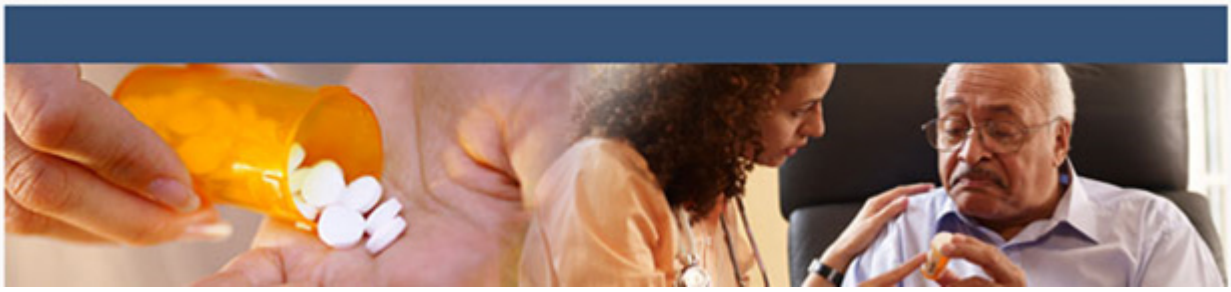
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés



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PMPRB *NEWSletter*

Health Canada launches consultation on potential changes to the *Patented Medicines Regulations*

On May 16, 2017, the Honourable Jane Philpott, Minister of Health, outlined a comprehensive plan for improving the pharmaceutical system in Canada. Included in the plan was the launch of a consultation process on potential changes to the *Patented Medicines Regulations* (Regulations) that would lower the cost of prescription drugs in Canada and better protect Canadians against excessive drug prices.

Health Canada's consultation document outlining these potential regulatory amendments builds on the written submissions received by the PMPRB in response to our recent *Rethinking the Guidelines* consultation. Five important improvements to the Regulations are proposed that would:

1. introduce new, economics-based price regulation factors that would ensure drug prices reflect Canada's willingness and ability to pay for drugs that provide demonstrably better health outcomes;
2. update the list of countries used for price comparison so that it is more aligned with the PMPRB's consumer protection mandate and median OECD (Organisation for Economic Co-operation and Development) prices;
3. formalize a move to a complaints-based system of oversight for patented generic drug products that are at lower risk of excessive pricing, thereby reducing regulatory burden for patentees;
4. set out the pricing information required of patentees to enable the PMPRB to operationalize the new pricing factors; and
5. require patentees to provide the PMPRB with third party information related to rebates and discounts on domestic prices.

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Notice to Readers

Updates

- PMPRB Executive Director Doug Clark spoke at the *Atlantic Benefits3 Conference*, organized and hosted by Medavie Blue Cross, on April 5, 2017 in Halifax, NS.
- PMPRB Policy and Economic Analysis Director Tanya Potashnik and members of the NPDUIS team presented posters at the Canadian

This online consultation will be open for a 45-day period, **ending June 28, 2017**. The Minister has indicated that it is her intention to seek Treasury Board approval to pre-publish proposed regulatory amendments in *Canada Gazette, Part I* in the ensuing months. Given the interdependency of the Regulations and the Guidelines, the PMPRB will await the outcome of that process before officially resuming its consultations on Guideline modernization. Any questions on the consultation process can be sent to the following email address:

Patented Medicines Regulations Consultations
Brooke Claxton Building
70 Colombine Drwy, Tunney's Pasture
Mail Stop 0910, Floor 10
Ottawa, Ontario K1A 0K9
Email: PMR-Consultations-RMB@hc-sc.gc.ca

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Status of ongoing proceedings: Soliris

Closing arguments in the Soliris matter were heard on April 18 and 19, 2017. The Hearing Panel took the matter under advisement and will issue its decision at a later date.

The purpose of this hearing is to determine whether, under sections 83 and 85 of the *Patent Act*, Alexion, the pharmaceutical company that exercises patent rights for Soliris and sells the medicine in Canada, is selling or has sold Soliris in any market in Canada at a price that, in the opinion of the Board, is or was excessive and if so, what order, if any, should be made.

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2017 Human Drug Advisory Panel meeting rescheduled

Due to scheduling conflicts, the second Human Drug Advisory Panel meeting of 2017, originally set for May 29, 2017, has been moved to June 5, 2017. Patentee submission deadlines for this meeting are unchanged.

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Reminder to patentees: Procedures for amending Form 2 regulatory data

To prevent delays in the price review process, patentees are reminded that they are required to provide a written explanation to support any revisions made when filing one or more amendments to Block 4 or Block 5 data. The explanation may be submitted to the PMPRB by email to compliance@pmprb-cepmb.gc.ca or in a covering letter as an email attachment.

Please also note that amended Form 2 (information on the identity and prices of the medicine) – Block 1, 2, and 3 data must be completed, signed, dated, and submitted electronically to

Agency for Drugs and Technologies in Health symposium on April 24 and 25, 2017 in Ottawa, ON.

- PMPRB Vice-chairperson Dr. Mitchell Levine delivered remarks at the Healthy Canada Conference on April 26, 2017 in Toronto, ON.
- Doug Clark attended and delivered a poster presentation at the Pharmaceutical Pricing and Reimbursement Information Network meeting on April 27 and 28, 2017 in Stockholm, Sweden.

Upcoming Events

- The next Board meeting is scheduled for **May 18, 2017**.
- Doug Clark will deliver remarks at the 3rd Annual Pharma Symposium on **May 30, 2017** in **Toronto, ON**.
- Doug Clark will be a panelist at the Canadian Pension and Benefits Institute National Forum Conference on **June 6, 2017** in **Winnipeg, MB**.

Reminders

- Product monographs and patentee submissions for the September 18, 2017 Human Drug Advisory Panel meeting are due on **May 25** and **June 22**, respectively.
- The deadline for filing Form 2 for the January to June 2017 reporting period is **July 31, 2017**.
- To be notified of new announcements, publications, and other initiatives, please follow us on Twitter or subscribe to our RSS feeds.

compliance@pmprb-cepmb.gc.ca with any amended Block 4 and 5 data.

Patentees may refer to the *Patentee's Guide to Reporting* for additional information on this topic. The Regulatory Affairs and Outreach branch remains available to offer individualized information sessions on the PMPRB price regulation framework to patentees. To request an information session, please contact Richard Lemay, Manager, Outreach and Investigations.

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NPDUIS update: Publications and engagement activities

New publication!

Meds Entry Watch, 2015 **(April 2017)**

This new annual PMPRB publication provides information on the market entry dynamics of drugs recently launched in Canada and select international markets. The analysis focuses on the availability, launch sequence, market penetration, sales, and prices of these new substances.

The first edition of this series provides a benchmark analysis of the Canadian and international new-drug space over a six-year period from 2009 to 2014, as well as a preliminary analysis of drugs launched in 2015. The international markets analyzed include the seven PMPRB comparator countries (France, the United Kingdom, Sweden, Switzerland, Germany, the United States, and Italy) and some high-level data on Canada's ranking within the OECD (Organisation for Economic Co-operation and Development) in terms of the number of drugs launched and their relative share of sales.

The study found that high-priced, so-called "specialty drugs" are increasingly dominating the new drug landscape in Canada and internationally. Results also show that the drugs that account for the vast majority of new drug sales internationally over the time period studied are available in Canada. Moreover, the average time between a drug's launch in its country of origin and its entry onto the Canadian market is well within the timelines observed in the United States (US) and Europe. In fact, many new drugs enter the Canadian market second only to the US. Whereas the prices of new drugs in Canada are also generally in line with those observed in the European markets analyzed—and considerably below those in the US—foreign prices declined relative to Canadian levels over time.

This report series is designed to inform decision makers, researchers, and patients of the evolving market dynamics of emerging drug therapies. Future annual editions will investigate new drug launches for each respective calendar year.

Presentations
New Patented Medicines Reported to PMPRB
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CompassRx, 3rd edition – 2015-16 **(May 2017)**

This annual PMPRB report monitors and analyzes the cost pressures driving change in prescription drug expenditures in Canada's public drug plans. This edition will focus on the 2015-16 fiscal year and include data from 2014-15, as well as a retrospective review of trends since 2011.

The report finds that after several years of low to moderate growth, public drug plan expenditures increased by 9.9% or $1 billion in 2015-16, mainly driven by a 12% growth in drug costs. This significant change is the result of increased pressure from higher-cost drugs combined with reduced savings from generic pricing and substitution. In 2015-16, higher-cost drugs pushed cost levels up by 12.1%, with new hepatitis C drugs accounting for 8.0% of that pressure. At the same time, price reductions and generic substitution lowered costs by 4.1%, a marked decline over previous years (e.g., 9.2% in 2012-13). Growth in the beneficiary population and the volume of drug use together increased costs by 4.2%, following a more stable trend.

The 3.8% growth in dispensing costs in 2015-16—approximately $90.7 million—represented a decrease from rates reported in previous years (e.g., 7.3% in 2014-15).

In addition to upcoming issues of annual NPDUIS publications, be on the lookout for the following first-time studies in 2017-18:

- *Potential savings from Biosimilars in Canada*
- *The Canadian Drug Reimbursement Landscape: A Review of Public and Private Markets*

Engagement activities

NPDUIS Advisory Committee

An NPDUIS Advisory Committee teleconference was held in February 2017 to discuss the NPDUIS research agenda and latest developments at the jurisdictional level.

Conferences

The NPDUIS team participated in the following conferences and presented the results of several analytical studies as posters, oral presentations, and panel discussions:

- The Centre for Health Services and Policy Research conference in Vancouver, March 9 and 10, 2017;
- The Biosimilars Workshop: From Authorization to Access in Ottawa, March 20, 2017;
- The Canadian Agency for Drugs and Technologies in Health conference in Ottawa, April 23-25, 2017; and
- The Conference Board of Canada's *Healthy Canada Conference* in Toronto, April 26 and 27.

The topics presented included: the Canadian market for biologic response modifier agents; potential savings from biosimilars; cost

drivers in Canadian public drug plans; fair pricing of pharmaceuticals; generic drugs in Canada; and a review of drug coverage in Canadian public plans. Copies of the posters and slide presentations presented in public forums are available in the Analytical Studies section on the PMPRB website.

NPDUIS staff will participate in the following conferences in May 2017:

- The International Society for Pharmacoeconomics and Outcomes Research in Boston, May 22-24; and
- The Canadian Association for Health Services and Policy Research conference in Toronto, May 22-26.

For more information on future research topics and publications, see the NPDUIS Research Agenda on the PMPRB website. Follow the PMPRB on Twitter or check the next quarterly *NEWSletter* for the most up-to-date information on planned NPDUIS engagement activities.

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Voluntary Compliance Undertaking: GlaxoSmithKline Inc.

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 2017, one VCU was accepted for multiple drug products, the patents for which are held in Canada by GlaxoSmithKline Inc. (GSK).

On February 17, 2017, the Vice-chairperson of the Board, acting as Chairperson pursuant to subsection 93(3) of the *Patent Act*, approved a VCU submitted by GSK regarding the price of multiple patented drug products. Under the terms of the VCU, GSK has agreed to offset cumulative revenues received in respect of the products in question as of December 31, 2016, by making a payment to the Government of Canada in the amount of $31,000,000. GSK further agreed to reduce the National Average Transaction Prices (NATPs) of several of these products that continued to be sold in 2016 to align with their respective 2017 National Non-excessive Average Prices (N-NEAPs). Finally, GSK will ensure the prices of the products that continue to be sold remain within the PMPRB's pricing guidelines in all future periods in which they are under the PMPRB's jurisdiction.

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Correction: Status of ongoing proceedings updates (February 2017 and November 2016)

The PMPRB would like to make the following correction to a paragraph appearing in the February 2017 (Volume 21, issue 1) and November 2016 (Volume 20, issue 4) *NEWSletter* in the article titled *Status of ongoing proceedings: Hearing updates*:

Baxalta Canada Corporation (Oncaspar)
The PMPRB Hearing Panel in this matter issued an Order on October 28, 2016, on consent of the parties, **discontinuing the application**.

The original version of this article indicated that the Hearing Panel issued an Order requiring that Baxalta provide the PMPRB with the pricing and sales information required by section 80 of the *Patent Act*. We apologize for any confusion.

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Update: Interpretation Policy

Further to the Government of Canada's commitment in 2014 to improving regulatory openness and transparency, reducing administrative burden, and modernizing regulations, the PMPRB implemented the following measures to foster awareness and understanding among stakeholders of the PMPRB's regulatory requirements:

Improving plain language

- The *Patentee's Guide to Reporting* was updated in July 2015 to further clarify filing requirements to patentees, including what information must be reported, and how and when it is to be submitted to the PMPRB.
- Through the quarterly PMPRB *NEWSletter*, the Regulatory Affairs and Outreach branch has published several concise articles covering topics of interest specific to patentee filing requirements.
- "PMPRB 101" information sessions tailored to the specific needs of individual patentees continue to be offered by the Regulatory Affairs and Outreach branch upon request.
- Public communications products and reports are drafted and reviewed with a focus on plain language, clarity, and concision.

Improving stakeholder engagement

- The Regulatory Affairs and Outreach branch developed instructional videos to assist patentees in understanding procedures and meeting regulatory requirements.
- The Regulatory Affairs and Outreach branch has established the capacity and process for Senior Regulatory Officers to

proactively reach out to new patentees and offer one or more PMPRB 101 information sessions when a new patentee files a drug product for the first time with the PMPRB.

- Since April 2015 the PMPRB has conducted two face-to-face outreach sessions for all patentees, at which participants were given the opportunity to provide feedback about the session by completing a questionnaire. Six one-on-one sessions have also been conducted with individual patentees.

- The PMPRB has put a greater emphasis on digital communications to effectively reach and engage a broad spectrum of stakeholders. Since 2014, the PMPRB has developed and implemented a social media strategy and now includes social media plans as an integral part of its formal communications approaches.

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