



October 2013, Volume 17, Issue 4
ISSN: 1920-3713

PMPRB NEWSletter

Since our last issue...

August 28: The PMPRB released a new NPDUIS report, *Analytical Snapshot: International Generic Price Comparison, Early 2011*.

September 5: Michelle Boudreau and Tanya Potashnik met with representatives of the Canadian Life and Health Insurance Association (CLHIA) in Toronto.

September 11: Tanya Potashnik and Elena Lungu met with delegates from the Canadian Generic Pharmaceutical Association (CGPA) in Toronto.

September 12: The Board held its quarterly meeting.

September 16: The Human Drug Advisory Panel (HDAP) held its quarterly meeting.

September 26: Executive Director Michelle Boudreau left the PMPRB for a new career opportunity.

October 2: Tanya Potashnik spoke at the Canadian Association of Healthcare Reimbursement (CAHR) National Day in Ottawa.

October 8: Tanya Potashnik and Elena Lungu presented information on upcoming NPDUIS reports to representatives of the Canadian Pharmacists Association (CPhA).

October 9–10: The NPDUIS-CIHI Steering Committee meeting was held in Ottawa.

October 16: The 2012 PMPRB Annual Report was tabled with the Clerks of the House of Commons and Senate.

October 18: The new CPI Initiative was announced; interested parties were invited to submit their written comments on the new initiative to the PMPRB by November 15.

October 22–24: Tanya Potashnik attended the Market Access World USA 2013 in Boston.

Table of Contents

- [Since our last issue...](#)
- [News from the Chairperson](#)
- [Comings and Goings](#)
- [2012 Annual Report](#)
- [NPDUIS Update](#)
- [Consequential Amendments to the Patented Medicines Regulations](#)
- [Voluntary Compliance Undertakings](#)
- [Hearings – Update](#)
- [Summary of the September 12, 2013, Board Meeting](#)

Upcoming Events

November

- November 1: Doug Clark, Ginette Tognet, Anna Chodos, Tanya Potashnik and Robert Squires will meet with representatives of sanofi pasteur
- November 4: Human Drug Advisory Panel (HDAP) quarterly meeting
- November 6–8: Tanya Potashnik will attend the 9th Annual Health Insurance Invitational Forum in Cambridge, Ont.
- November 13–14: Tanya Potashnik will participate in the 12th Annual Market Access Summit in Toronto

October 28: Douglas Clark began work as the new Executive Director of the PMPRB.

October 29–30: Delia Lewis attended the Canadian Institute's 12th Annual Forum on Pharma Patents: *Practical Strategies for Prosecuting and Litigating Pharmaceutical Patents* in Toronto.

October 30–31: The Chairperson attended the Conference Board of Canada's 2nd Summit on Sustainable Health and Health Care in Toronto.

October 30–31: The Regulatory Affairs and Outreach Branch held outreach sessions for patentees in Montreal and Toronto.

See our [News and Events](#) page to access recent presentations and keep up-to-date with all PMPRB activities.

News from the Chairperson

My colleagues and I are very pleased to welcome Douglas Clark as the PMPRB's new Executive Director.

As a career public servant, Doug brings a wealth of knowledge to the PMPRB, vast experience in the area of intellectual property policy and an in-depth understanding of the inner workings of the pharmaceutical industry. Doug joins the PMPRB from Industry Canada where he held several positions, including Assistant Deputy Commissioner of Civil Matters at the Competition Bureau and Director of the Patent and Trademark Policy Directorate.

Doug will be a great asset to the PMPRB as the organization moves forward on its priorities and continues to develop its community of stakeholders.

We take this opportunity to thank Michelle Boudreau for her contribution to the PMPRB over the last three years and wish her success in her future endeavours.

Mary Catherine Lindberg

Comings and Goings

We are pleased to welcome Jean-Sébastien Veilleux Forget, Blake Wladyka, Denis Cadieux and Christine Ouellette to the Corporate Services Branch (CSB) of the PMPRB. Jean-Sébastien is the new Human Resources Generalist; Blake Wladyka is supporting the Records Management System implementation project; Denis Cadieux is working with the Financial Services Team; and Christine Ouellette is currently the Administrative Assistant for the CSB.

We would like to extend our congratulations and appreciation to Martine Richard, who has taken on new challenges as General Counsel at the Office of the Conflict of Interest and Ethics Commissioner. Best wishes also go to John Buffone, who recently left the PMPRB for a new career opportunity at Employment and Social Development Canada.

In August our colleague Normand Savard, Chief of Finance, passed away. Normand had been at the PMPRB for 15 years.

December

- December 4: Quarterly Board meeting
- See our [Calendar of Events](#) to see all upcoming events.



Presentations



Calendar of Events



New Patented Medicines Reported to PMPRB



NPDUIS



Hearings



VCUs



Contact us



Visit our website



Follow Us

Canada

He will long be missed, as a mentor and a friend. His family is in our thoughts.

2012 Annual Report

The PMPRB's Annual Report for the year ending December 31, 2012, was tabled by the Minister of Health with the Clerks of the House of Commons and Senate on October 16, 2013.

The Annual Report details the regulatory activities of the PMPRB and provides information on sales and price trends of patented drugs sold in Canada. It also provides data on pharmaceutical R&D expenditures in Canada.

For the second year, the PMPRB also released a summarized version of the full Annual Report. *The PMPRB Annual Report 2012: In Brief* provides stakeholders/subscribers with all of the pertinent information contained within the Annual Report in a condensed form. Both reports are available in PDF and HTML formats and can be accessed from our homepage.

In 2012, sales of patented drug products in Canada declined slightly by 0.3% to \$12.8 billion. The share of patented drug products as a percentage of total sales rose from 58.6% in 2011 to 59.3% in 2012. The prices of patented drug products sold by patentees, as measured by the Patented Medicines Price Index, increased, on average, by 0.6% and the Consumer Price Index rose by 1.5%. Canadian prices were the fourth highest of the seven comparator countries, lower than prices in Switzerland, Germany and the US.

Patentees reported 82 new patented drug products to the PMPRB in 2012. A total of 1,328 patented drug products for human use were under the PMPRB's jurisdiction in 2012. Up to May 31, 2013, the Board approved 15 Voluntary Compliance Undertakings (VCUs). The Board issued decisions and/or orders effectively completing matters: Copaxone (redetermination) on price; Pentacel and Quadracel on remedy; Sandoz Canada Inc., on failure to file; and Tactuo on price. There were no decisions pending. Two matters remained before the Board: Apotex Inc., on failure to file, and Apo-Salvent CFC Free, on price.

Patentees reported total R&D expenditures of \$894.8 million, a decrease of 9.8% over 2011. Members of Rx&D (Canada's Research-Based Pharmaceutical Companies) reported \$782.8 million in R&D expenditures, a 13.1% decline over 2012. The ratio of R&D-to-sales also decreased for all patentees from 5.6% in 2011 to 5.3% in 2012, while the R&D-to-sales ratio for members of Rx&D declined from 6.7% in 2011 to 6.6% in 2012.

NPDUIS Update

Following the recommendations of the participating jurisdictions, NPDUIS is continuing to monitor and report on generic international price comparisons. As part of this work, the PMPRB published a new report entitled [Analytical Snapshot – International Generic Price Comparison: Early 2011](#) in August.

Building on previous published analyses, this snapshot compares generic drug prices in Canada with those of other industrialized

countries. The report highlights the changes in Canadian generic pricing that occurred between 2008 and the first quarter of 2011. Generic prices from IMS Health's MIDAS™ database and the Ontario formulary were used to conduct price comparisons. Future work planned for 2014/15 will provide a more comprehensive assessment of the current generic prices in Canada relative to international levels.

In addition to this report, two other studies are planned for release in 2013:

The Drivers of Prescription Drug Expenditures – A Methodological Report

This methodological report provides insight into the many factors that drive prescription drug expenditures. It approaches the topic on several levels: first listing and broadly explaining each cost driver; then outlining the basic approach used for the analysis; and finally delving into the complex methodology used in the analysis. Policy decision makers will appreciate the general overview, while researchers will be provided with the tools required to use (and adapt) this methodology for their own analyses.

The New Drug Pipeline Monitor – Fifth Edition

This is the latest edition of the New Drug Pipeline Monitor (NDPM). The NDPM provides information on drugs currently under development that may have an impact on Canadian drug plan expenditure. The drugs are selected based on their phase of development, their indication and mechanism of action, and their potential impact on clinical practice.

See the [NPDUIS homepage](#) for links to the NPDUIS Research Agenda and all recently released analytical studies.

Consequential Amendments to the Patented Medicines Regulations

Last June, Health Canada amended the *Food and Drugs Act* ([Canada Gazette, Part II](#)), under the *Jobs, Growth, and Long-term Prosperity Act*, to enable the Minister of Health to establish a Prescription Drug List (PDL).

The PDL will replace Schedule F in the *Food and Drug Regulations*. Currently, Schedule F lists the medicinal ingredients that require a prescription when sold as a drug in Canada. Adding or removing medicinal ingredients requires approval from the Governor in Council. The creation of the PDL will now eliminate the need for GIC approval, bringing greater efficiency to the process.

The amendments to the *Food and Drug Regulations* resulted in additional consequential amendments to the *Patented Medicines Regulations*, since there is a reference to Schedule F drugs in both paragraphs 4(2) and 4(3). The amendments to the *Patented Medicines Regulations* ensure that the paragraphs will track the language used in the *Food and Drug Regulations* when referencing “prescription drug”.

The amendments will come into force on December 19, 2013. At this time, the three PMPRB documents referencing Schedule F will also be amended and posted on the website: the *Compendium of Policies, Guidelines and Procedures*, the *Patentee's Guide to Reporting*, and Form 1 – *Medicine Identification Sheet*.

The PMPRB took the opportunity to amend the definition of "Notice of Compliance" found in s. 2 of the *Patented Medicines Regulations* to include a notice issued under the new C.08.004.01 of the *Food and Drug Regulations* for an extraordinary use new drug (EUND). The *Patented Medicines (Notice of Compliance) Regulations* (PMNOC Regulations) had been amended in March 2011 to include EUND. The consequential amendments that should have been made to the *Patented Medicine Regulations* at the time have been included in this round of regulatory amendments.

Voluntary Compliance Undertakings

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 Board Staff concludes, following an investigation, that the price set forth 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.

Since the July issue of the *NEWSletter*, there have been no VCUs.

See the full list of the VCUs at [Voluntary Compliance Undertakings](#)

Hearings – Update

The PMPRB's regulatory mandate is to ensure that prices charged by patentees for their patented medicines sold in Canada are not excessive.

In the event that the price of a patented medicine appears to be excessive, the Board can hold a public hearing and, if it finds that the price is excessive, it may issue an order to reduce the price and to offset revenues received as a result of excessive prices. Board decisions are subject to judicial review in the Federal Court of Canada.

Status of Board Proceedings

Patented Drug Product	Indication / Use	Patentee	Date of Notice of Hearing	Status
Apo-Salvent CFC-Free	Asthma	Apotex Inc.	July 8, 2008	Ongoing

Copaxone–Redetermination	Multiple sclerosis	Teva Canada	New panel struck May 2013 Notice: June 28, 2013	Dates on the hearing on the merits to be announced
ratio-Salbutamol HFA	Asthma	ratiopharm Inc. (now Teva Canada)	July 18, 2008	Board Order: May 27, 2011 Federal Court hearing: November 4–5, 2013

Patentee	Issue	Date of Notice of Application	Status
Apotex Inc.	Failure to file (jurisdiction)	March 3, 2008	Ongoing
ratiopharm Inc. (now Teva Canada)	Failure to file (jurisdiction)	August 28, 2008	Board Order: June 30, 2011 Amended: October 17, 2011 Federal Court hearing: November 4–5, 2013
Sandoz Canada Inc.	Failure to file (jurisdiction)	March 8, 2010	Board Decision: August 1, 2012 Re-issued: October 1, 2012 Federal Court hearing: November 19-20, 2013

Get more information on Board decisions and orders at [Decisions and Orders](#).

Summary of the September 12, 2013, Board Meeting

The Board held a strategic planning session during which it identified key issues that it will be addressing in 2014/2015. The issues included addressing price review and reporting obligations. Board Staff is currently conducting an analysis of the legislation and Guidelines, identifying issues, evaluating the impact of any proposed changes on pricing, examining the risks, vis-à-vis the PMPRB's overall framework, and identifying an effective approach and consultation vehicles.

The Board's next quarterly meeting is scheduled for December 4, 2013.

For additional information, please contact the Director, Board Secretariat and Communications, at 1-877-861-2350 or 613-954-8299 or at sylvie.dupont@pmprb-cepmb.gc.ca.

See the [Summary of Board Meetings](#) page for summaries of previous quarterly meetings.
