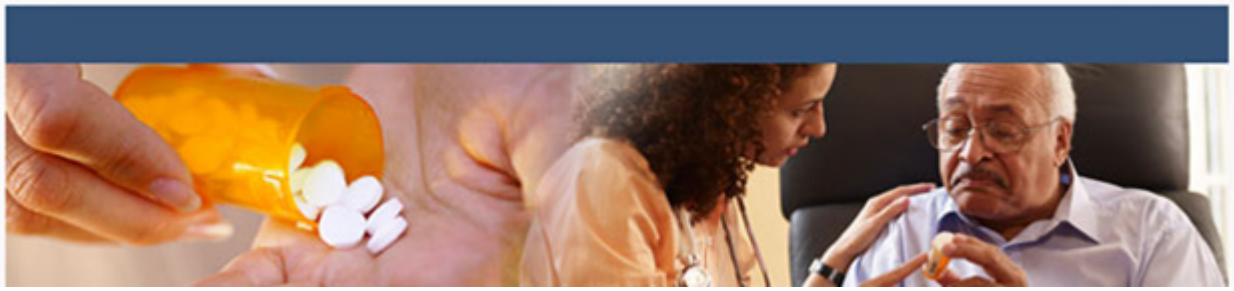
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés



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PMPRB *NEWSletter*

Message from the Executive Director

A new year begets an impulse to reflect on the year that was and anticipate the one to come. I will do my best to resist that impulse here, as there are other avenues for government agencies to account for past performance and proclaim future priorities. Suffice it to say that, from the perspective of PMPRB staff, the predominant theme that emerges from 2014 was renewal, whereas the expected theme for 2015 is relevance.

In terms of the former, there was an obvious renewal that took place in personnel in 2014, the specifics of which are available to readers in our quarterly newsletters, including this one. This included some new faces not only in the executive ranks, including myself as Executive Director, but also new talent at the working level in policy analysis and communications, as we look to build capacity in those areas. That is not to say that 2014 was devoid of substantive accomplishment, as we saw the consensual resolution of several important investigations in the form of payments to the Crown resulting from Voluntary Compliance Undertakings, including the longstanding Copaxone matter. In 2014, we were also proud to have been accepted as a member of the WHO organization for Pharmaceutical Pricing and Reimbursement Information (PPRI), and to have obtained observer status with both the Drug Policy Advisory Committee (DPAC) and the Non-Insured Health Benefits (NIHB) Drugs and Therapeutics Advisory Committee, all of which speaks to our elevated strategic engagement with stakeholders and the increased productivity and quality of our NPDUIS reporting. Last but not least, although it is technically true that the PMPRB's recent filing of its first notice of hearing since 2012 occurred in 2015, it was the culmination of a great deal of legwork undertaken primarily in 2014, and a true team effort.

2014 was a year of renewal not only on the staffing front but also in terms of how we think about our mission, vision and priorities. This time last year, we embarked on an exciting new strategic planning initiative, the first dividends of which will be reflected in our upcoming Report on Plans and Priorities, to be tabled in Parliament in the spring. As the year unfolds, we look forward to implementing those plans and priorities and continuing to engage

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Notices to Readers

Updates

- The Monitoring and Evaluation Plan for the Major Changes in the Guidelines (GMEP) has been updated for 2014

and collaborate with our partners and stakeholders at the federal, provincial, territorial, and international levels with the goal of improving the health of Canadians through a responsible, accessible, and sustainable health system.

The PMPRB remains committed to protecting Canadian consumers through proactive, rigorous enforcement of our pricing guidelines and continuing to serve as an effective counterweight to the patent rights of pharmaceutical manufacturers by ensuring Canadians do not pay excessive prices for patented drugs, while recognizing the value of innovative new health technologies.

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New Staff Members

The PMPRB would like to extend a warm welcome to new staff members Sofie McCoy-Astell and Nathalie Beaulieu, both of whom are new additions to the Board Secretariat, Communications and Strategic Planning team.

Sofie McCoy-Astell, Manager of the communications team, joins us from the Canadian Environmental Assessment Agency where she was a communications advisor and spokesperson. She brings with her a breadth of experience in communications and public affairs, including five years at the Treasury Board Secretariat.

Nathalie Beaulieu, Senior Hearing Officer, joins us from the Supreme Court of Canada where she was an acting Senior Registry Officer. A graduate of the University of Ottawa in both Common and Civil Law, Nathalie has been a member of the Quebec Bar since 2008.

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Notice of Hearing: Soliris and Alexion Pharmaceuticals Inc.

The PMPRB will hold a public hearing in the matter of the price of the patented medicine Soliris, and Alexion Pharmaceuticals Inc. (Alexion), the pharmaceutical company that holds the patent for Soliris and sells the medicine in Canada. Further details on the public hearing and a case management conference will be announced at a later date.

The purpose of the hearing is to determine whether, under section 83 of the *Patent Act*, Alexion

- is selling or has sold the medicine known as Soliris in any market in Canada at a price that, in the Board's opinion, is or was excessive; and
- if so, what order, if any, should be made to remedy the excessive pricing.

Soliris is the first and only treatment for patients with Paroxysmal Nocturnal Hemoglobinuria—a rare and life-threatening blood disorder characterized by excessive destruction of red blood cells—and Atypical Hemolytic Uremic Syndrome, a rare and life-

- The PMPRB interpretation policy has been published online

Upcoming Events

- Elena Lungu and Gary Warwick will present posters for six NPDUIS research topics at the CHSPR Health Policy Conference – March 3, 2015 – Vancouver, B.C.
- Doug Clark will be speaking at Pharma Symposium Canada – March 31, 2015 – Toronto, Ontario
- Tanya Potashnik and Elena Lungu will deliver oral and poster presentations on four NPDUIS research topics at the CADTH Symposium – April 12-14, 2015 – Saskatoon, Saskatchewan

Reminders

- The deadline for filing Form 3 is March 2, 2015

Presentations
New Patented Medicines Reported to PMPRB
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Hearings
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Canada

threatening genetic disorder characterized by blood clots in small vessels.

Those wishing to participate in this proceeding must apply to the Board for leave to intervene. For further information on the application process, please contact:

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Patented Medicine Prices Review Board
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Voluntary Compliance Undertaking: Gelnique

*A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust its price to conform to the Board's Guidelines (*Compendium of Policies, Guidelines and Procedures*). 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 fourth quarter of 2014, one VCU was accepted, for the patented medicine Gelnique.

Gelnique, Actavis Specialty Pharmaceutical Co.

On November 29, 2014, the Chairperson of the Board approved a VCU submitted by Actavis Specialty Pharmaceutical Co. (Actavis) regarding the price of Gelnique. Under the terms of the VCU, Actavis agreed to make a payment to the Crown in the amount of $573,648.09 to offset cumulative excess revenues received by Actavis as of June 30, 2014. In addition, Actavis agreed to offset any excess revenues received by Actavis from July 1, 2014 to the date of implementation of the VCU, as calculated by Board Staff.

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

Gelnique 100 mg/gram (oxybutynin chloride) is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

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Recent Publications

Two new National Prescription Drug Utilization Information System (NPDUIS) studies were released in December 2014:

- *Generic Drugs in Canada, 2013*
  This analytical report compares the 2013 generic drug prices

and markets in Canada with those of other industrialized countries. It updates previous NPDUIS research (PMPRB 2013), highlighting the changes in Canadian generic pricing that have taken place since 2011.

- *New Drug Pipeline Monitor, 6th edition*
  The *New Drug Pipeline Monitor* (NDPM) provides information on drugs currently under development that may have a significant impact on future drug plan expenditures in Canada. The latest NDPM, the sixth edition, provides an update on the 31 pipeline drugs previously identified in the December 2013 edition of the NDPM and identifies 10 new additions to the pipeline list.

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Coming Soon: Public Drug Plan Expenditure Report

Explore trends and change drivers in public drug plan expenditures with our new annual NPDUIS Compass Rx.

The *Public Drug Plan Expenditure Report* is a PMPRB publication that provides a comprehensive cost driver analysis of prescription drug spending for a number of provincial public drug plans. It monitors major changes in the Canadian pricing and reimbursement environment, reports on recent trends in costs and utilization patterns in public plans, and explores the major factors behind the overall drug and dispensing fee expenditures.

The recent low rates of growth in expenditures are the net result of important and opposing “push” and “pull” effects. On the one hand, factors such as the aging of the population, the increased use of drugs, and the use of more expensive drugs, to name a few, are putting an upward pressure (“push”) on expenditures. At the same time, the expenditure levels are pulled downward by generic substitution and price reductions. The analysis in the report disaggregates and investigates the impact of each of the principal contributing factors.

The first edition of this annual publication, to be released this spring, will provide a baseline for drug expenditures beginning with 2012/13. Subsequent editions will use the latest available data to build on this information, highlighting trends and changes in the cost drivers over time.

Identifying the major drivers of change and understanding the effect they have on prescription drug expenditures will allow policy makers and researchers to understand the current trends and anticipate future cost pressures and expenditure levels.

Other upcoming publications

Two additional NPDUIS studies are earmarked for publication over the coming months:

- ***Private Drug Plans in Canada: Generic Market, 2013***
  This report is the first in a series of NPDUIS reports that analyze price, utilization, and cost trends in private drug plans. *Private Drug Plans in Canada: Generic Market, 2013* will evaluate the recent trends in generic use and pricing in

the private market and will provide a comparative analysis with public drug plan markets.

- ***International Retail Price Comparison, 2013***
  This report will provide an up-to-date comparison and assessment of Canadian and international drug prices at the retail level based on December 2013 data.

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

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2014 CPI-Based Price-Adjustment Factors

Preliminary Price-Adjustment Factors (Based on Forecast Inflation Rates)

The following table reproduces preliminary price-adjustment factors for 2014 published in the April 2013 *NEWSletter*. These factors were based on forecasted annual Consumer Price Index (CPI) inflation rates of 1.3% and 2.0% for 2013 and 2014, respectively.

Forecast 2014 Price-Adjustment Factors for Patented Drug Products			
Benchmark Year	**(1) 2011**	**(2) 2012**	**(3) 2013**
Price-Adjustment Factor	1.049	1.033	1.020

These figures imply:

- a maximum allowable cumulative price increase between 2011 and 2014 of 4.9% for patented drug products with Canadian sales in 2011 (i.e., products whose “benchmark year” is 2011);
- a maximum allowable cumulative price increase between 2012 and 2014 of 3.3% for products whose first Canadian sales occurred in 2012; and
- a maximum allowable cumulative price increase between 2013 and 2014 of 2.0% for products whose first Canadian sales occurred in 2013.

In addition, the forecast inflation rate of 2.0% for 2014 implies a year-over-year price increase cap applicable to all drug products, regardless of benchmark year, of 3.0% (=1.5 x 2.0%).

Final Price-Adjustment Factors (Based on Actual Inflation Rates)

The 2013 actual rate of CPI inflation of 0.9% was published in the January 2014 *NEWSletter*. The 2014 actual rate of CPI, which is now available, was 2.0%. These rates, along with the actual 2012 CPI-inflation rate of 1.5%, yield the following final price-adjustment factors:

Final 2014 Price-Adjustment Factors for Patented Drug Products (Based on Actual CPI-Inflation Rates for 2013 and 2014)			
Benchmark	**(1) 2011**	**(2) 2012**	**(3) 2013**

Year			
Price-Adjustment Factor	1.044	1.029	1.020

The year-over-year price increase cap for 2014 is 3.0% (=1.5 x 2.0%).

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2016 CPI-Based Price-Adjustment Factors for Patented Drug Products

***New methodology in effect as of January 1, 2015**

The *Patent Act* specifies the factors to be used by the PMPRB in determining whether the price of a patented drug product sold in Canada is excessive. One of these factors is the CPI. The Board's *Compendium of Policies, Guidelines and Procedures* (Guidelines) requires the cumulative increase in a product's price over any three-year period to be no more than the increase in the CPI over the same period. The Guidelines also sets a cap on year-over-year price increases equal to one and one-half times the CPI-inflation rate for the year in question.

The January 2014 *NEWSletter* announced that, effective January 1, 2015, a new Lagged CPI Adjustment Methodology will be implemented based on actual CPI. As such, the April *NEWSletter* will no longer publish preliminary price-adjustment factors.

The following table provides the CPI-Based Price-Adjustment factors for 2016. These factors were based on the actual rate of CPI inflation of 2.9% in 2011, 1.5% in 2012, 0.9% in 2013, and 2.0% in 2014.

Benchmark Year	2013	2014	2015
Price-Adjustment Factor	1.044	1.029	1.020

Based on these factors, one can derive:

- a maximum allowable cumulative price increase between 2013 and 2016 of 4.4% for patented drug products with Canadian sales in 2013;
- a maximum allowable cumulative price increase between 2014 and 2016 of 2.9% for patented drug products with Canadian sales in 2014; and
- a maximum allowable cumulative price increase between 2015 and 2016 of 2.0% for patented drug products with Canadian sales in 2015.

The year-over-year price increase cap for the 12-month period ending December 2015 is 3.0% (=1.5 x Actual Inflation in 2014).

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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 using the PMPRB electronic filing requirements. Based on previous experience with these filing requirements, the PMPRB is proposing some adjustments to format:

Proposal for new format for electronic submission

Patentees filing submissions for the **May 4, 2015** HDAP meeting may use either the current electronic format or the newly proposed electronic format requirements. Patentees will be required to file all submissions in the newly proposed electronic format **as of the September 14, 2015** HDAP meeting.

Final filing requirements will be published in the April 2015 issue of the *NEWSletter* and will be incorporated into the yearly update of the Guidelines in June 2015. For submission deadlines, please see the HDAP schedule.

Proposed requirements for electronic submissions

Patentees choosing to file their electronic submission for the May 4, 2015 HDAP meeting using the new format requirements must provide the following:

- 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 May 4, 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 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. 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

Next steps

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

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Patentees Reporting on R&D and Sales for 2014

Patentees are reminded that the deadline for filing Form 3 information on revenues and R&D expenditures is March 2, 2015.

Under the *Patented Medicines Regulations* (Regulations), all patentees are required to file information on revenues and R&D expenditures (Form 3).

Failure to File

If a patentee fails to file complete information by March 2, 2015, the patentee will be advised in writing that the information required to be filed under the Regulations has not been received by the PMPRB and will be given a further seven (7) days to provide the information. Should the patentee not file within the further period, Board Staff shall request that the Board issue an order pursuant to section 88 of the *Patent Act* requiring that the patentee file the required information. Orders issued by the Board are reported in the PMPRB's publications and posted on the website.

For more information on Licencees, Revenues and Expenditures, see the *Patentee's Guide to Reporting*.

Form 3 should be filed at compliance@pmprb-cepmb.gc.ca

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Foreign Price Verification Policy

Using public information, the PMPRB established a foreign price verification methodology to validate foreign prices patentees submit for each of the seven comparator countries (France, United Kingdom, Sweden, Switzerland, Germany, United States, Italy) listed in the Regulations.

Under the *Patent Act* and the Regulations, patentees are required to file information showing publicly available ex-factory prices for patented medicines sold in the seven comparator countries. Ex-factory prices include any price of a patented medicine that is agreed upon by the patentee and the appropriate regulatory authority and are typically net of rebates, discounts, distribution margins, and taxes as appropriate.

In the six European comparator countries, retail and wholesale markups are regulated and it is possible to derive or "back out" ex-factory prices by removing the retail and wholesale markups and the value-added tax from retail prices. This approach allows the PMPRB to obtain independent information on foreign ex-factory prices and verify the accuracy of the publicly available ex-factory prices submitted by patentees.

Increasingly, the ex-factory price is being published in the recognized sources used by the PMPRB and deriving the ex-factory price is often not necessary as part of the foreign price verification process. Nonetheless, the PMPRB will continue to publish this information on its website as the information may be relevant in cases where it is necessary to derive the ex-factory price from alternate price sources.

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Change in Foreign Price Verification Policy

As announced at the December 2014 Outreach sessions in Toronto and Montreal, please note that the PMPRB will conduct a verification of international prices starting with **all** new medicines with introductory periods in 2014(2).

In the event that an ex-factory price is not available in the PMPRB recognized source, the PMPRB will use a consistent approach in determining whether an alternate source is acceptable. The alternate source must be publicly available and must either include an ex-factory price or one must be derivable due to the country-specific regulations of retail and distribution margins.

A decision tree, available on the PMPRB website, has been developed by Board Staff to provide patentees with greater certainty and transparency regarding these case-specific assessments. The decision-tree will be used to guide Board Staff **only** in cases where a price is not available in the recognized source used by the PMPRB.

The Foreign Price Verification Policy does not change any of the existing requirements in the Regulations requiring patentees to file publicly available ex-factory prices for all drugs that are sold in

Canada by the patentee, nor does it change PMPRB practice of requiring patentees to submit price data from the country-specific approved recognized price source (if available). The substance of the policy relates to the creation of the decision-tree, which summarizes the Board Staff decision-making process when an alternative price source is submitted by a patentee.

Furthermore, Board Staff will track each instance in which a non-recognized price source is submitted by a patentee for a given Drug Identification Number (DIN) and a summary of accepted price sources will be published on the PMPRB website on an annual basis beginning in January 2016. As part of this new approach, the PMPRB will regularly review its recognized sources to ensure best available information is used in a consistent and transparent manner.

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The Recognized Price Source for Germany is Changing to Lauer-Taxe Effective 2016

The PMPRB is continuously seeking ways to contribute to sustainable health care spending in Canada through a modern and progressive framework for regulating patented drug prices that keeps pace with the latest developments in the domestic and international pharmaceutical environment. To that end, based on an internal review of current price sources, the PMPRB concluded that the Lauer-Taxe is a better and more reliable, publicly available, and comprehensive source of ex-factory prices in Germany.

As a result, the PMPRB will be switching its recognized price source for Germany from the Rote Liste to the Lauer-Taxe **effective January 2016**. Going forward from that date, the PMPRB foreign price verification for Germany will be based on ex-factory prices published in the Lauer-Taxe, net of all publicly available rebates.

In order to ensure patentees have an opportunity to adjust to the new recognized price source, Board Staff will accept either Lauer-Taxe or Rote Liste as valid sources for the 2015 calendar year; however, patentees are encouraged to use the Lauer-Taxe.

Patentees affected by this change will be notified.

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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Clarification: Existing Drug Products Subsequently Sold by Another Patentee

Section C.12.8 of the Guidelines stipulates that existing drug products subsequently sold by another patentee, in the case of a merger or an acquisition, will be treated as if the DIN continues to be sold by the initial patentee— also known as the DIN continuation policy.

For example: if, as part of a merger and acquisition agreement, a patentee ceases to sell a patented drug product and transfers the marketing rights to the product to another patentee, the DIN sold by the new patentee will, for purposes of the application of the Guidelines—including the DIP and CPI-Adjustment Methodology—be considered a continuation of the original DIN.

Please note Board Staff will interpret “acquisition” as including individual DIN transfers outside of the specific case of mergers between companies, or acquisitions of entire companies, as long as this interpretation is in compliance with Section 87 of the *Patent Act* and Section A.9.1 of the Guidelines. That is, 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.

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Summary of the Board’s December 15, 2014 Meeting

The Board held its fourth quarterly meeting on December 15, 2014.

The Chairperson provided an update on Board operations. Board Members discussed the issue of escalating drug prices and the effectiveness of the current policy. Board Members also received an update on the results from the PMPRB Town Hall Meeting, held in October, and the current strategic planning exercise.

Board Members were updated on recent NPDUIS initiatives, including the latest studies: *Generic Drugs in Canada, 2013* and the *New Drug Pipeline Monitor, 6th edition*.

The Board’s next meeting is scheduled for February 20, 2015.

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