature of the changes that have taken place in the PMPRB's operating environment and identify aspects of the current Guidelines which the PMPRB believes may be in particular need of reform as a result of those changes. The *Discussion Paper* seeks public and stakeholder feedback on a range of questions relating to potential Guideline reform and its release will be followed by a number of events that will provide further opportunity for public participation in this process as it unfolds, including:

- cross-country face to face meetings with interested members of the public and key stakeholders
- a public policy hearing
- a multi-stakeholder round table

The release of the *Discussion Paper* is planned for spring 2016. We look forward to engaging with our stakeholders and the public as we embark on this important exercise in support of a sustainable pharmaceutical system where payers have the information they need to make smart reimbursement choices and Canadians can afford the patented drugs they need to live healthy and productive lives.

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Notice to Readers

Update: Notice and Comment on incremental changes to the Guidelines

On December 4, 2015 a Notice and Comment initiative was announced on two proposed amendments to the *Compendium of Policies, Guidelines and Procedures* (Guidelines). Stakeholders were given until January 29, 2016 to provide feedback on the proposed amendments. The PMPRB received written submissions from 12 stakeholders, which are publicly available in the Past Notice and Comment Initiatives section of the PMPRB website.

The PMPRB is currently analyzing the feedback received on the proposed amendments and is developing options for the Board to consider at its next quarterly meeting in May 2016. As such, the proposed amendments have not yet been implemented and their implementation date remains to be determined.

The PMPRB is committed to an effective consultation process and would like to thank those stakeholders who submitted written comments on the proposed Guideline amendments. Next steps in this process will be announced in June 2016 following the Board's meeting.

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Form 2 filing requirements for new patented medicines

Under the *Patented Medicines Regulations*, a patentee is required to file a Form 2 (information on the identity and prices of the medicine) for each drug product for which at least one patent pertains to the medicine. Form 2 is to be filed with the PMPRB no later than thirty days after the first day of sale in Canada of the new drug product. Form 2 must then be filed semi-annually:

- by July 30, for the period of January 1 to June 30
- by January 30, for the period of July 1 to December 31

The requirement to file a Form 2 thirty days after the first day of sale in Canada is in addition to the requirement to file semi-annually. If a patentee does not file the semi-annual filing for a new drug product, it will be considered a failure to file and Board Staff will act accordingly.

For more information on PMPRB filing requirements, please consult the *Patentee's Guide to Reporting*.

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Information sessions available: PMPRB price regulation framework

Patentees may request one-on-one introductory information sessions on the PMPRB price regulation framework. Information sessions are facilitated by the Regulatory Affairs and Outreach branch, and can be conducted in person at the PMPRB offices in Ottawa or remotely using webinar technology.

Updates

- The NPDUIS team presented its research findings at the CHSPR Health Policy Conference in Vancouver, BC (April 5-6) and at the CADTH Symposium in Ottawa, ON (April 10-12, 2016)
- Tanya Potashnik, Director, Policy & Economic Analysis, attended the Pharmaceutical Pricing and Reimbursement Information network meeting in Lisbon, Portugal (April 28-29, 2016).

Upcoming Events

- Doug Clark, Executive Director, will be the keynote speaker at the Canadian Institute Pharma Symposium in Toronto, ON (May 3-4, 2016)
- The NPDUIS team will present their research at the CAHSPR Conference in Toronto, ON (May 9-12)
- Doug Clark will be a discussion leader at the Northwind Professional Institute's 9th annual Life Sciences Forum in Cambridge, ON (May 25-27, 2016)

Reminders

- Product monographs and patentee submissions for the September 12, 2016 HDAP meeting are due on **May 12 and June 9**, respectively.
- The deadline for filing Form 2 for the January to June 2016 reporting period is **August 2, 2016**.
- The PMPRB no longer issues e-bulletins. To be notified of new announcements, publications, and other initiatives, please follow us on Twitter or subscribe to

To request an information session, please contact Richard Lemay, Manager, Outreach and Investigations.

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Notices of Hearing: Galderma Canada Inc. and Baxalta Canada Corporation

The PMPRB will hold separate public hearings with respect to allegations that Galderma Canada Inc. (Galderma) and Baxalta Canada Corporation (Baxalta) each failed to provide the PMPRB with pricing and sales information required by the *Patent Act* and the *Patented Medicines Regulations*. Details on the date and location of these hearings will be announced at a later time.

Galderma

The Galderma proceeding relates to the medicines branded as Differin, Differin XP, TactuPump, and TactuPump Forte, for which Galderma holds the patent. These medicines are generally indicated for the treatment of acne.

Baxalta

The Baxalta proceeding relates to the patented medicine Oncaspar. Oncaspar is sold in Canada under Health Canada's Special Access Programme and is used in the treatment of patients with Acute Lymphoblastic Leukemia.

The purpose of these hearings is for the Board Panel to receive evidence and argument of Board Staff, the patentees, and any interveners regarding allegations that the patentees are in breach of their legal reporting requirements.

If the Board Panel finds the patentees to be in breach of their reporting requirements, the Board Panel may order the patentees to provide the PMPRB with the required pricing and sales information.

Those wishing to participate in the Baxalta proceeding must apply to the Board for leave to intervene **by May 2, 2016**. The application period for the Galderma proceeding is now closed.

For more information on the application process, please contact:

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Hearing update: the Soliris matter

The Board Panel held a public pre-hearing conference on March 18, 2016, in the matter of the price of the patented medicine

our RSS feeds.

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Hearings

Soliris. A pre-hearing conference allows parties to identify or circumscribe the issues related to the hearing and resolve any other issues that may facilitate the conduct of the hearing.

The purpose of the pre-hearing conference was to address a motion filed by the Respondent to strike expert evidence as inadmissible. The Panel issued a decision on these motions on March 29, 2016. **The public hearing in this matter is scheduled to begin on June 27, 2016**.

For more information, please visit the Status of Ongoing Proceedings section of the PMPRB website, which contains the latest public documents in this matter.

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Voluntary Compliance Undertakings: Mitosol (mitomycin) and Neoral, Apprilon (doxycycline monohydrate), and Angiomax (bivalirudin)

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 the price set 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. VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties in view of the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

In the first quarter of 2016, four VCUs were accepted: for the patented medicines Mitosol (Labtician Ophthalmics Inc.), Neoral (Novartis Pharmaceuticals Canada Inc.), Apprilon (Galderma Canada Inc.), and Angiomax (Sunovion Pharmaceuticals Canada Inc.).

Mitosol

Mitosol (mitomycin) is an antimetabolite used as an adjunct to *ab externo* glaucoma surgery.

On January 14, 2016, the Chairperson of the Board approved a VCU submitted by Labtician Ophthalmics Inc. (Labtician) regarding the price of Mitosol. Under the terms of the VCU, Labtician agreed to offset cumulative excess revenues it received since July 1, 2015 by making a payment to the Government of Canada in the amount of $190.58 and ensuring the price of Mitosol remains within the PMPRB's pricing guidelines in all future periods in which Mitosol is under the PMPRB's jurisdiction.

Neoral

Neoral is used in the prevention of graft rejection following solid organ transplantation and in the treatment of transplant rejection in patients previously receiving other immunosuppressive agents.

On February 2, 2016, the Chairperson approved a VCU submitted

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by Novartis Pharmaceuticals Canada Inc. (Novartis) regarding the price of Neoral 50 mg capsule, for which the last remaining reported patents expired in September 2014. Under the terms of the VCU, Novartis agreed to offset cumulative excess revenues it received in 2014 by making a payment to the Government of Canada in the amount of $96,466.51 and agreeing to notify the PMPRB in the event that additional patents pertaining to Neoral are issued in the future.

Apprilon

Apprilon (doxycycline monohydrate) is used in the treatment of inflammatory lesions (papules and pustules) or rosacea in adult patients.

On March 30, 2016, the Chairperson approved a VCU submitted by Galderma Canada Inc. (Galderma) regarding the price of Apprilon modified-release capsule. Under the terms of the VCU, Galderma agreed to ensure that both the National Average Transaction Price (N-ATP) and the average transaction price within each market in which Apprilon is sold comply with the 2016 National Non-excessive Average Price (N-NEAP) as calculated by Board Staff and that the price of Apprilon remains within the PMPRB's pricing guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Angiomax

Angiomax (bivalirudin) is used as an anticoagulant in patients undergoing percutaneous coronary intervention and in the treatment of patients with moderate- to high-risk acute coronary syndromes due to unstable angina or non-ST-segment elevation in whom early percutaneous coronary intervention is planned.

On April 4, 2016, the Chairperson approved a VCU submitted by Sunovion Pharmaceuticals Canada Inc. (Sunovion) regarding the price of Angiomax 250 mg vial. Under the terms of the VCU, Sunovion agreed to offset cumulative excess revenues it received as of December 31, 2015, by making a payment to the Government of Canada in the amount of $88,412.60, and to offset any excess revenues calculated by Board Staff for the first half of 2016. Sunovion further agreed to ensure the 2016 National Average Transaction Price (N-ATP) for Angiomax 250 mg vial does not exceed the 2016 National Non-excessive Average Price (N-NEAP) and that the price of the product remains within the PMPRB's pricing guidelines in all future periods in which it is under the PMPRB's jurisdiction.

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NPDUIS update: Engagement activities

NPDUIS Advisory Committee

An NPDUIS Advisory Committee teleconference was held in February 2016 to discuss the current NPDUIS research agenda and the latest developments at the jurisdictional level.

Oral and poster presentations

Several posters highlighting the latest NPDUIS analytical research findings were presented at conferences in April 2016.

Elena Lungu and Jeffrey Biggs presented four posters at the Centre for Health Services and Policy Research (CHSPR) Conference in Vancouver on April 5 and 6. The posters focused on the following topics:

- Cost Pressures in the Canadian Hospital Drug Market, 2006-2014
- Private Drug Plans in Canada: Cost Drivers, 2008-2015
- The Use of Diabetes Drugs in Canadian Public Drug Plans
- New Drug Launch Monitor, 2009–2015

Elena Lungu and the NPDUIS analytical team, Nevzeta Bosnic, Karine Landry, Greg McComb, and Gary Warwick, also attended the 2016 Canadian Agency for Drugs and Technologies in Health (CADTH) Symposium in Ottawa from April 10 to 12. Along with the poster on cost pressures in the Canadian hospital drug market, the following research topics were presented:

- Cost Pressure of the New Hepatitis C Drugs in Canada
- Private Drug Plans in Canada: High-Cost Drugs and Beneficiaries, 2005–2015

Upcoming presentations

From May 9 to12, Elena Lungu, Nevzeta Bosnic, and Gary Warwick will attend the Canadian Association for Health Services and Policy Research (CAHSPR) Conference in Toronto where they will deliver four oral and four poster presentations.

The presentations will include overviews of the recently published *Generics360: Generic Drugs in Canada, 2014* and the upcoming *CompassRx 2013/14*.There will also be presentations on the use and cost of diabetes drugs in Canadian public drug plans and on cost drivers in private drug plans in Canada. The four posters to be presented include the Private Drug Plans in Canada: High-Cost Drugs and Beneficiaries, 2005 to 2015, Cost Pressures in the Canadian Hospital Drug Market, and an overview of two upcoming studies: the *New Drug Launch Monitor* and the *Orphan Drug Launch Monitor*. Conference participants are encouraged to drop by and meet the researchers.

The 2016 conference posters will be made available on the Analytical Studies section of the PMPRB website following theformal presentation of the research topics.

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New and upcoming publications

Generics360: Generic Drugs in Canada, 2014 **(February 2016)**

This is the most recent edition in a series of reports that compares generic drug prices in Canada with those of up to 11 other industrialized countries. The report takes a comprehensive analytical approach, covering 554 leading generic drugs and analyzing the issue of generic drug pricing in Canada from various angles, including reference brand-name prices,

international generic drug prices, and market segmentation.

The study found that provincial generic drug pricing policies, including those initiated by the pan-Canadian Pharmaceutical Alliance, achieved significant price reductions in Canada in recent years. While these declines exceeded the generic drug price reductions in foreign markets, prices of generic drugs still remain appreciably higher in Canada.

Key findings:

- From 2010 to 2014 average generic drug prices in Canada fell from 63% to 36% of their brand-name counterparts.
- The difference between generic drug prices in Canadian and foreign markets gradually decreased from 40% in 2010 to 19% in 2014.
- Generic drug price differences were more pronounced for drugs with estimated annual Canadian sales of more than $10 million and for drugs with six or more suppliers.

CompassRx, 2013/14 **(May 2016)**

This is the second edition of a flagship NPDUIS annual report that explores the major factors driving changes in prescription drug expenditures in public drug plans in Canada. Building on the findings of the first edition, this study will use the latest available data to highlight trends and the impact of changes in demographics, drug utilization, higher-cost drugs, and generic drug pricing. This study is an important resource for policy makers and researchers.

For additional information on all future research topics and publications, please refer to the NPDUIS Research Agenda on the PMPRB website.

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Summary of the Board's February 2016 meeting

The Board held its first quarterly meeting of 2016 on February 3.

The Chairperson provided an update on Board operations and the comments received from stakeholders on the proposed incremental changes to the Guidelines were discussed. The Board was also updated on recent and upcoming NPDUIS research initiatives.

The Board's next meeting is scheduled for May 19, 2016.

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