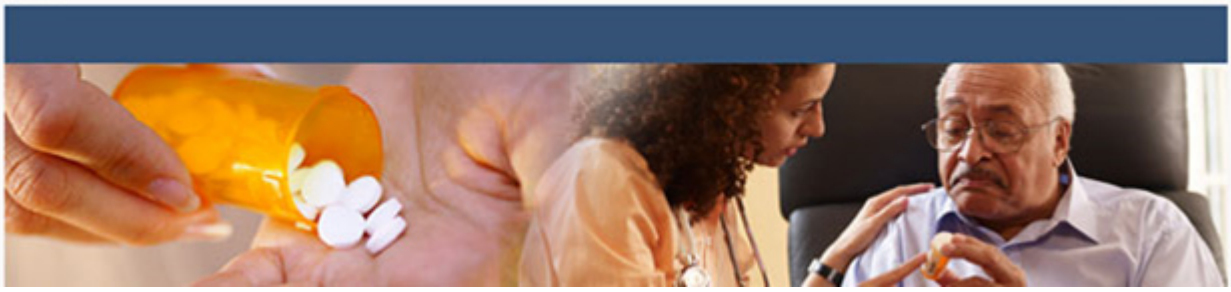
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés



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PMPRB *NEWSletter*

Message from the Executive Director

I would like to take this opportunity to wish our readers a belated happy New Year on behalf of the Patented Medicine Prices Review Board. The past year was an eventful one us as we began to execute on the objectives identified in our December 2015 *Strategic Plan*.

Our most public efforts to-date have been focused on framework modernization and I would be remiss not to express my gratitude — to PMPRB staff and stakeholders alike — whose participation in the first phase of the *Rethinking the Guidelines* consultation initiative made it such a resounding success. This was a true team effort and an exciting example of what can be accomplished when we work collaboratively within and across organizations toward a common goal. While PMPRB staff review and analyze the feedback we received on our *Guidelines Modernization Discussion Paper*, I encourage everyone to take the time to view the submissions, which are available on the PMPRB website.

Although consultations were the highlight of 2016, the PMPRB counts a great many achievements over the past year: settling longstanding litigation on our jurisdiction over patented generic drugs, the affirmation by the Federal Court of Canada of the constitutionality of the PMPRB and its price regulation powers, and the management of an unprecedented number of proceedings before the Board, to name a few.

As the new year opens with the first excessive price hearing in more than five years, 2017 promises to be no less eventful. While we work on developing our policy response to the record number of submissions received during Phase 1 of the consultation process, we look forward to continuing to work with our stakeholders to improve the affordability of, and access to prescription drugs for all Canadians.

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Notice to Readers

Upcoming Events

- PMPRB Executive Director Doug Clark will speak at the *Atlantic Benefits3 Conference*, organized and hosted by Medavie Blue Cross, on **April 5, 2017** in **Halifax.**

Vice-chairperson of the Board reappointed for a second term

In November 2016, the PMPRB announced the reappointment of Dr. Mitchell Levine of Hamilton, Ontario as Vice-chairperson of the Board for a second five-year term. Dr. Levine was reappointed by His Excellency the Governor General in Council, on the recommendation of the Minister of Health, the Honourable Jane Philpott, following an open, transparent, and merit-based selection process.

Dr. Levine is a professor in the departments of Medicine and Clinical Epidemiology and Biostatistics in the Faculty of Health Sciences at McMaster University, and the Director of the Centre for Evaluation of Medicines at St. Joseph's Healthcare in Hamilton. He was first appointed Vice-chairperson of the Board in March 2011.

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New and departing staff members

Retirement of Ginette Tognet, Director, Regulatory Affairs and Outreach
It is with a heavy heart and great fondness that we bid farewell to Ginette Tognet, Director, Regulatory Affairs and Outreach, who retired in December 2016, after 18 years with the PMPRB. Ginette has played a formative role in shaping the professional lives of all who had the pleasure of working with her and will be sorely missed.

Richard Lemay, Manager, Outreach and Investigations will serve as acting Director, Regulatory Affairs and Outreach until Ginette's successor arrives in early 2017.

New staff members
The PMPRB would like to extend a warm welcome to Livia Aumand in the Legal Services Division and Matt Kellison, the PMPRB's incoming Director, Regulatory Affairs and Outreach.

Livia joins the PMPRB from the Ottawa office of Gowling WLG (Canada) LLP. Over the past six years, Livia practiced primarily in the area of patent litigation, including actions for infringement and proceedings under the *Patented Medicines (Notice of Compliance) Regulations*.

Matt Kellison will soon be joining the PMPRB from the Department of Innovation, Science and Economic Development where he was responsible for the conception and implementation of *Connect to Innovate*, a $500 million broadband infrastructure program. Prior to that, Matt was an Assistant Deputy Commissioner at the Competition Bureau where he led a number of high-profile investigations and prosecutions under the *Competition Act*, and was the driving force behind the modernization of the Bureau's approach to enforcing abuse-of-dominance cases.

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Reminders

- The deadline for filing Form 3 is **March 1, 2017**.
- To be notified of new announcements, publications, and other initiatives, please follow us on Twitter or subscribe to our RSS feeds.

Presentations
New Patented Medicines Reported to PMPRB
NPDUIS
Hearings
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Status of ongoing proceedings: Hearing updates

Alexion Pharmaceuticals Inc. (Soliris)
The Board held a public hearing in the matter of the price of the patented medicine Soliris and Alexion Pharmaceuticals Inc. (Alexion) from January 16 to January 29, 2017 and from January 23 to January 27, 2017. The purpose of the hearing is to determine whether Alexion is selling or has sold the medicine at a price that is or was excessive. **The hearing will resume on February 20, 2017 in Ottawa**.

Soliris is indicated for the treatment of Paroxysmal Nocturnal Hemoglobinuria, a rare and life-threatening blood disorder characterized by excessive destruction of red blood cells, and Atypical Hemolytic Uremic Syndrome, a rare and life-threatening genetic disorder characterized by blood clots in small vessels.

Galderma Canada Inc. (Differin, Differin XP)
The PMPRB Hearing Panel in this matter issued an Order on December 19, 2016 relating to the medicines Differin and Differin XP, manufactured and marketed in Canada by Galderma Canada Inc. (Galderma). The Hearing Panel found that one of the three patents at issue in the proceedings pertains to Differin and ordered Galderma to provide PMPRB staff with pricing and sales information required by section 80 of the *Patented Medicines Regulations* with respect to that medicine for the period between January 1, 2010 and March 14, 2016. The Hearing Panel dismissed PMPRB staff's application with respect to the other two patents at issue.

Differin and Differin XP are generally used for the treatment of acne.

Baxalta Canada Corporation (Oncaspar)
The PMPRB Hearing Panel in this matter issued an Order on October 28, 2016 requiring that Baxalta Canada Corporation (Baxalta) provide the PMPRB with the pricing and sales information required by section 80 of the *Patent Act* and sections 3 and 4 of the *Patented Medicines Regulations*. The Order relates to the medicine Oncaspar, which is sold in Canada under Health Canada's Special Access Programme and is used in the treatment of patients with Acute Lymphoblastic Leukemia. Baxalta agreed to provide the information sought by the PMPRB for the period commencing July 1, 2015, when Baxalta began selling Oncaspar in Canada.

The Hearing Panel's Order resolved this matter and, as such, no hearing was held in November 2016.

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New policy: Complaint process for patented generic-drug price reviews

The PMPRB strives to make its price review process open and transparent to all stakeholders and is committed to a regulatory framework that is relevant, responsive and appropriate.

PMPRB staff regularly review existing policies as part of an ongoing commitment that the framework continues to have a positive impact for consumers; policies, guidelines, and

procedures are responsive to relevant developments; the regulatory burden be reduced where possible; and the PMPRB continues to use its limited resources efficiently.

The PMPRB has jurisdiction over the prices of all patented medicines, including patented generic drugs. From the point of view of risk of abuse of market power, the PMPRB recognizes that patented generic drugs represent a potentially lower-risk category of patented medicines, and therefore a lower priority for PMPRB regulatory investigation. Accordingly, the PMPRB will be moving patented generic-drug price reviews to a complaint-based process, similar to the provisions for new and existing veterinary and over the counter drug products.

All manufacturers of patented generic drugs are required to continue reporting information identifying the medicines, using Form 1, no later than the earlier of seven days after the day on which the first Notice of Compliance is issued in respect of the medicine, and the medicine is first offered for sale in Canada — whichever comes first. **As of the July 1 to December 31, 2016 reporting period**, PMPRB staff will only review information relating to the identity of the medicine and/or pricing upon the commencement of an investigation. An investigation of the price of a patented generic drug will only be commenced upon receiving a substantiated complaint.

In accordance with the applicable guidelines and policies, an investigation into the price of a patented generic drug will be commenced if **all** the following conditions are met:

1. a substantiated complaint has been received in respect of the patented generic drug;
2. the patentee of the patented generic drug is the only company in Canada selling a generic version of the drug in Canada; and
3. the patented generic drug is not the subject of a pricing agreement with the pan-Canadian Pharmaceutical Alliance (pCPA), to which it is compliant. The onus of proving to PMPRB staff that a patented generic drug is subject to, and compliant with, a pricing agreement with the pCPA will rest with the patentee for that patented generic drug.

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Rethinking the Guidelines: Public submissions now available

As a first step to framework modernization, the PMPRB launched the *Rethinking the Guidelines* consultation initiative to explore possible reform to its *Compendium of Policies, Guidelines and Procedures*. Phase 1 of this consultation ran from June to October 2016 and included the publication of a *Guidelines Modernization Discussion Paper* on which Canadians were invited to provide feedback as to how the PMPRB could rethink its drug pricing guidelines to improve its performance in ensuring pharmaceutical patent holders do not charge excessive prices. Phase 1 public submissions are being analyzed by the PMPRB and are now available online.

Timelines for Phase 2 of the consultation process will be

announced at a later date.

By *Rethinking the Guidelines*, the PMPRB seeks to contribute to a sustainable pharmaceutical system where payers have the information required to make smart reimbursement choices and Canadians can access the medicines they need to live healthy and productive lives.

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2017 CPI-based price adjustment factors for patented drug products

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

The following table provides the CPI-based price-adjustment factors for 2017. These factors were based on the actual rate of CPI inflation of 0.9% in 2013, 2.0% in 2014, and 1.1% in 2015.

Benchmark year	**2014**	**2015**	**2016**
Price-adjustment factor	1.040	1.031	1.011

Based on these factors, one can derive:

- a maximum allowable cumulative price increase between 2014 and 2017 of 4.0% for patented drug products with Canadian sales in 2014;
- a maximum allowable cumulative price increase between 2015 and 2017 of 3.1% for patented drug products with Canadian sales in 2015; and
- a maximum allowable cumulative price increase between 2016 and 2017 of 1.1% for patented drug products with Canadian sales in 2016.

The year-over-year price increase cap for the 12-month period ending December 2017 is 1.7% (=1.5 x Actual Inflation in 2015).

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Patentees reporting on R&D and sales for 2016

Patentees are reminded that the deadline for filing Form 3 information on revenues and R&D expenditures is March 1,

2017.

Under the *Patented Medicines Regulations* (Regulations), all patentees are required to file information on revenues and R&D expenditures (Form 3).

Failure to File

If a patentee fails to file complete information by March 1, 2017, 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 it. 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 *Patent Act* requiring that the patentee file the required information. Orders issued by the Board are reported in the PMPRB's publications and posted on the website.

For more information on Licensees, Revenues and Expenditures, see the *Patentee's Guide to Reporting*.

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

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NPDUIS update: Publications and engagement activities

Two National Prescription Drug Utilization Information System (NPDUIS) reports are slated for publication in early 2017:

New publication: *Meds Entry Watch*
This new report series explores the market entry dynamics of drugs recently launched in Canada and other relevant international markets, with the analysis focusing on the availability, launch sequence, market penetration, sales and price comparisons of these new drugs. *Meds Entry Watch* will inform patients, researchers, and decision-makers of emerging drug therapies, and will support policy decision-making by providing insight into the evolving pharmaceutical environment and associated cost implications.

The first edition of this series will provide a retrospective look at the Canadian and international new-drug space over a six-year period from 2009 to 2014, and report on related sales for the last quarter of 2015. Findings suggest the number of new drugs launched in Canada was similar to other relevant foreign markets, and show all top-selling new drugs were launched in Canada. This first edition of *Meds Entry Watch* will provide a benchmark for subsequent annual editions, which will investigate new drug launches for each respective calendar year.

CompassRx, 3rd edition – 2015/16
The *CompassRx* annual public drug plan expenditure report monitors and analyzes cost pressures driving change in prescription drug expenditures in Canada's public drug plans, provides insight into the factors contributing to these changes, and includes a retrospective review of trends since 2011/12. This third edition shows that, after several years of low-to-moderate growth, expenditures increased sharply by 10.4% in 2015/16, mainly driven by the emergence of new hepatitis C treatments

and other high-cost drugs.

The analysis in *CompassRx* focuses on public drug plans participating in the NPDUIS research initiative, which account for approximately one third of total annual spending on prescription drugs in Canada. The NPDUIS initiative includes all provincial public plans — with the exception of Quebec — and Health Canada's Non-Insured Health Benefits drug plan.

Coming soon
A number of studies are planned for publication over 2017-18. Be on the lookout for:

- *A Canadian Budget Impact Analysis on potential savings from Biosimilar drugs*
- *The Canadian Drug Reimbursement Landscape: A Review of Public and Private Markets*

Engagement activities
The NPDUIS team plans to participate in several conferences this spring, including the *Healthy Canada Conference 2017* organized by the Conference Board of Canada. More details will be released in the coming months.

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: Oncaspar (pegaspargase)

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 fourth quarter of 2016, one VCU was accepted for the patented medicine Oncaspar (Baxalta Canada Corporation).

Oncaspar
Oncaspar (pegaspargase) is sold in Canada under Health Canada's Special Access Programme and is used in the treatment of patients with Acute Lymphoblastic Leukemia.

On December 16, 2016, the Vice-chairperson of the Board approved a VCU submitted by Baxalta Canada Corporation (Baxalta) regarding the price of the patented medicine Oncaspar. Under the terms of the VCU, Baxalta agreed to reduce the price of Oncaspar and to offset cumulative excess revenues of

$2,866,888.60 by making repayments to customers that purchased Oncaspar between July 1, 2015 and June 30, 2016, to be determined in amounts proportional to their purchases in the specified timeframe.

Baxalta further agreed to provide notice to customers of a price reduction for Oncaspar, and that this price reduction and repayments are the result of an undertaking to the PMPRB; to provide a reference to the PMPRB website for the complete text of the VCU; to provide copies of these notifications and payments to PMPRB staff; and to notify the PMPRB in the event that patents pertaining to Oncaspar are issued in any future period.

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Summary of the Board's December 14 meeting

The Board held its last meeting of 2016 on December 14.

The Vice-chairperson provided an update on Board operations. Board members were updated on preliminary results from the first phase of the *Rethinking the Guidelines* consultation initiative, and were presented with information on recent and upcoming NPDUIS initiatives, a report on the PMPRB's Blueprint 2020 activities, and the results of a recent employee survey.

The Board's next meeting is scheduled for March 2017.

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