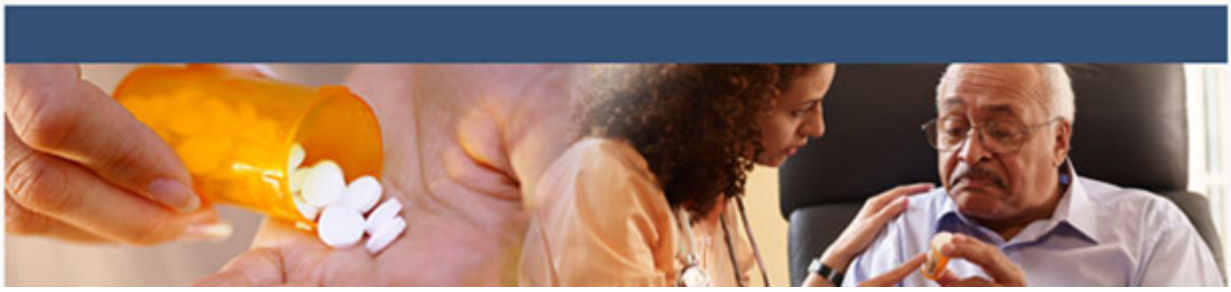
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés



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PMPRB *NEWSletter*

Rethinking the Guidelines: Update on consultations

The PMPRB is consulting with Canadians on the need for reform to its *Compendium of Policies, Guidelines and Procedures* (Guidelines). In June 2016, the PMPRB launched the first phase of this process by publishing a Discussion Paper entitled "PMPRB Guidelines Modernization." The Discussion Paper provides a framework for consultations by identifying aspects of the Guidelines that appear to be particularly outdated and asking a series of questions intended to inform a later phase of the consultation process when specific changes to the Guidelines will be proposed.

The public posting of the Discussion Paper on the PMPRB's website was announced through a news release, on Twitter, and other media platforms. It was also disseminated directly, via email, to more than 550 individuals representing 268 organizations that have a stake in the continuing sustainability of the Canadian pharmaceutical system, including public and private payers, patient advocacy groups, pharmaceutical industry associations, health sector professionals, academics, and labour unions. Meetings were subsequently arranged between PMPRB Staff and many of these stakeholder organizations, and a Researchers Forum on Guideline reform was held on October 3, 2016. The PMPRB received 65 submissions by the October 31 deadline from patients, provinces, academics, private insurers, pharmaceutical companies, health professionals, and advocacy groups representing more than 500 Canadian pharmaceutical stakeholders. The submissions will soon be accessible to the public in the *Rethinking the Guidelines* section on the PMPRB website.

Phase 2 of the consultation process will consist of a public policy hearing before the Board where stakeholders who commented on the Discussion Paper will have the opportunity to speak to their written submissions.

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Notice to Readers

Upcoming Events

- PMPRB Executive Director Doug Clark will be a panelist at the **Canadian Expert Patients in Health Technology Conference** on **November 8, 2016** in **Toronto, ON**
- Doug Clark will be a panelist at the **Drug Pricing in Canada: Mobilizing Patients to Action Summit** on **November 15, 2016** in **Toronto, ON**
- Doug Clark will be a speaker at the **15th Annual Market Access Summit** on **November**

New release: *2015 PMPRB Annual Report*

The *2015 Annual Report* of the PMPRB was tabled by the federal Minister of Health with the Clerks of the House of Commons and Senate on August 17, 2016.

The *2015 Annual Report* sets out detailed information on the PMPRB's regulatory activities; patentees' compliance with the Board's pricing guidelines; sales and trends of patented drugs in Canada, including international price comparisons, trends in all drug expenditures, and spending on pharmaceutical research and development.

The *2015 Annual Report of the* PMPRB is available on the PMPRB website.

Highlights

- Canadian patented drug prices remain third-highest among the seven comparator countries under the *Patented Medicines Regulations* (the "PMPRB7"), lower only than prices in Germany and the United States.
- Sales of patented drug products increased by 9.5% in 2015, from $13.8 billion to $15.2 billion, tying the record for the single-largest increase in patented drug sales in Canadian history.
- General anti-infective drugs, including new treatments for Hepatitis C, accounted for 15.8% of sales growth in 2015, an increase of 49.9% from 2014.
- Research and development investment in 2015 was reported at 4.4% of sales revenue for all pharmaceutical patentees, up from 4.3% in 2014, but far below the industry's 10% commitment and lowest of the PMPRB7.
- At the end of 2015, there were 93 active investigations into possible excessive patented drug pricing.
- Five Voluntary Compliance Undertakings were accepted in 2015 with over $7 million in excess revenues paid back by patentees to the Government of Canada, in addition to price reductions.

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Status of ongoing proceedings: Hearing updates

Soliris

The Board will hold a public hearing in the matter of the price of the patented medicine Soliris and Alexion Pharmaceuticals Inc. (Alexion) **beginning on January 16, 2017, in Ottawa.** The purpose of the hearing is to determine whether Alexion is selling or has sold the medicine at a price that is or was excessive.

Soliris is indicated for the treatment of 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-threatening genetic disorder characterized by blood clots in small vessels.

16, 2016 in **Toronto, ON**

Reminder

- To be notified of new announcements, publications, and other initiatives, please follow us on Twitter or subscribe to our RSS feeds.

Presentations

New Patented Medicines Reported to PMPRB

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Galderma

The Board held a public hearing on September 26 and 27, 2016 with respect to allegations that Galderma Canada Inc. failed to provide Board Staff with the pricing and sales information required under section 80 of the *Patent Act* and sections 3 and 4 of the *Patented Medicines Regulations*. This proceeding pertained to the medicines sold under the brand names Differin, Differin XP, TactuPump, and TactuPump Forte, which are generally used for the treatment of acne. If the Board finds that Galderma is in breach of its reporting requirements, it may order the company to provide the PMPRB with the requisite pricing and sales information.

A decision from the Board has yet to be issued.

Baxalta

On the consent of Baxalta Canada Corporation (Baxalta) and Board Staff, the Panel issued an Order on October 28, 2016 requiring Baxalta to provide the PMPRB with the information referred to in section 80 of the *Patent Act* and sections 3 and 4 of the *Patented Medicines Regulations* with respect to the medicine Oncaspar. Baxalta agreed to provide the information sought by Board Staff for the period commencing July 1, 2015, when Baxalta began selling Oncaspar in Canada.

The Panel's Order resolved this matter and, as such, no hearing will be held in November 2016.

Oncaspar is sold in Canada under Health Canada's Special Access Programme and is used in the treatment of patients with Acute Lymphoblastic Leukemia.

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

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2017 CPI-based price-adjustment factors for patented drug products

The following table provides the CPI-based price-adjustment factors for 2017. These factors were based on the actual rate of CPI inflation of 0.9% in 2013, 2.0% in 2014, and 1.1% in 2015.

CPI-based price-adjustment factors for 2017			
Benchmark year	2014	2015	2016
Price-adjustment factor	1.040	1.031	1.011

Based on these factors, one can derive:

- a maximum allowable cumulative price increase between 2014 and 2017 of 4.0% for patented drug products with Canadian sales in 2014;

- a maximum allowable cumulative price increase between 2015 and 2017 of 3.1% for patented drug products with Canadian sales in 2015; and

- a maximum allowable cumulative price increase between 2016 and 2017 of 1.1% for patented drug products with Canadian sales in 2016.

The year-over-year price increase cap for the 12-month period ending December 2017 is 1.7% (=1.5 x Actual Inflation in 2015).

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Amended Form 2 regulatory data

Where a patentee files an amended Form 2 for multiple DINs or for both Block 4 and 5 and an error is found in any part of the document, the patentee must update the initial amendment and resubmit the entire Form 2 package. For further information, patentees should contact their Senior Regulatory Officer.

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Patentee submissions in support of the scientific review process

As explained in the January and April 2015 editions of the PMPRB *NEWSletter*, a new format for submissions filed by patentees for consideration by the Human Drug Advisory Panel came into effect in September 2015.

Patentees filing such submissions are reminded that all documents must be provided in a single PDF document that is unlocked, searchable, and printable. Any references or data being relied upon for the purpose of the submission must be provided in full (e.g., simply providing links to webpages or noting that data is available on file is not sufficient). A submission which does not meet these requirements may be returned to the patentee in its entirety. Patentees are also asked to ensure any individual document to which reference is made in the submission is numbered for ease of reference.

Further to an announcement in the January 2016 edition of the PMPRB *NEWSletter*, patentees are encouraged to continue to bear in mind the need for brevity and relevance in preparing their submissions. To that end, patentees should focus on and include only the most recent and pertinent evidence-based materials bearing directly on the subject matter and issues under consideration, such as clinical trial results, clinical practice guidelines, expert reviews, meta-analyses, drug assessments carried out by regulatory bodies and other specialized organizations, and product monographs for proposed comparators.

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NPDUIS update: Publications and engagement activities

New publication

On October 25, 2016, the PMPRB released the first issue of its new NPDUIS *Market Intelligence Report* analytical research series. Each publication in this series will explore a specific market segment of therapeutic and/or economic importance to Canadians.

Market Intelligence Report: Biologic response modifier agents, 2015

This edition of the *Market Intelligence Report* analyzes the Canadian market for a select number of biologic response modifier agents including Remicade, Humira and Enbrel. These drugs, which are used in the treatment of chronic inflammatory diseases such as rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriasis, represent a significant cost driver for both public and private drug plans in Canada. Since 2010, Canadian sales have nearly doubled, reaching $2.2 billion (10.3% of the Canadian pharmaceutical market) in 2015.

The report explores the market dynamics from a national and international perspective, focusing on the 2015 calendar year, and includes a retrospective review of recent trends. The analysis considers the price, use, and cost of these drugs both as a class and individually, and positions Canadian costs relative to international benchmarks. The report finds that Canadians use a greater share of the highest-cost drugs than patients in comparator countries, despite the availability of lower-cost options, such as biosimilars. Canadians also pay a much higher list price for some of these drugs – for example, Remicade, which is almost exclusively delivered through manufacturer-sponsored clinics in Canada, costs an average of 25% less in comparable foreign markets.

Coming soon

Another new publication series is slated for launch early in 2017:

Meds Entry Watch

The top new drugs launched in Canadian and international markets are featured in this new NPDUIS series. Each edition explores market entry dynamics from the perspective of availability, sales, launch sequence, market penetration, and price comparisons. The first report in the series will provide a comprehensive review of drugs launched between 2009 and 2014. Subsequent editions will update this information using the latest available data.

The report highlights drugs with potential therapeutic and/or economic significance, including new biologics, cancer treatments, and orphan drugs. It provides an international context for drugs newly launched in Canada and identifies new international launches that have the potential to enter the Canadian market. This report will be of particular interest to policy makers and other stakeholders affected by the availability of new drug therapies in Canada and their potential cost pressures.

Also watch for the next edition of the *CompassRx,* the NPDUIS annual flagship publication:

CompassRx 2015/16

The most recent edition of the renewed and updated *Annual Public Drug Plan Expenditure Report* reviews some interesting developments. For the first time in recent years, there has been a significant increase in the growth in drug costs. This report identifies and analyses the key factors driving this trend.

Engagement activities

The NPDUIS group continues to engage with stakeholders to exchange information and share the results of their analyses. In conjunction with the publication of major studies, presentations of the findings are offered to key stakeholders including policy-makers, and consumer and industry groups. Webinar presentations that offered an overview of the report highlights were delivered to coincide with the release of the *Market Intelligence Report*.

On October 4, the PMPRB held its third annual invitational Researchers Forum. At the meeting, the NPDUIS group participated in a discussion on the concept of fair pricing with academics and other subject-matter experts.

On October 5, the NPDUIS group hosted its annual face-to-face meeting with its Advisory Committee. The Advisory Committee guides the analytical direction of the NPDUIS initiative and is composed of public drug plan representatives and participants from Health Canada, the Canadian Institute for Health Information and the Canadian Agency for Drugs and Technologies in Health. NPDUIS staff presented the preliminary results of a number of new studies and explored future analytical priorities.

For more information on future research topics and publications, see the NPDUIS Research Agenda on the PMPRB website.

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