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

January 2016, Volume 20, Issue 1
ISSN: 1920-3713

PMPRB *NEWSletter*

Message from the Executive Director

Greetings and a belated happy New Year on behalf of Board Staff. 2016 promises to be another busy but exciting year at the PMPRB. With the recent release of our much anticipated 2015-2018 Strategic Plan, the PMPRB has clearly signalled the direction it plans to take over the course of the coming three years. As that direction is probably well known at this point to the bulk of our readership and available to the unfamiliar on our website, this year's message will focus more on the accomplishments of the past year than on what the future holds for 2016. Indeed, when I take a moment to reflect back on the year that was, it is startling to realize just how much Staff packed in to those whirlwind 12 months.

One key development that took place early in 2015 and kept many of us busy in the ensuing months was the filing of the Notice of Hearing in the Soliris matter. Not only is this the first notice of hearing to be filed in several years, it is the first such set of proceedings in which both a group of provincial health ministers and the private insurance industry have sought to participate.

The Soliris notice of hearing was followed fairly shortly by another precedent setting event, the release, under the National Prescription Drug Utilization Information System (NPDUIS) banner, of the inaugural CompassRx report, the PMPRP's new flagship annual report and the first of its kind to identify the major drivers behind changes in drug spending in public plans in Canada.

Later in the year, the PMPRB's jurisdiction was bolstered by the Federal Court of Appeal's strongly worded decision that not only validated our approach to regulating all patented drugs, regardless of the identity of the patentee (i.e., both patent licensees and patent owners), but also reaffirmed the constitutionality of our enabling legislation.

Around the same time, our reformatted *Annual Report*, which is much more visually appealing and accessible to readers, was tabled in Parliament. The result of months of creative thinking and

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Notice to Readers

Updates

- A PDF version of the list of patented drug products for human use reported to the PMPRB in 2014 is now available on the PMPRB website.

Upcoming Events

- The public hearing in the matter of the price of the patented medicine Soliris is scheduled to begin on **June 27, 2016**. For more information, please visit

painstaking attention to detail, the revamped report is part of the PMPRB's broader effort to transform and modernize our approach to communications and increase public awareness of our work.

Finally, 2015 also saw the consensual resolution of five investigations in the form of Voluntary Compliance Undertakings. Notably, in addition to a payment to the Crown of over $5.6 million, Sigma-Tau, the manufacturers of Carnitor IV, agreed to distribute over $5.5 million to Canadian customers — mainly hospitals and clinics — who, according to Sigma-Tau's records, purchased the drug at an excessive price.

As is well known by many of our stakeholders, the PMPRB was described as the "consumer protection pillar" of its originating legislation, Bill C-22. That legislation was very contentious at the time, and the credibility and effectiveness of the PMPRB as a regulator was seen as key to ensuring the long-term viability of the policy compromise embodied within it. However, with Canadian patented drug prices outpacing many of our comparators, record-low investment in pharmaceutical research and development (R&D), and public and private payers struggling to cope with an influx of high-cost drugs, many are questioning the effectiveness of the PMPRB in meeting the government's original policy objectives. As we embark on our journey toward reform and renewal, our focus for this year will therefore be on consulting with the public on potential changes to PMPRB Guidelines that will enable us to better deliver on the government's original policy objectives having regard to the realities of the modern day pharmaceutical market.

As the year unfolds, we look forward to working with all our stakeholders in realising our vision of a sustainable pharmaceutical system where payers have the information they need to make smart reimbursement choices and Canadians have access to patented drugs at affordable prices.

Doug Clark
Executive Director, Patented Medicine Prices Review Board

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Patentee submissions in support of the scientific review process

As set out in Section C.2.1 of the PMPRB's *Compendium of Policies, Guidelines and Procedures* (Guidelines), the scientific review of a new patented drug product is based on information from a variety of sources, which can include a patentee submission. Pursuant to that section, patentees may provide Board Staff with a brief submission that clearly explains the rationale for the patentee's proposals regarding the level of therapeutic improvement, drug products identified for comparison purposes, and comparable dosage regimens.

Following the transition in 2015 to electronic patentee submissions, patentees have increasingly sought to include documents in their submissions that are not germane to the issues the Human Drug Advisory Panel is mandated to consider in making its recommendation or that are of materially lower probative value than other available documentation as

the Status of Ongoing Proceedings section of the PMPRB website, which contains the latest public documents in this matter.

Reminders

- The deadline for filing Form 3 is **March 1, 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 our RSS feeds.

Presentations
New Patented Medicines Reported to PMPRB
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determined by the hierarchy of evidence described in Schedule 1 to the Guidelines. Patentees are reminded that Section C.2.1 explicitly directs that their submissions are to be “brief,” and references Schedule 1 to the Guidelines for information about the supporting evidence to be provided.

Board Staff will continue to monitor the quantity and quality of patentee submissions under Section C.2.1 and will implement measures to promote brevity if required.

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2016 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 2016. These factors were based on the actual rate of CPI inflation of 1.5% in 2012, 0.9% in 2013, and 2.0% in 2014.

Benchmark Year	2013	2014	2015
Price-Adjustment Factor	1.044	1.029	1.020

Based on these factors, one can derive:

- a maximum allowable cumulative price increase between 2013 and 2016 of 4.4% for patented drug products with Canadian sales in 2013;
- a maximum allowable cumulative price increase between 2014 and 2016 of 2.9% for patented drug products with Canadian sales in 2014; and
- a maximum allowable cumulative price increase between 2015 and 2016 of 2.0% for patented drug products with Canadian sales in 2015.

The year-over-year price increase cap for the 12-month period ending December 2016 is 3.0% (=1.5 x Actual Inflation in 2014).

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The recognized price source for Germany has changed to Lauer-Taxe

The PMPRB is continuously seeking ways to contribute to sustainable health care spending in Canada through a modern and progressive framework for regulating patented drug prices that keeps pace with the latest developments in the domestic and international pharmaceutical environment. To that end, based on an internal review of current price sources, the PMPRB concluded that Lauer-Taxe is the best and most reliable, publicly available, and comprehensive source of ex-factory prices in Germany.

Accordingly, as announced in the January 2015 *NEWSletter*, the PMPRB has changed its recognized price source for Germany from Rote Liste to Lauer-Taxe **effective January 1, 2016**. Going forward, the PMPRB foreign price verification for Germany will be based on ex-factory prices published in Lauer-Taxe, net of all publicly available rebates.

For further guidance on Lauer-Taxe data submission, patentees are encouraged to refer to the *Formulas for Foreign Price Verification* page on the PMPRB website.

Questions and comments on the Foreign Price Verification Policy can be directed by e-mail to Tanya Potashnik, Director, Policy & Economic Analysis.

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Alternate price sources when recognized sources were unavailable in 2015

In the event that an ex-factory price is not available in the PMPRB list of recognized sources, the PMPRB uses a consistent approach in determining whether an alternate source is acceptable based on a clearly defined decision tree. The alternate source must be publicly available and either include an ex-factory price, or one must be derivable from country-specific regulation of retail and distribution margins.

The following table provides summary statistics for the 2015 filing periods of alternate sources that patentees submitted when ex-factory prices from the PMPRB's recognized sources were unavailable:

Alternate Source*	Country	Outcome	Frequency	Reason
Apoteket	Sweden	Rejected	4 times	Distribution margins for non-reimbursed medicines in Sweden are unregulated, so Apoteket cannot be used to generate ex-factory prices from Sweden.
E-mediat	Switzerland	Accepted	1 time	E-mediat publishes ex-

				factory prices that are publicly available.
IMS MIDAS	All	Accepted	2 times	IMS MIDAS publishes ex-factory prices that are publicly available.
Lauer-Taxe**	Germany	Accepted	3 times	Lauer-Taxe publishes ex-factory prices that are publicly available.
Thériaque	France	Accepted	1 time	Thériaque publishes publicly available prices that are agreed upon with a regulatory authority.

*Alternate sources are accepted on a case by case basis.

**Note that the three instances in which Lauer-Taxe data were accepted as an alternate source occurred before the official adoption of Lauer-Taxe as the PMPRB's recognized source for Germany. As noted in this issue of the *NEWSletter*, Lauer-Taxe is the recognized ex-factory price source for Germany as of January 1, 2016.

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Patentees reporting on R&D and sales for 2015

Patentees are reminded that the deadline for filing Form 3 information on revenues and R&D expenditures is March 1, 2016.

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, 2016, 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: New and upcoming publications

Recent publications

Two new NPDUIS studies were released in December 2015:

- *Private Drug Plans in Canada – Part 1: Generic Market 2005-2013*
  The first in a series of three NPDUIS reports that explore issues in private drug plans in Canada, this instalment focuses on the 2013 calendar year with a retrospective look at trends since 2005, providing an important benchmark for measuring future changes in the generic market. The report assesses the increased use of generic drugs in private drug plans following the loss of market exclusivity for many blockbuster brand-name drugs, and whether there are opportunities for further increases in generic drug use in private plans compared to public plans. The report also identifies cost savings resulting from generic pricing policies implemented by most provincial governments in recent years.

- *New Drug Pipeline Monitor (NDPM) – 7th edition*
  This annual publication provides information on drugs currently under development that may have a significant impact on future drug plan expenditures in Canada. The latest edition provides an update on the 27 pipeline drugs previously identified in the December 2014 edition of the NDPM and identifies 10 new additions to the pipeline list.

Coming soon

- ***Generics 360: Generic Drugs in Canada, 2014***
  This series monitors and reports on the latest developments in generic drug pricing and markets in Canada and compares them with those of other industrialized countries. The series takes a comprehensive approach, covering a broad array of drugs and countries, and analyzes the issue of generic pricing in Canada from various angles, including reference brand-name prices, international generic prices, and market segmentation. This report updates previous PMPRB research, highlighting recent trends in Canadian generic pricing at a national level. Publication is planned for February 2016.

- ***CompassRx 2013/14, 2nd Edition***
  This flagship annual report, first released in 2015, identifies the major factors driving changes in prescription drug expenditures in public drug plans in Canada – an important element in allowing policy makers and researchers to understand current trends and anticipate future cost pressures and expenditure levels. Building on the findings of the first edition, this edition will use the latest available data to highlight trends and changes in these cost drivers over time. Publication is planned for March 2016.

Other upcoming publications

- ***New Drug Launch Monitor, 1st Edition***
  This annual report will identify the top new drugs launched in Canada and the PMPRB's seven comparator countries (France, United Kingdom, Switzerland, Sweden, Germany,

United States, and Italy). The *New Drug Launch Monitor* will include international drug price comparisons, market penetration information, and will assess the drugs' entry into international markets with respect to geographic location, timing, and availability in Canada.

- ***Orphan Drug Launch Monitor, 1st Edition***
  This annual report will focus on orphan drugs (i.e., drugs intended to treat rare diseases) that have received market approval in the United States and the European Union, assessing the extent to which these drugs are available in Canada, and reporting on pricing, market penetration, patent availability, as well as decisions made with respect to the launch of these drugs.

For more information on future research topics and publications, see the NPDUIS Research Agenda on the PMPRB website.

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Voluntary Compliance Undertakings: Dificid (fidaxomicin) and Zaxine (rifaximin)

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 2015, two VCUs were accepted: for the patented medicines Dificid (Merck Canada Inc.) and Zaxine (Salix Pharmaceuticals Inc.)

Dificid

On December 10, 2015, the Chairperson of the Board approved a VCU submitted by Merck Canada Inc. (Merck) regarding the price of the Dificid 200 mg tablet. Under the terms of the VCU, Merck agreed to offset cumulative excess revenues it received by making a payment to the Government of Canada in the amount of $400,000, reducing the list price of Dificid, and ensuring the price of the Dificid 200 mg tablet remains within the PMPRB's pricing guidelines in all future periods in which Dificid is under the PMPRB's jurisdiction.

Dificid (fidaxomicin) is used to treat *Clostridium difficile* infection in adults 18 years of age and older.

Zaxine

On December 10, 2015, the Chairperson of the Board approved a VCU submitted by Salix Pharmaceuticals Inc. (Salix) regarding the price of the Zaxine 550 mg tablet. Under the terms of the

VCU, Salix agreed to offset cumulative excess revenues it received as of February 4, 2015 by making a payment to the Government of Canada in the amount of $915,738.19, reducing the list price of Zaxine, and ensuring the price of the Zaxine 550 mg tablet remains within the PMPRB's pricing guidelines in all future periods in which Zaxine is under the PMPRB's jurisdiction.

Zaxine (rifaximin) reduces the risk of overt hepatic encephalopathy recurrence in patients 18 years of age or older.

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Summary of the Board's November meeting

The Board held its final meeting of 2015 on November 12.

The Chairperson provided an update on Board operations and discussed future consultations on ways to modernize and simplify the PMPRB's *Compendium of Policies, Guidelines and Procedures* (Guidelines). Board members received updates on the latest proposed changes to the Guidelines, recent and upcoming NPDUIS research initiatives, and the PMPRB's new, more proactive communications strategy.

The Board's next meeting is scheduled for February 3, 2016.

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