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

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PMPRB NEWSletter

New Board Member Appointed

I am pleased to welcome Carolyn Kobernick to the PMPRB as the newest member of the Board. Ms. Kobernick is an accomplished lawyer and distinguished former public servant. Prior to her retirement in 2013, she was Assistant Deputy Minister, Public Law, at the Department of Justice.

During her career in the public service, Ms. Kobernick played an important role in many high-profile and crosscutting national issues. She was Senior General Counsel on the Mackenzie Valley Pipeline File and the Government's Senior Legal Advisor on the Sponsorship Inquiry. She was also Chair of the National Legal Advisory Committee and Departmental Champion for Aboriginal People and Gender Equity.

Ms. Kobernick's knowledge and depth of experience will be an asset to our Board. My colleagues and I look forward to working with her.

Mary Catherine Lindberg

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Staffing Changes

Sylvie Dupont's retirement

In June, Sylvie Dupont, Director of the Board Secretariat and Communications, retired from the public service. Sylvie had worked at the PMPRB almost since its inception. Throughout that time, she worked closely with the Board Members and Chairpersons. Sylvie played a vital role in many hearing processes and in orchestrating the consultation process for the most recent version of the *Compendium of Policies, Guidelines and Procedures*. In addition to overseeing the publication of all of the PMPRB communications products, Sylvie championed the development of the PMPRB website and liaised with Health Canada, other Government departments and the public. We would like to express our heartfelt gratitude for her dedication and all the excellent advice she provided over many years.

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Notice to Readers

What's New at the PMPRB

- Patentees can now file Form 2 online.

Updates

- The *Compendium of Policies, Guidelines and Procedures* has been updated for 2014. Revisions include minor changes to Schedule 1 and Schedule 9.
- The Regulatory Filing Initiative is currently proceeding in accordance with the Federal Regulatory Development Process. Pre-publication in *Canada Gazette*, Part I, is anticipated for the fall of 2014.

Guillaume Couillard joins the PMPRB

We would like to extend a warm welcome to Guillaume Couillard. Guillaume joined the PMPRB in June as the new Director of the Board Secretariat, Communications and Strategic Planning. Guillaume comes from the Competition Bureau's Civil Matters Branch where he was a Major Case Director and Strategic Policy Advisor.

Appointments of Tanya Potashnik and Elena Lungu

We are pleased to announce that Tanya Potashnik and Elena Lungu have been promoted to Director of the Policy and Economic Analysis Branch and Manager of the National Prescription Drug Utilization Information System (NPDUIS), respectively. Both Tanya and Elena had been acting in these positions prior to the competitive staffing processes that led to their appointments.

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Decisions in Cases: 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").

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Voluntary Compliance Undertakings: Gonal F and Lamisil

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 July 2014, the Chairperson accepted two VCUs.

Gonal F, EMD Inc.

On July 13, 2014, the Chairperson of the Board approved a VCU submitted by EMD Inc. regarding the price of Gonal F 300 IU, 450 IU and 900 IU pens. Under the terms of the VCU, EMD Inc. agreed to make a payment to the Government of Canada in the amount of $1,667,002.48 to offset the cumulative excess revenues received from January 1, 2010, to December 31, 2013. In addition, EMD Inc. agreed to offset any excess revenues received by EMD from January 1, 2014, to June 30, 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.

Upcoming Events

- The NPDUIS Advisory Committee will meet on October 7.
- Doug Clark will be attending the 10th Annual Health Insurance Invitational Forum on November 5–7.
- Doug Clark will be speaking at the 13th Annual Market Access Summit in Toronto on November 12–13. Tanya Potashnik will be attending the meeting and participating in a panel discussion.
- Doug Clark will be speaking at the Green Shield Canada Board of Directors Education Session on November 24.

Reminders

- The next HDAP meeting will be held on November 10. The deadline for patentee submissions for this meeting is August 18.

Presentations
Calendar of Events
New Patented Medicines Reported to PMPRB
NPDUIS
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Gonal F (follitropin alfa) is indicated for the stimulation of multiple follicular development in ovulatory patients undergoing Assisted Reproductive Technologies. It is also indicated for the stimulation of follicular development in patients with hypothalamic-pituitary dysfunction who present either oligomenorrhoea or amenorrhoea.

Lamisil®, Novartis Pharmaceuticals Canada Inc.

On July 14, 2014, the Chairperson of the Board approved a VCU submitted by Novartis Pharmaceuticals Canada Inc. regarding the price of Lamisil® 250 mg/tablet. Under the terms of the VCU, Novartis Pharmaceuticals Canada Inc. agreed to offset the cumulative excess revenues received by making a payment of $425,034.25 to the Government of Canada.

The price of Lamisil® is to remain within the Board´s Guidelines in all future periods in which it is under the PMPRB´s jurisdiction.

Lamisil® 250 mg/tablet (terbinafine hydrochloride) is indicated in the treatment of fungal infections of the skin and nails.

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NPDUIS Update

Upcoming Publications

Three new NPDUIS studies are highlighted for publication this fall:

- *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.

- *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.

- *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.

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

Engagement Activities

The NPDUIS Advisory Committee will meet on October 7th in Ottawa.

Other activities are being planned to better engage the broader stakeholder community in the NPDUIS initiative.

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2015 HDAP Schedule

The Human Drug Advisory Panel (HDAP) provides expertise and advice to Board Staff in conducting the scientific review.

HDAP meets four times a year. Meeting dates and deadlines for submission for 2015 are given below:

HDAP Meeting/ Conference Call	Requirements	Deadline
February 9, 2015	1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement	Oct. 30, 2014
	1 electronic copy of patentee submission	Nov. 27, 2014
May 4, 2015	1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement	Jan. 15, 2015
	1 electronic copy of patentee submission	Feb. 19, 2015
September 14, 2015	1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement	May 14, 2015
	1 electronic copy of patentee submission	June 18, 2015
November 30, 2015	1 copy of product monograph or information similar to that included in a product monograph (if product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement	July 23, 2015
	1 electronic copy of patentee submission	Aug. 20, 2015

HDAP´s last meeting in 2014 will be held on November 10. Patentees who have already filed their product monograph and Form 1 (on or before July 18, 2014) have until August 18 to file their submissions.

For further information on HDAP and a detailed list of submission requirements, see HDAP Meeting Schedule and Filing Requirements.

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Summary of the Board's May 8, 2014, Meeting

The Board reviewed and approved the Annual Report for 2013. The Report was submitted to the Minister of Health on June 11, 2014, for tabling in Parliament.

The Board's next meeting is scheduled for September 2014.

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