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

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PMPRB NEWSletter

PMPRB Town Hall Meeting

PMPRB staff held a Town Hall meeting on October 1 at the Ottawa Convention Centre.

As the PMPRB is engaged in a three-year strategic planning exercise, the point of departure for the day's discussion involved staff taking a fresh look at the organization's vision and mandate. Later in the day, staff was sounded out on potential new strategic priorities for the PMPRB and discussed ideas on how to operationalize them going forward.

To lay the groundwork for the day's discussion and help put the entire exercise into its broader context, staff was joined during the first half of the morning by a distinguished panel of experts who shared their unique perspectives on the Canadian pharmaceutical pricing and reimbursement environment. The panel had a lively discussion on various domestic and international issues impacting the current and future work of the PMPRB. We would like to extend our gratitude to the following panellists for taking part in this event and sharing their respective insights:

- Marc-André Gagnon - Assistant Professor, Carleton University, School of Public Policy & Administration
- Chander Sehgal - MBA, Director, Common Drug Review (CDR) at the Canadian Agency for Drugs and Technologies in Health (CADTH)
- Kevin Wilson - Executive Director, Drug Plan & Extended Benefits Branch, Saskatchewan
- Durhane Wong-Riger - President and CEO of the Institute for Optimizing Health Outcomes
- Johanne Brosseau - MBA, Principal, Mercer

The Town Hall is part of a strategic planning process which will culminate in the presentation of a business plan to the Board in the new year.

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Notices to Readers

Now Available

- The HDAP Terms of Reference are now available on the PMPRB website.

Must Read

- Doug Clark's *Meet the Manager* interview will be featured in the November edition of IMS Brogan's *Provincial Reimbursement Advisor*.

Upcoming Events

- Tanya Potashnik will be attending the 10th Annual Health Insurance Invitational Forum in

New Staff Members

We would like to extend a warm welcome to Jeffrey Biggs, Brad Gash, Branka Pejcic-Karapetrovic and Parul Shah, all of whom joined the PMPRB in the last quarter. Jeff, Brad and Branka are the newest members of the Policy and Economic Analysis Branch, and Parul Shah joined the Legal Services Branch as counsel.

Jeffrey Biggs is now the Manager of Policy Development. Before joining the PMPRB, Jeff worked as an economist for the Canadian Forest Service. He brings a breadth of experience, including eight years of work in academia, the non-profit sector and private consulting.

Brad Gash is a senior economic analyst with the NPDUIS team. Brad previously worked for the Audit and Evaluation Sector of Aboriginal Affairs and Northern Development Canada. Brad has a strong grounding in population health and program evaluation.

Branka Pejcic-Karapetrovic is currently working for the Policy and Economic Analysis Branch as a pharmaceutical analyst. Branka is a medical doctor with a PhD in medical sciences. Her background includes working as a medical advisor with Health Canada's Assisted Human Reproduction Implementation Office.

Parul Shah came to the PMPRB courtesy of the Competition Bureau where she was litigation counsel on a number of high profile competition law cases. Prior to that, she completed a clerkship at the Supreme Court of Canada with Madam Justice Louise Charron and acted as counsel in legal Services at Health Canada.

We are very fortunate to have these talented individuals join our experienced, professional staff.

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PMPRB Appears Before the Senate Standing Committee on National Finance

On October 21, 2014, the PMPRB was invited to appear before the Senate Standing Committee on National Finance on the issue of the Main Estimates. Doug Clark, Executive Director, answered questions on the Main Estimates and other relevant topics, including drug pricing, R&D levels and Canada's free-trade agreement with the European Union.

Click on the following link to view the entire session:

http://senparlvu.parl.gc.ca/Guide.aspx?viewmode=4&categoryid=484&currentdate=2014-10-21&languagecode=12298&eventid=9728#

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Cambridge on November 5–7.

- Doug Clark will be speaking at the 13th Annual Market Access Summit in Toronto on November 12–13. Tanya Potashnik and Jeffrey Biggs will be attending the meeting and Tanya will be participating in a panel discussion.
- Tanya Potashnik will be attending the PPRI Network Meting in The Hague, the Netherlands on November 20–21.
- Tanya Potashnik will be meeting with the Drug Policy Advisory Committee (DPAC) on November 24.
- Doug Clark will be speaking at the Green Shield Canada Board of Directors Education Session in Toronto on November 24.
- Doug Clark and Tanya Potashnik will be presenting the NPDUIS Research Agenda at a meeting with DPAC hosted by CADTH in Ottawa on November 25.
- The PMRPB will be attending an F/T/P meeting on Health Canada's new Orphan Drug Regulations in Victoria on December 10–11.

Reminders

- The Regulatory Affairs and Outreach Branch will be holding Outreach Sessions for Patentees in Montreal on December 2 and in Toronto on December 3.

Newly Enhanced PMPRB Website

We are pleased to announce that the PMPRB website now has a fresh new look. The enhanced site is more accessible and has a scalable, mobile-friendly format. Although the architecture is a little different, the content is largely the same.

Over the next few months we will be continuing to improve the navigation and functionality. We invite you to take some time to explore the new format and update your bookmarks.

If you have any comments, please contact us. We always welcome your feedback.

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Appeal Update: ratio-Salbutamol, ratiopharm and Sandoz

On June 25, 2014, the Attorney General of Canada appealed the May 27, 2014, Federal Court decisions in Sandoz Canada Inc. and ratiopharm Inc. which allowed the applications for judicial review and referred the matters back to the Patented Medicine Prices Review Board ("Board"). The appeal books were recently filed and we will keep you posted as to the other key dates as soon as they are available.

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Voluntary Compliance Undertakings: Lodalis

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 2014, one VCU was accepted, for the patented medicine Lodalis.

Lodalis, Valeant Canada Inc.

On September 17, 2014, the Chairperson of the Board approved a VCU submitted by Valeant Canada LP (Valeant) regarding the price of Lodalis. Under the terms of the VCU, Valeant agreed to make a payment to the Government of Canada in the amount of $63,199.56 to offset cumulative excess revenues received by Valeant as of December 31, 2013. In addition, Valeant agreed to offset any excess revenues received by Valeant from January 1, 2014, to September 17, 2014, as calculated by Board Staff.

The price of this drug product is to remain within the Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Lodalis (colesevelam hydrochloride) is indicated for the reduction of cholesterol blood level in patients with hypercholesterolemia

Presentations
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(Frederickson Type IIa) as an adjunct to diet and lifestyle changes, when the response to these measures has been inadequate, in patients who are not adequately controlled with an HMG-CoA reductase inhibitor (statin) alone, or who are unable to tolerate a statin.

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NPDUIS Update

Upcoming Publications

Three new NPDUIS studies are earmarked for publication over the coming months:

- *Generic Drug Prices in Canada: 2013*
  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 to take place before the end of year.

- *New Drug Pipeline Monitor (NDPM) – 6th edition*
  This edition will provide a list of drugs currently under development that may have a significant impact on federal, provincial and territorial drug plan expenditure in Canada. Publication is planned before the end of year.

- *Public Drug Plan Expenditure (PDPEx) Report*
  This is the first edition of an annual report detailing current trends in prescription drug expenditures in a select number of Canadian public drug plans. This report is an essential tool for anyone interested in the forces driving change in prescription drug costs. It will provide insight into primary cost pressures and shifts in utilization, cost and pricing trends. Publication is planned for the New Year.

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

Engagement Activities

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

On August 21, the NPDUIS group organized a researchers' forum with interested academics and policy experts to discuss current research into pharmaceutical use in Canada. Attendees presented the results of a number of current studies and discussed emerging areas for future study.

On September 16, the PMPRB hosted a webinar for NPDUIS participating jurisdictions to walk them through the highlights of the PMPRB *2013 Annual Report* and the details of the NPDUIS cost driver model used for calculating prescription drug expenditures.

On October 3, the PMPRB hosted an informal meeting of Canadian researchers organized by Dr. Steve Morgan, Director of the UBC Centre for Health Services and Policy Research.

Discussion focused on high-cost drugs and their potential impact on the sustainability of the Canada's healthcare system.

On October 7, 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 analysis.

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2013 PMPRB Annual Report is Now Available

The PMPRB's *2013 Annual Report* was tabled by the Minister of Health with the Clerks of the House of Commons and Senate on September 15, 2014.

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. A condensed version of the full *Annual Report*, the PMPRB *Annual Report 2013: In Brief* provides stakeholders/subscribers with all of the pertinent information contained within the Annual Report. Both reports are available on our website.

Highlights

In 2013, sales of patented drug products in Canada increased by 6.5% to $13.6 billion. The share of patented drug products as a percentage of total sales rose from 59.3% in 2012 to 61.8% in 2013. The prices of patented drug products sold by patentees, as measured by the Patented Medicines Price Index, increased, on average, by 0.5% and the Consumer Price Index rose by 0.9%. Canadian prices were the third highest of the seven comparator countries, lower than prices in Germany and the US.

Patentees reported 115 new patented drug products to the PMPRB in 2013. A total of 1,343 patented drug products for human use were under the PMPRB's jurisdiction in 2013. Up to May 30, 2014, the Board approved 6 Voluntary Compliance Undertakings (VCUs) resulting in price reductions and a total of $10.5 million in excess revenues offset by way of payment to the Government of Canada. The Board completed two matters: Copaxone (redetermination) on price; 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. Federal Court decisions were issued in three matters: ratio-Salbutamol HFA, ratiopharm Inc. and Sandoz Canada Inc.

Patentees reported total R&D expenditures of $752.8 million, a decrease of 15.9% over 2012. Members of Rx&D (Canada's Research-Based Pharmaceutical Companies) reported $652.0 million in R&D expenditures, a decrease of 16.7% over 2012. The ratio of R&D-to-sales also decreased for all patentees from 5.3% in 2012 to 4.5% in 2013, while the R&D-to-sales ratio for members of Rx&D declined from 6.6% in 2012 to 5.4% in 2013.

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Summary of the Board's September 18, 2014, Meeting

The Board held its third quarterly meeting on September 18, 2014.

Board Members discussed an environmental scan of the external and internal challenges facing the PMPRB moving forward, including R&D and price levels, non-transparent pricing, orphan drugs, recent cost containment initiatives in Canada and internationally and the recently completed text of the Comprehensive Economic and Trade Agreement (CETA). The Chairperson also provided an update on the Board operations.

Board Members were updated on recent NPDUIS initiatives, including the Researchers' Forum held in late August, and presentations were made on the recently enhanced PMPRB website and the agenda for the October 1 Town Hall.

The Board's next meeting is scheduled for December 15, 2014.

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