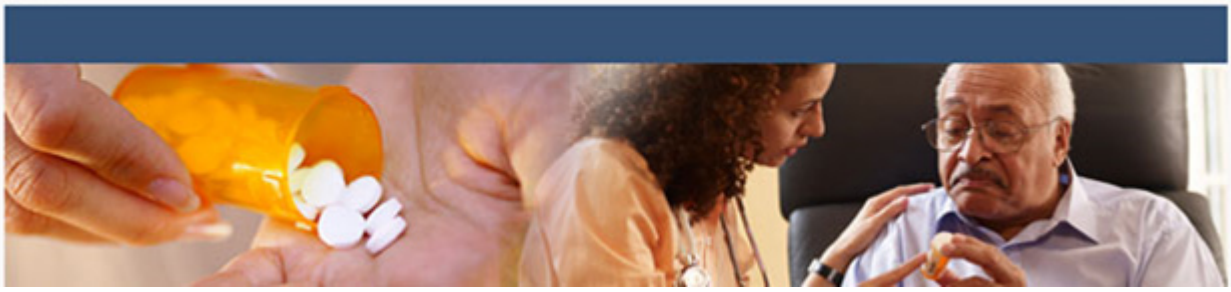
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés



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PMPRB *NEWSletter*

PMPRB bids farewell to Chairperson Mary Catherine Lindberg

The PMPRB bade a fond farewell to Chairperson Mary Catherine Lindberg, who completed her second and final term as a member of the Board on June 26.

Ms. Lindberg, a pharmacist, former Assistant Deputy Minister of Health and Long-Term Care of Ontario, and former Executive Director of the Council of Academic Hospitals of Ontario, was first appointed member and Vice-Chairperson of the Board in June 2006, and was officially appointed Chairperson of the Board in March 2011. Over the course of her tenure as a Board member, she made an invaluable contribution to the leadership of the PMPRB, particularly in her last five years as Chairperson, where she set the PMPRB on a much-needed course towards renewal, reform, and framework modernization.

A public, merit-based selection process will be launched to appoint a qualified candidate to succeed Ms. Lindberg and to appoint a Vice-Chairperson.

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Federal Court dismisses challenge to constitutionality of PMPRB

In a decision dated June 23, 2016, Canada's Federal Court dismissed a constitutional challenge brought against the PMPRB by Alexion Pharmaceuticals Inc., which sells the patented drug Soliris. This drug is currently the subject of a legal proceeding before the Board into allegations that the drug is priced excessively in Canada.

In dismissing Alexion's case, the Federal Court agreed with the Attorney General of Canada that the challenge was "bereft of any chance of success" given that the constitutionality of the PMPRB and its price regulation powers have already been affirmed on multiple occasions by Canadian court decisions.

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Notice to Readers

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Rethinking the Guidelines: Public and stakeholder comments invited

Stakeholders and members of the public are invited to submit feedback in response to the *Guidelines Modernization Discussion Paper* and the series of questions it puts forward as part of the first phase of a major consultation that will ultimately modernize and simplify the regulatory framework around patented drug pricing in Canada. Feedback in response to the *Guidelines Modernization Discussion Paper* will shape later phases of the consultation process, when specific technical changes to the PMPRB's drug pricing Guidelines (*Compendium of Policies, Guidelines and Procedures*) will be proposed.

Written comments and feedback must be submitted to the PMPRB **by October 24, 2016**. All comments will be considered public and will be published on the PMPRB website. Comments and feedback may be submitted by e-mail, letter mail or fax to:

Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1
Fax: 613-952-7626
E-mail: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

About the consultation

The PMPRB is rethinking its drug pricing guidelines and is seeking to generate an open, informed dialogue with stakeholders and members of the public on areas in need of reform as a result of changes to the pharmaceutical environment in Canada and abroad. Rethinking the Guidelines is an important step toward ensuring the long-term sustainability of the Canadian pharmaceutical system, and continuing to improve the accessibility and affordability of prescription drugs.

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Results of the Notice and Comment period on incremental reforms to the *Compendium of Policies, Guidelines and Procedures*

On December 4, 2015, the PMPRB announced the start of a Notice and Comment initiative to seek stakeholder feedback on two proposed amendments to the *Compendium of Policies, Guidelines and Procedures* (Guidelines): the "Reasonable Relationship Test (Schedule 4)" and the "List Price Relative to Maximum Average Potential Price (MAPP) Verification (section C.11)."

Following a thorough review of stakeholder comments and further analysis by Board Staff, the Board concluded the "Reasonable Relationship Test" proposal raised issues that are larger than the narrow set of line extensions the proposal was intended to

Updates

- An instructional video on how to complete a Form 1: Medicine Identification Sheet is now available on the PMPRB website.

Upcoming Events

- The annual Outreach sessions with patentees will be held earlier this fall to also provide the opportunity to consult on the *Guidelines Modernization Discussion Paper*. Information on, and invitations to these sessions will be made available in mid-August.

Reminders

- The next HDAP meetings will be held on September 12 and November 28, 2016. The deadline for patentee submissions for the November HDAP meeting is **August 18, 2016**.
- To be notified of new announcements, publications, and other initiatives, please follow us on Twitter or subscribe to our RSS feeds.

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address and, as such, decided against implementing the amendment. It is the Board's view that these larger issues should be addressed within the context of a broader framework modernization initiative.

The Board decided in favour of the "List Price Relative to MAPP Verification" amendment, which will be implemented **effective September 1, 2016** with minor modifications from the original proposal.

The prices found in the *Association québécoise des pharmaciens propriétaires*; IMS Health; McKesson Canada; Ontario Drug Benefit Programs; PPS Pharma; and the *Régie de l'assurance maladie du Québec* for a new patented drug product shall not exceed the MAPP established by the appropriate introductory price test(s). A price from these sources found to exceed the MAPP would trigger an investigation by Board Staff, who would, as a first step, confirm with patentees whether the list price in question is a price at which ex-factory sales are being made to one or more customers in any market in Canada. If it is found that such sales have taken place, an investigation would proceed in accordance with the Guidelines.

A detailed review of both amendments, as originally proposed, is available on the PMPRB website. The finalized text of the "List Price Relative to MAPP Verification" amendment will be made available online in September.

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

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2017 Human Drug Advisory Panel schedule

The Human Drug Advisory Panel (HDAP) provides credible, independent, and expert scientific advice to Board Staff in conducting scientific reviews of information submitted by patentees. The HDAP meets four times a year. Meeting dates and deadlines for 2017 submissions are indicated below:

2017 Human Drug Advisory Panel schedule

HDAP Meeting / Conference Call	Requirements	Deadline
Monday, February 27, 2017	**Form 1 –** Medicine Identification Sheet • One 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	November 14, 2016

	One electronic copy of patentee submission	December 8, 2016
Monday, May 29, 2017 (face-to-face*) *To be confirmed	**Form 1** – Medicine Identification Sheet • One 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	January 19, 2017
	One electronic copy of patentee submission	February 16, 2017
Monday, September 18, 2017	**Form 1** – Medicine Identification Sheet • One 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 25, 2017
	One electronic copy of patentee submission	June 22, 2017
Monday, December 4, 2017	**Form 1** – Medicine Identification Sheet • One 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 27, 2017
	One electronic copy of patentee submission	August 24, 2017

The 2017 HDAP meeting schedule and more information on requirements for filing electronic submissions are available on the PMPRB website.

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New expression of interest process for potential outside counsel to Board Staff

The PMPRB Legal Services unit hires external counsel from the private sector on an as-needed, case-by-case basis to represent PMPRB Staff in hearings before the Board. The Legal Services unit has launched a new expression of interest process to identify private sector lawyers who would like to be considered for retention as Board Staff outside counsel.

To learn more about the expression of interest process or to submit an application for consideration, visit the PMPRB website.

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Voluntary Compliance Undertakings: Samsca (tolvaptan), Actimmune (interferon gamma 1b), Cialis (tadalafil), Spiriva Respimat (tiotripium bromide monohydrate), Xalkori (crizotinib), and Fibristal (ulipristal acetate)

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 second quarter of 2016, six VCUs were accepted: for the patented medicines Samsca (Otsuka Canada Pharmaceutical Inc.), Actimmune (Horizon Pharma Ireland Limited), Cialis (Eli Lilly Canada Inc.), Spiriva Respimat (Boehringer Ingelheim (Canada) Ltd.), Xalkori (Pfizer Canada Inc.), and Fibristal (Allergan Inc.).

Samsca

Samsca (tolvaptan) is used to treat clinically important, non-hypovolemic hyponatremia.

On May 4, 2016, the Chairperson approved a VCU submitted by Otsuka Canada Pharmaceutical Inc. (Otsuka) regarding the price of the 15 mg and 30 mg strengths of Samsca. Under the terms of the VCU, Otsuka agreed to offset cumulative excess revenues it received as at December 31, 2015 by making a payment to the Government of Canada in the amount of $200,000, and to offset any excess revenues calculated by Board Staff for the first half of 2016. Otsuka further agreed to ensure the 2016 National Average Transaction Prices (N-ATPs) for the 15 mg and 30 mg strengths of Samsca do not exceed the 2016 National Non-excessive Average Prices (N-NEAPs) and that the prices of both strengths

of Samsca remain within the PMPRB's pricing guidelines in all future periods in which they are under the PMPRB's jurisdiction.

Actimmune

Actimmune (interferon gamma 1b) is used to treat Chronic Granulomatous Disease and severe, malignant osteoporosis. Actimmune is not approved in Canada, is made available by the manufacturer to Canadian patients under the Health Canada Special Access Programme (SAP), and has been made available at no cost to Canadian patients under the SAP since April 2015.

On May 19, 2016, the Chair approved a VCU submitted by Horizon Pharma Ireland Limited (Horizon) regarding the price of Actimmune 100 mcg/vial. Under the terms of the VCU, Horizon agreed to offset cumulative excess revenues it received since 2013 by making a payment to the Government of Canada in the amount of $590,519.57. Remaining excess revenues will be offset by continuing to provide Actimmune free of charge via the SAP until December 2017. Horizon further agreed that it or Board Staff may initiate a review of the price of Actimmune under the PMPRB's pricing guidelines should Horizon recommence sales of Actimmune in Canada on or after January 1, 2018.

Cialis

Cialis (tadalafil) is used to treat erectile dysfunction and/or benign prostatic hyperplasia.

On June 10, 2016, the Chair approved a VCU submitted by Eli Lilly Canada Inc. (Eli Lilly) regarding the price of the 10 mg and 20 mg "on-demand" strengths, and the 2.5 mg and 5.0 mg "once-a-day" strengths of Cialis. Under the terms of the VCU, Eli Lilly agreed to offset cumulative excess revenues it received since 2014 by ensuring the 2016 National Average Transaction Prices (N-ATPs) for the 10 mg, 20 mg, 2.5 mg, and 2.0 mg strengths of Cialis do not exceed the 2016 National Non-excessive Average Prices (N-NEAPs), and reducing the 2016 N-ATPs for all strengths of Cialis below their respective 2015 N-NEAPs. Eli Lilly further agreed to offset any remaining excess revenues at the end of the second half of 2016 by making a payment to the Government of Canada.

Spiriva Respimat

Spiriva Respimat (tiotripium bromide monohydrate) is used as an add-on maintenance bronchodilator to treat adult patients with asthma.

On June 10, 2016, the Chair approved a VCU submitted by Boehringer Ingelheim (Canada) Ltd. (Boehringer) regarding the price of Spiriva Respimat 2.5 mcg/actuation. Under the terms of the VCU, Boehringer agreed to offset cumulative excess revenues of $61,147.70, received since December 19, 2014, by reducing the price of Spiriva Respimat to a level below the 2015 Maximum Average Potential Price. Boehringer further agreed to make a payment to the Government of Canada if not all cumulative excess revenues are offset by June 30, 2016.

Xalkori

Xalkori (crizotinib) is used as monotheraphy for use in patients with anaplastic lymphoma kinase (ALK)-positive advanced (i.e., not responsive to curative therapy) or metastatic non-small cell lung cancer.

On June 16, 2016, the Chairperson approved a VCU submitted by Pfizer Canada Inc. (Pfizer) regarding Xalkori 200 mg/capsule and 250 mg/capsule. Under the terms of the VCU, Pfizer agreed to the Maximum Average Potential Price and National Non-excessive Average Prices (N-NEAPs) set out in the VCU and to reduce the price of both strengths of Xalkori to be below the 2016 N-NEAPs set out in the VCU by the end of 2016. The confidential undertaking between Board Staff and Pfizer referred to in the VCU will not be made public.

Fibristal

Fibristal (ulipristal acetate) is used to treat moderate to severe signs and symptoms of uterine fibroids in adult women of reproductive age who are eligible for surgery.

On June 26, 2016, the Chair approved a VCU submitted by Allergan Inc. (Allergan) regarding Fibristal 5 mg/tablet. Under the terms of the VCU, Allergan agreed to offset cumulative excess revenues it received in 2013 and 2014 by making a payment to the Government of Canada in the amount of $809,568.89. Allergan further agreed to ensure the 2016 National Average Transaction Price (N-ATP) of Fibristal 5 mg/tablet remains at or below the 2015 Highest International Price Comparison until the N-ATP is considered within the Guidelines at or below $11.46/tablet, and that the price of Fibristal remains within the PMPRB's pricing guidelines in all future periods in which it is under the PMPRB's jurisdiction.

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Summary of the Board's May 2016 meeting

The Board held its second quarterly meeting of 2016 on May 19.

The Chairperson provided an update on Board operations and Board members were briefed on plans for the release of the *Guidelines Modernization Discussion Paper* and consultation initiative. The Board approved recommendations made by Board Staff on the proposed incremental changes to the Guidelines, and were updated on recent and upcoming NPDUIS research initiatives. Board members were also presented with information on trends in pharmaceutical pricing and investment in research and development, which will be published in the PMPRB *2015 Annual Report.*

The Board's next meeting is scheduled for September 2016.

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