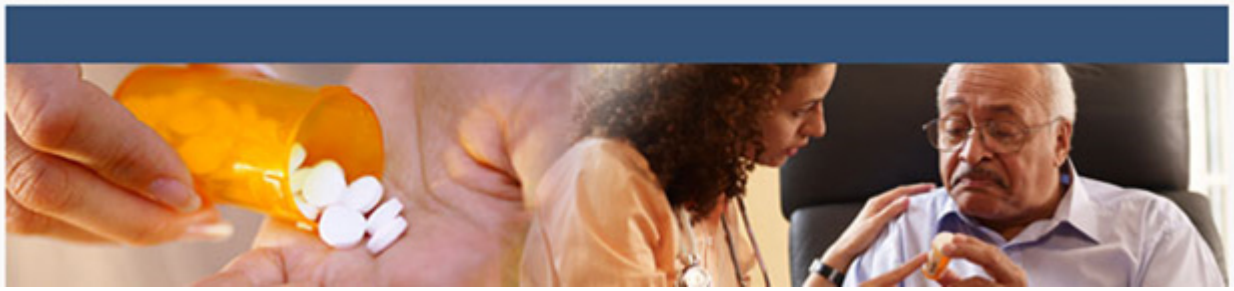
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés



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PMPRB *NEWSletter*

New appointments to the Human Drug Advisory Panel

In February we bid adieu to Dr. Jean Gray, who has been a member of the Human Drug Advisory Panel (HDAP) since 2004. Dr. Gray's knowledge, wisdom, common-sense air, and unwavering commitment to the integrity of the scientific review process served as a galvanizing force within the HDAP over the past decade and earned her the admiration and respect of Board Staff. We are eternally grateful for her selfless contribution to the PMPRB's consumer protection mandate and wish her every happiness in the years ahead.

With Dr. Gray's departure, we welcome some new HDAP members: Dr. Michael Rieder and Dr. Peter Jamieson. Dr. Rieder is a medical doctor who also holds a Ph.D. in pharmacology and is currently a professor with the Department of Paediatrics (with a cross-appointment to the Department of Physiology and Pharmacology) in the Faculty of Medicine and Dentistry at the University of Western Ontario in London. Dr. Jamieson is a medical doctor with a background in family practice who currently serves as Associate Zone Medical Director in Calgary for Alberta Health Services and as Clinical Associate Professor in the Department of Family Medicine at the University of Calgary.

Both Dr. Rieder and Dr. Jamieson will be commencing their participation in the scientific review process with the May 2015 HDAP meeting. Welcome Dr. Rieder and Dr. Jamieson.

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New staff members

The PMPRB would like to extend a warm welcome to Richard Lemay to the Regulatory Affairs and Outreach Branch as Manager, Outreach and Investigations. Richard joins us from the Public Health Agency of Canada and brings with him a wealth of experience in the federal public service in the areas of project management and health.

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Notices to Readers

Updates

- Executive Director Doug Clark delivered a presentation at Pharma Symposium Canada on March 31, 2015.
- The PMPRB's Corporate Services Branch personnel have been working diligently to ensure PMPRB year-end

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Recent publication: CompassR$_x$

On March 31, the PMPRB, through the National Prescription Drug Utilization Information System (NPDUIS) research initiative, released the first edition of *CompassR$_x$*, a flagship annual report and the first of its kind to identify the major drivers behind changes in prescription drug expenditures in public drug plans in Canada— an important element in allowing policy-makers and researchers to understand current trends and anticipate future cost pressures and expenditure levels. This report is an essential tool for anyone interested in the forces driving change in prescription drug costs.

CompassR$_x$ and the accompanying Analysis Brief are available online in PDF and HTML formats.

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Coming soon: the PMPRB's 2015-2018 Strategic Plan and NPDUIS report on generic drugs in Canadian private plans

2015-2018 Strategic Plan

As announced in recent editions of the *NEWSletter*, the PMPRB has been engaged over the last year in a strategic planning process to set a fresh course for the next three years. The plan is now in its final stages and will be published on our website in the coming months.

If you would like to be notified of the release of the new PMPRB strategic plan and other key publications and initiatives, please subscribe to our e-bulletin.

Generic Drugs in Canadian Private Plans, 2005-2013

The NPDUIS research initiative's latest report, *Generic Drugs in Canadian Private Plans, 2005-2013*, slated for release in summer 2015, assesses the changing landscape of private drug plans with a focus on trends in the generic drug market. This report will provide a comparative analysis of generic utilization and pricing between the private and public drug plans, and will identify potential opportunities for savings and efficiency.

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Update: Interpretation Policy

The Government of Canada has recently taken steps to improve regulatory openness and transparency, reduce administrative burden, and modernize regulations through a variety of initiatives. To support this priority, the PMPRB is aiming to identify further improvements in the way it provides information and guidance on regulatory requirements to patentees. The PMPRB currently uses a variety of ways to promote awareness and understanding of regulatory requirements. In addition to corporate reporting and renewal activities are completed on time.

Upcoming Events

- Doug Clark will participate in the Northwind Professional Institute's 8th Annual *Life Sciences Invitational Forum* from May 20-22, 2015 in Cambridge, Ontario. Doug will be discussing how to determine the value of high-cost breakthrough medications.
- Elena Lungu and Greg McComb will deliver oral presentations at the CAHSPR Conference, to be held in Montreal, QC from May 25-28. The NPDUIS research topics discussed will be: *Cost Drivers of Private Drug Plans in Canada*; *Cost Drivers of Public Drug Plans in Canada*; and *Generic Drugs in Canada, 2013.*
- Tanya Potashnik and Elena Lungu will present at the IMS Brogan Data Supplier Roundtable meeting in early June 2015.

Reminders

- Product monograph and patentee submissions for the September 14, 2015 HDAP meeting are due on **May 14 and June 18**, respectively.
- The deadline for filing Form 2 is **July 30, 2015.**

responding to questions from regulated parties, the PMPRB issues guidance and information materials, and engages patentees through various mechanisms (e.g., webinars, outreach). As a follow-up to our December 2014 outreach sessions on this subject, we will be emailing a brief survey to patentees in the coming weeks, to give you the opportunity to help us identify areas where we can improve the way in which we provide you with information on regulatory requirements. For more information, please see the PMPRB's recently released Interpretation Policy, which outlines our commitments to predictability, service, and engagement.

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Submissions by Patentees on Level of Therapeutic Improvement

Submissions for consideration by the Human Drug Advisory Panel (HDAP) must be made in accordance with PMPRB electronic filing requirements.

Patentees filing submissions for the **September 14, 2015** HDAP meeting are now required to file all submissions using the new electronic format requirements. For submission deadlines, please consult the HDAP schedule.

New requirements for electronic submissions

Patentees must provide the following for the September 14, 2015 HDAP meeting:

- One CD or memory stick must be filed within the HDAP submission deadlines
- The CD or memory stick should be labelled according to the following naming convention: **[*Name of drug under review*]**
- All documents must be provided in **a single PDF document** that is unlocked, searchable, and printable to enable users to extract information
- The PDF document should be labelled according to the following naming convention: **[*Name of drug under review*] Patentee Submission for the [*Date of HDAP meeting*] HDAP Meeting**
  (e.g., Drug XX Patentee Submission for the September 14, 2015 HDAP Meeting)
- Documents that have been merged into one PDF should be labelled and organized as indicated below. They must also appear in the following order and format in the PDF Bookmarks:

  A. Cover Letter

  B. Proposal of the Patentee – refer to Schedule 1 of the Guidelines for details on the required contents of the proposal. Do not include any price justification or pricing details; if this information is included, the submission will be

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returned to the patentee.

C. References – please do not provide duplicate references or references that are not included in your submission. For the naming of articles/references, please minimize the characters used.

1. Smith 2014
2. (Company Name) Study
   a. Clinical Trial
   b. Relevant Findings

Do not include the Product Monograph or Form 1 of the drug submitted for HDAP review. See *Patented Medicines Regulations* and HDAP schedule for the timelines for submission of Form 1 and the Product Monograph.

- CDs or memory sticks should be mailed or couriered to:

  Regulatory Affairs and Outreach Branch
  Patented Medicine Prices Review Board
  Box L40, 333 Laurier Avenue West, Suite 1400
  Ottawa, Ontario K1P 1C1

Questions or comments regarding HDAP submissions can be directed to Amber MacPherson, Regulatory Affairs and Outreach Branch.

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Instructional Video: Acquisition of DIN(s) From a Former Patentee

The Regulatory Affairs and Outreach Branch released in March 2015 an instructional video to clarify requirements with respect to existing drug products subsequently sold by another patentee. The video shows the necessary steps to complete an amended Form 1, where the new patentee has demonstrated that it has access to the protected information of the former patentee.

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NPDUIS Engagement Activities

NPDUIS Advisory Committee

An NPDUIS Advisory Committee teleconference was organized in February 2015 to discuss the current NPDUIS research agenda and the latest developments at the jurisdictional level.

NPDUIS Oral and Poster Presentations

Elena Lungu and Gary Warwick attended the 2015 CHSPR Health Policy Conference: *Sticker Shock*, held in Vancouver, B.C. on March 3, and presented six posters on recently completed and ongoing NPDUIS research projects: *Generic Drugs in Canada 2013*; *Cost Drivers of Private Drug Plans in Canada*; *Cost Drivers of Public Drug Plans in Canada*; *Use of Gabapentin in Public Drug Plans*; *Monitoring New Drugs*; and *Generic Drugs in*

Canadian Private Plans 2005-2013.

Tanya Potashnik and Elena Lungu participated in the CADTH Symposium, held in Saskatoon, SK from April 12-14, delivering an oral presentation: *Cost Drivers of Public Drug Plans in Canada*; and three poster presentations: *Cost Drivers of Private Drug Plans in Canada*; *Generic Drugs in Canadian Private Plans 2005-2013;* and *Use of Gabapentin in Public Drug Plans*.

The 2015 NPDUIS research posters are available in PDF and accessible HTML formats in the Poster Presentations section of the PMPRB website.

Canadian Network for Environmental Scanning in Health

On April 12, Elena Lungu represented NPDUIS during her participation in a face-to-face meeting of the Canadian Network for Environmental Scanning in Health (CNESH), of which the PMPRB recently became a member in February 2015.

CompassR$_x$

Tanya Potashnik, Elena Lungu, and Greg McComb organized a number of outreach activities, information sessions, and webinars for interested stakeholders in anticipation of, and subsequent to, the inaugural public release of the *CompassR$_x$* flagship report on Canadian public drug plan expenditures.

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Participation in March 2015 PPRI conference, Prague

The PMPRB participated in the latest Pharmaceutical Pricing and Reimbursement Information Network meeting in Prague, Czech Republic, on March 19 and 20, 2015. The meeting, hosted by Czech Medicines Agency SUKL, discussed pre-, peri-, and post-launch pharmaceutical strategies, complemented by international insights, with an additional session devoted to horizon scanning. Guillaume Couillard, Director, Board Secretariat, Communications and Strategic Planning delivered remarks on the PMPRB's latest strategic efforts in support of the organization's reporting mandate— including the NPDUIS research initiative's latest achievements— and on the upcoming hearing in the matter of Soliris and Alexion Pharmaceuticals Inc.

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Summary of the Board's February 20, 2015 meeting

The Board held its first quarterly meeting on February 20, 2015.

The Chairperson provided an update on Board operations and Board members discussed the most recent policy and regulatory developments. It was also decided that the *Monitoring and Evaluation Plan for the Major Changes in the Guidelines* (Plan) will conclude this year, more than five years after the implementation of the revised Guidelines on January 1, 2010.

Board Members were updated on recent Pharmaceutical Pricing and Reimbursement Information network activities and the PMPRB's latest publication, *CompassR*$_x$.

The Board's next meeting is scheduled for May 15, 2015.

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