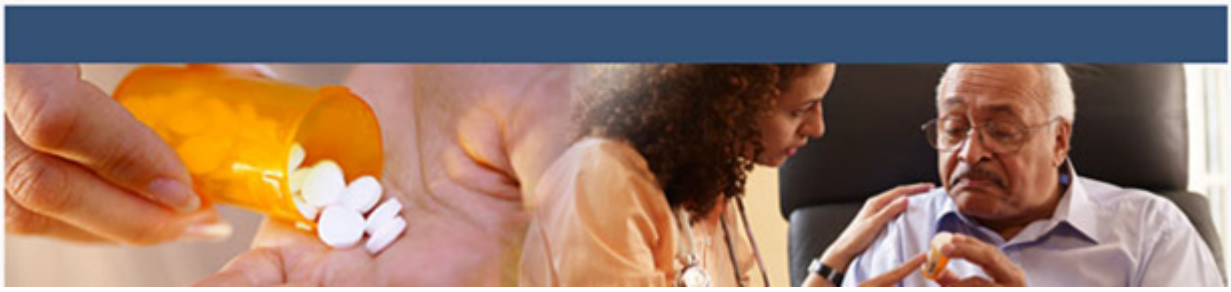
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés



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PMPRB *NEWSletter*

New Release: PMPRB *Strategic Plan*

As noted in the April 2015 *NEWSletter*, the PMPRB has been engaged over the last year in a strategic planning process to set a fresh course for the next three years. We are pleased to announce the 2015-2018 PMPRB *Strategic Plan* is now available on our website.

To be notified of the release of other key PMPRB publications and initiatives, please follow us on Twitter or subscribe to our RSS feed.

[Table of Contents]

New Release: *2014 PMPRB Annual Report*

The 2014 *Annual Report* of the PMPRB was tabled by the federal Minister of Health with the Clerks of the House of Commons and Senate on December 7, 2015.

The 2014 *Annual Report* provides detailed information on the PMPRB's regulatory activities; patentees' compliance with the Board's price Guidelines; sales and price trends of patented drugs in Canada, including international price comparisons, trends in all drug expenditures and spending on pharmaceutical research and development (R&D).

The *2014 PMPRB Annual Report* is now available on our website.

Highlights

- Sales of patented drug products in Canada increased by 3.1% in 2014 to $13.7 billion. This was driven by greater sales of existing and new drugs, which offset a decrease in sales of drugs whose patents expired in 2014.
- The average price of patented drug products in Canada was stable in 2014, increasing at a lower rate than inflation, as measured by the Consumer Price Index, with no impact on sales growth.
- Canadian prices were third-highest among the Patented

Table of Contents

Notice to Readers

- As of December 15, 2015 the PMPRB will no longer be issuing e-bulletins. To be notified of new announcements, publications, and other initiatives, please follow us on Twitter or subscribe to our RSS feed.
- The public hearing in the matter of the price of the patented medicine Soliris is scheduled to begin on **June 27, 2016**.

Medicine Prices Review Board's seven comparator countries in 2014, lower than prices in Germany and the United States, and higher than prices in France, the United Kingdom, Italy, Sweden and Switzerland.
- Spending on pharmaceutical R&D in Canada declined to 4.4% for patentees and 5.0% for Rx&D member companies, the lowest rate since the Patented Medicine Prices Review Board began its reporting function in 1988.
- A total of 1,363 patented drug products for human use were under the Patented Medicine Prices Review Board's jurisdiction in 2014, including 103 newly reported drugs. Sales of patented drug products accounted for 59.6% of all drug sales in 2014.
- In 2014, the Patented Medicine Prices Review Board had 61 open investigations into excessive drug pricing.
- Five Voluntary Compliance Undertakings were entered into in 2014, with over $2.7 million in excess revenues paid back by patentees to the Government of Canada.
- In January 2015, the Patented Medicine Prices Review Board issued a Notice of Hearing in the matter of the Canadian price of the patented medicine Soliris. Proceedings are ongoing.

[Table of Contents]

Federal Court of Appeal Decision in salbutamol HFA

On November 6, 2015, the Federal Court of Appeal issued its decision on appeals regarding the PMPRB's jurisdiction related to salbutamol HFA and other products of ratiopharm Inc. (now Teva Canada Limited) and to a number of products sold in Canada by Sandoz Canada Inc.

The Court of Appeal upheld the finding of the original Board Panel decision that held that Sandoz and ratiopharm were patentees under section 79 of the *Patent Act* (the Act) because they were exercising a right to sell their products under licenses from the owners of a number of patents. In broadly interpreting section 79 of the Act, the Federal Court of Appeal found the construction of the language in the Act that relates to the PMPRB must focus on the persons in need of protection from excessive pricing (consumers) and not on those in a position to cause such pricing (patentees).

The decision also reaffirmed the constitutionality of sections 79-103 of the Act. In this regard, the Federal Court of Appeal found that the Board correctly held that the control of prices charged for patented medicines comes within the jurisdiction conferred on Parliament over patents under subsection 91(22) of the *Constitution Act 1867* when applied to patent holders, patent owners, or any other persons exercising rights under patents (such as licensees).

The full text of the Federal Court of Appeal decision can be found on the Federal Court of Appeal website.

[Table of Contents]

Presentations
New Patented Medicines Reported to PMPRB
NPDUIS
Hearings
VCUs
Contact us
Visit our website
Follow Us
Canada

Upcoming Notice and Comment: Incremental reforms to *Compendium of Policies, Guidelines and Procedures*

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.

To ensure the framework continues to have a positive impact for consumers and is responsive — within an appropriate timeframe — to relevant developments, two new proposals have been identified to amend the *Compendium of Policies, Guidelines and Procedures*.

- "Reasonable Relationship Test" (Schedule 4) amendment
- "List Price Relative to Maximum Average Potential Price (MAPP) Verification" amendment

On December 4, 2015, a Notice and Comment was posted on the PMPRB website seeking stakeholder comment and feedback on proposals related to the two initiatives.

Based on stakeholder feedback, further consultation may be undertaken on the proposed text in the Guidelines, as well as on operational/transitional details, prior to final adoption and implementation.

Questions and comments on this Notice and Comment initiative can be directed by e-mail to Tanya Potashnik, Director, Policy and Economic Analysis.

[Table of Contents]

Update: Germany Recognized Price Source

As announced at the December 2014 outreach sessions in Montreal and Toronto, and in the January and July 2015 *NEWSletter*s, the recognized (i.e., usual and customary) price source for Germany will be changing from the Rote Liste to the Lauer-Taxe **effective January 2016**.

Board Staff provided a detailed briefing on this subject during the 2015 outreach sessions in Montreal on November 5 and in Toronto on November 6. The backing-out formulas for Foreign Price Verification have now been updated to reflect this change.

In the meantime, as noted in the January 2015 *NEWSletter*, prices from the Rote Liste will continue to be accepted for 2015 filings. Patentees impacted by the change of foreign price source for Germany will be notified by Board Staff in order to support patentees in their compliance efforts.

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

[Table of Contents]

NPDUIS update: Publications and engagement activities

New publications

- ***New Drug Pipeline Monitor (NDPM) – 7th edition***
  This edition provides a list of drugs currently under development that may have a significant impact on federal, provincial, and territorial drug plan expenditures in Canada.

- ***Private Drug Plans in Canada – Part 1: Generic Market 2005-2013***
  The first in a series of three reports that analyze trends in Canadian private drug plans, this study provides insight into the evolving generic market, including information on market shares, reimbursed unit costs, and dispensing patterns and their impact on overall prescription costs. A comparative analysis with Canadian public drug plans and select international markets is included.

Upcoming publication

- ***Generic Drug Prices in Canada: 2014***
  Building on previously published NPDUIS research, this report will provide an update on generic drug pricing in Canada. As with previous reports, it compares Canadian generic drug prices and markets with those in other industrialized countries. Publication is planned for January 2016.

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

Engagement Activities

The NPDUIS group continued to expand its engagement activities over the past few months, meeting with a variety of interested stakeholders.

On September 29, the PMPRB hosted a webinar with federal, provincial, and territorial public plan representatives to present the results of a cost impact analysis of the draft *Tamper-Resistant Properties of Drugs Regulations* and answer questions related to the methodology and results.

On October 6, the NPDUIS group held its second annual invitational Researchers Forum with academics and subject-matter experts to discuss current areas of policy-relevant research in the pharmaceutical marketplace. Attendees presented the results of a number of current studies and discussed emerging areas for future consideration.

On October 8, the PMPRB held its annual face-to-face meetings with the NPDUIS Advisory Committee. Staff presented preliminary results of a number of studies and explored topics for future analytical priorities.

[Table of Contents]

Voluntary Compliance Undertakings: Carnitor IV (levocarnitine) and Loprox (ciclopirox olamine)

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.

In the third quarter of 2015, two VCUs were accepted: for the patented medicines Carnitor IV (Sigma-Tau Pharmaceuticals Inc.) and Loprox (Valeant Canada Inc.)

Carnitor IV

On September 23, 2015, the Chairperson of the Board approved a VCU submitted by Sigma-Tau Pharmaceuticals Inc. (Sigma-Tau) regarding the price of Carnitor IV. Under the terms of the VCU, Sigma-Tau agreed to offset cumulative excess revenues they received between July 2001 and January 2015 by making a payment to the Government of Canada in the amount of $5,688,632.64, and distributing $5,522,604.96 to Canadian customers — mainly hospitals and clinics — who purchased Carnitor IV at an excessive price based on Sigma-Tau's historic records.

There is no provision for a price reduction for Carnitor IV as, with no remaining valid patents as of January 2015, the medicine is no longer under the jurisdiction of the PMPRB.

Carnitor IV (levocarnitine) prevents and treats carnitine deficiency in patients with end-stage renal disease who are undergoing dialysis.

Loprox

On November 2, 2015, the Chairperson of the Board approved a VCU submitted by Valeant Canada LP regarding the price of Loprox 10mg/millilitre (ciclopirox olamine). Under the terms of the VCU Valeant Canada Inc. agreed to offset cumulative excess revenues they received as of December 31, 2014 by making a payment to the Government of Canada in the amount of $23,947.35, and ensuring the price of Loprox 10 mg/millilitre remains within the PMPRB's pricing guidelines in all future periods in which Loprox is under the PMPRB's jurisdiction.

Loprox (ciclopirox olamine) is indicated for the topical treatment of dermal infections.

[Table of Contents]

Soliris pre-hearing conferences

The Board Panel held public pre-hearing conferences on September 16 and October 28, 2015 in the matter of the price of the patented medicine 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 these pre-hearing conferences was to address various motions filed by the parties. The Panel issued decisions on these motions on October 5, 2015 and November 24, 2015.

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.

[Table of Contents]
