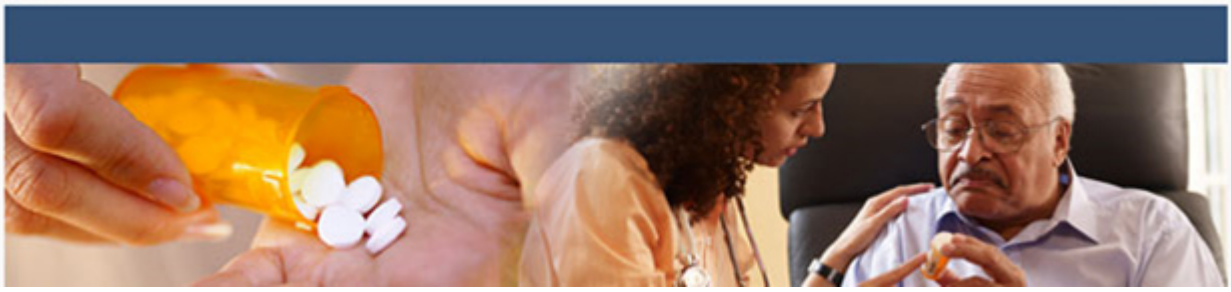
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés



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PMPRB *NEWSletter*

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Notices to Readers

Updates

- As a result of updates to Schedule 2 of the *Compendium of Policies, Guidelines and Procedures* to include additional comparable dosage forms, Appendix C of the *Patentee's Guide to Reporting* has been updated to provide codes for filing the new comparable dosage forms.
- An updated NPDUIS Research Agenda, which lists and describes all current NPDUIS research projects slated for publication in 2015-16 and 2016-17, is now available on the PMPRB website. These research topics were selected in accordance with identified priorities and analytical needs of the participating

Soliris pre-hearing conference

The PMPRB held a public, pre-hearing conference on Monday, June 22 and Tuesday, June 23, 2015, in the matter of the price of the patented medicine Soliris and Alexion Pharmaceuticals Inc., the pharmaceutical company that exercises patent rights for Soliris and sells the medicine in Canada. The purpose of the pre-hearing conference was to allow 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 pre-hearing conference will resume in Ottawa on **September 16, 2015**.

For more information, please visit the Status of Ongoing Proceedings section of the PMPRB website, which contains the latest public documents in this matter.

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New staff member – Legal Services

The PMPRB is pleased to announce the appointment of Isabel Jaen Raasch as Director, Legal Services and General Counsel. Isabel joins the PMPRB from Gowling Lafleur Henderson LLP, where she was a partner and practiced in the area of patent litigation, including infringement actions, references for damages, and proceedings under the *Patented Medicines (Notice of Compliance) Regulations*. Isabel has over 14 years of patent litigation experience on a wide range of scientific subject matter. Prior to working at Gowlings, Isabel was an associate with Ropes & Gray LLP – Fish & Neave IP Group, a leading intellectual property firm in New York City.

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Update: *Compendium of Policies, Guidelines and Procedures*

On June 30, 2015, the PMPRB published the following updates to the *Compendium of Policies, Guidelines and Procedures* (the Guidelines):

Part C – Guidelines and Procedures

As noted in the January edition of the PMPRB *NEWSletter*, Part C, Section C.12.8 has been updated to clarify the policy on DIN continuation, which stipulates that existing drug products subsequently sold by another patentee, in the case of a merger or acquisition, will be treated as if the DIN continues to be sold by the initial patentee. The subsequent patentee must provide the PMPRB with proof of authorization as part of the DIN transfer so the PMPRB can disclose privileged information or documents provided by the initial patentee.

Schedule 9 – CPI-Adjustment Methodology

Further updates to the Guidelines were made to Part C, Section C.12.3 (rescinded) and Schedule 9 in accordance with the January 1, 2015 adoption of a new lagged CPI-adjustment methodology to be used when determining whether the price of a patented drug product sold in Canada is excessive.

Schedule 2 – Comparable Dosage Forms

The table of comparable dosage forms has been expanded to include additional dosage forms, and organized in alphabetical order for convenience.

The above-noted changes, in addition to past updates, are summarized in a table at the end of the document (see "Updates to the *Compendium of Policies, Guidelines and Procedures*"). The *Compendium of Policies, Guidelines and Procedures* is **now also available in PDF format**.

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2016 HDAP 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 submission for 2016 are indicated below:

HDAP Meeting / Conference Call	Requirements	Deadline
Monday, February 29, 2016	**Form 1 –** Medicine Identification Sheet • One copy of product monograph or information similar to that included in a product monograph (if	November 12, 2015

NPDUIS jurisdictions.

Upcoming Events

- Please mark your calendars for the next Outreach sessions to be held **in Montreal on Thursday, November 5**, and **in Toronto on Friday, November 6, 2015**. Invitations will be sent out in mid-September.

Reminders

- The next HDAP meetings will be held on September 14 and November 30, 2015. The deadline for patentee submissions for the November HDAP meeting is **August 20, 2015**.

Presentations
New Patented Medicines Reported to PMPRB
NPDUIS
Hearings
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	product has not yet been approved for sale in Canada) and the proposed level of therapeutic improvement	
	One electronic copy of patentee submission	December 10, 2015
Monday, May 2, 2016 (face-to-face)	**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 7, 2016
	One electronic copy of patentee submission	February 4, 2016
Monday, September 12, 2016	**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 12, 2016
	One electronic copy of patentee submission	June 9, 2016
Monday, November 28, 2016	**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 21, 2016
	One electronic copy of patentee submission	August 18, 2016

The 2016 HDAP meeting schedule and more information on requirements for filing electronic submissions are available on the PMPRB website.

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PMPRB transition to Canada.ca

The Government of Canada launched the Canada.ca website in December 2013 as a first step in what will eventually be the online portal for all Government of Canada information and services. The PMPRB is in the process of migrating its content and services to Canada.ca and published its institutional profile to this new platform in June 2015. Please be advised that the current PMPRB website will remain available until the move to Canada.ca is complete.

If you have any questions, comments or concerns about the new PMPRB institutional profile, please direct them to Communications@pmprb-cepmb.gc.ca.

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Update: Germany Recognized Price Source

As announced at the December 2014 Outreach sessions in Montreal and Toronto, and in the January 2015 *NEWSletter*, 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**.

In order to use the data available in the Lauer-Taxe in price submissions, it is necessary to deduct the publicly available rebates from the prices published in the Lauer-Taxe to determine customer class-specific ex-factory prices. Board Staff will provide a detailed briefing on this subject during the November 2015 Outreach sessions in Montreal and Toronto. In the meantime, as noted in the January 2015 *NEWSletter*, prices from the Rote Liste will continue to be accepted for 2015 filings.

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

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Summary of the Board's May 15, 2015 meeting

The Board held its second quarterly meeting on May 15, 2015.

The Chairperson provided an update on Board operations and examined ways to modernize them. Board Members were briefed on the PMPRB's Strategic Objectives for 2015-2018, and updated on recent and upcoming NPDUIS research initiatives. They were also presented with a summary of pharmaceutical pricing and R&D trends, which will be published in the PMPRB's 2014 Annual Report.

The Board's next meeting is scheduled for September 17, 2015.

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