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

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PMPRB NEWSletter

Update on Guideline reform

Since June 2018, the PMPRB has been consulting select stakeholders on the broad strokes of a new pricing framework that would give effect to Health Canada's proposed amendments to the *Patented Medicines Regulations* and support the agency's move to a more risk-based approach to regulating drug prices. As part of that process, an expert Working Group was struck to provide insight and advice on some of the more technical aspects of the new regime. The Working Group's report was completed on March 6, 2019 and is now available on the PMPRB's website.

We are grateful to the members of the Working Group for their active participation in advancing this important initiative and would like to express a special thank you to professor Mike Paulden for his exemplary work as Chair.

As this phase of the PMPRB's consultation process draws to a close, the Steering Committee on Guidelines Modernization will hold its final meeting on May 13, 2019, to discuss a draft report of its deliberations and to hear from Professor Paulden on the content of the Working Group's report. Once the Steering Committee report has been finalized and made available on the PMPRB's website and the regulatory amendments have been published in Part II of the *Canada Gazette*, the PMPRB will release new draft Guidelines for public consultation. Details on the nature, scope and timing of those consultations will be provided at that time.

The PMPRB looks forward to an open and constructive consultation process on its new Guidelines with all of its stakeholders and interested members of the public.

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2020 CPI-Based Price-Adjustment Factors for Patented Drug Products

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Notice to Readers

The following table provides the CPI-Based Price-Adjustment factors for 2020. These factors were based on the actual rate of CPI inflation of 1.4% in 2016, 1.6% in 2017 and 2.3% in 2018.

CPI-Based Price-Adjustment factors for 2020			
Benchmark Year	2017	2018	2019
Price-Adjustment Factor	1.054	1.039	1.023

Based on these factors, one can derive: (1) a maximum allowable cumulative price increase of 5.4% between 2017 and 2020 for patented medicines with Canadian sales in 2017; (2) a maximum allowable cumulative price increase of 3.9% between 2018 and 2020 for patented medicines with Canadian sales in 2018; and (3) a maximum allowable cumulative price increase of 2.3% between 2019 and 2020 for patented medicines with Canadian sales in 2019.

The year-over-year price increase cap for the 12-month period ending December 2020 is 3.5% (=1.5 x Actual Inflation in 2018).

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NPDUIS update

NPDUIS Advisory Committee
A teleconference was held with the NPDUIS Advisory Committee on February 6, 2019, to discuss current and upcoming projects and priorities. The Committee advises and supports the PMPRB in establishing research priorities, in the development of research methodologies, and in the interpretation of analytical results. It is composed of public drug plan representatives and participants from Health Canada, the Canadian Institute for Health Information (CIHI), the Canadian Agency for Drugs and Technologies in Health (CADTH), and the pan-Canadian Pharmaceutical Alliance (pCPA) Office.

Conference participation

PMPRB officials will be participating in the following conferences this spring:

- The Canadian Centre for Applied Research in Cancer Control (ARCC) conference in Halifax, May 27–28; and
- The Canadian Association for Health Services and Policy Research (CAHSPR) Scientific Conference in Halifax, May 29–31.

NPDUIS presentations at these events will provide up-to-date information on a variety of key topics including cost pressures in

Updates

- Director, Policy and Economics Analysis Branch, Tanya Potashnik attended SNOWCAP: UBC International Summit on Orphan Drug Pricing and Policy in Vancouver, BC from March 14-15, 2019.
- Manager, Elena Lungu spoke at the World Pharma Pricing, Evidence and Market Access Congress in Amsterdam, NL from March 19-20, 2019.
- Director, Guillaume Couillard spoke at the Telus Conference in Quebec City, QC on March 13 and in Montreal, QC on March 27, 2019.
- Manager, Elena Lungu spoke at the Telus Conference in Toronto, ON on April 2, 2019.
- Executive Director, Doug Clark, spoke at the 3rd Annual Care Congress in Toronto in Biosimilars on April 5, 2019.
- Manager, Thy Dinh spoke at the Telus Conference in Vancouver BC, on April 10, 2019.
- Manager, Elena Lungu spoke at the World Orphan Drug Congress USA in Washington DC from April 10 to 12, 2019.
- Executive Director, Doug Clark spoke at the World Health Organization 2nd Fair Pricing Forum in Johannesburg, South Africa on April 12, 2019.
- Director, Policy and Economics Analysis Branch, Tanya Potashnik, and Manager, Elena Lungu participated in an expert panel on expensive drugs for rare diseases (EDRDs) at the CADTH Symposium in Edmonton from April 14 to 16, 2019.

Canadian public and private drug plans; the market for select anti-asthmatics in Canada; highlights of new medicines in the pipeline; the alignment of oncology drug coverage across Canada; the oncology drug market in Canada; and the Canadian market for biosimilars.

Poster presentations are available on the website following the events.

Details on the content and timing of future presentations will be available through the PMPRB Twitter account closer to the conference dates.

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New and upcoming publications

New Releases

Meds Entry Watch, 2017 (February 19, 2019)

Meds Entry Watch explores the market entry dynamics of new medicines in Canadian and international markets. The third installment in this series examines the availability, sales, uptake, pricing, and treatment costs of new medicines approved by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada in 2016 and 2017, and provides a look at trends since 2009. This edition of the report also includes a one-time retrospective analysis of new biosimilars approved between 2006 and 2017.

The report finds that the number of new medicines launched in Canada is generally in line with the average for the Organisation for Economic Development (OECD), but less than that of all seven of the PMPRB comparator countries, many of which have lower average patented medicine prices. Most new medicines came with a high treatment cost; over one quarter were cancer therapies, close to half had orphan designations, and many were biologic.

Market Intelligence Report: Anti-Vascular Endothelial Growth Factor (Anti-VEGF) Drugs for Retinal Conditions, 2017
(December 12, 2018)

The *Market Intelligence Report* series provides detailed information on specific therapeutic market segments of importance to Canadians. Biologic anti-VEGF drugs used to treat wet (neovascular) age-related macular degeneration (AMD) and other retinal conditions are a rapidly growing market with relatively high treatment costs and a sizable patient population. AMD is the leading cause of visual impairment in adults over 50, with the more serious “wet" form affecting over 100,000 Canadians. This study focuses on Lucentis (ranibizumab) and Eylea (aflibercept), the two biologic anti-VEGF drugs approved for retinal conditions, and also reports on Avastin (bevacizumab), an anti-VEGF approved for cancer treatment that has widespread off-label use for retinal conditions.

Upcoming Events

- Director, Regulatory Affairs and Outreach Branch, Matthew Kellison will speak at the Public Policy Forum Energy Regulator Dialogues in Calgary, AB on May 8, 2019.
- Director, Policy and Economics Analysis Branch, Tanya Potashnik will attend the ISPOR HTA RoundTable in New Orleans, Louisiana on May 19, 2019.

Director, Policy and Economics Analysis Branch, Tanya Potashnik will attend the PPRI Network Meeting in Tallinn, Estonia, from May 20-22, 2019.

Reminders

- The PMPRB no longer issues e-bulletins. 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

NPDUIS

Hearings

While anti-VEGF drugs offer substantial therapeutic improvements for these conditions, they have had a significant impact on pharmaceutical sales. Anti-VEGFs for retinal conditions are a $700 million market in Canada, marked by strong sales growth over the last decade, and now account for 2.8% of Canadian pharmaceutical sales. The report finds that Canadian per capita spending and consumption rates of anti-VEGFs are among the highest in the OECD, with list prices that are second highest only to the US among the PMPRB7 countries and substantially higher than the OECD median.

Coming Soon

Several studies are slated for publication in the coming months:

Meds Pipeline Monitor (previously the *New Drug Pipeline Monitor*)

The *New Drug Pipeline Monitor* is returning with enhanced methodology and new title. This report highlights novel medicines in the late stages of clinical evaluation that may impact future clinical practice and/or drug spending in Canada. This report focuses on new medicines that may address previously unmet therapeutic needs, offer a therapeutic benefit over existing treatments, and/or treat serious conditions. In addition to the main list of medicines, this edition includes a feature section on upcoming gene therapies. *Meds Pipeline Monitor* is a companion publication to *Meds Entry Watch*. Together these two PMPRB publications provide readers with information on the new and emerging drug landscape by monitoring the market continuum of late-stage pipeline medicines and recent launches.

Generics360, 2017

This report series examines the latest trends in Canadian generic drug sales, utilization, and pricing within an international context. The coming issue tracks 2018 data to capture the impact of the latest generic pricing policy that reduced the prices of nearly 70 generic drugs to as little as 10% of their brand reference price. The report highlights the extent to which generic prices have declined in Canada and provides an assessment of Canada's relative position internationally following the implementation of the latest pricing policy.

CompassRx 2017/18

This flagship NPDUIS publication explores the recent trends in public drug plan costs and utilization in Canada, as well as the shifting cost pressures that contribute to the growth in prescription drug expenditures. This edition provides insight into the factors driving the growth in drug and dispensing costs in 2017/18, including the initial impact of the OHIP+ program, as well as a retrospective review of recent trends in public drug plan costs and utilization.

Staying Informed

The PMPRB presents information sessions immediately following the release of each report. These one-hour webinars explain the key findings of each study.

If you are interested in receiving notifications related to the release on NPDUIS reports as well as invitations to join information sessions, please send a request to: pmprb.npduis-sniump.cepmb@pmprb-cepmb.gc.ca.

For more information on future research topics and publications, see the NPDUIS Research Agenda on the PMPRB website and follow the PMPRB on Twitter.
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Voluntary Compliance Undertakings

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 thresholds in the Guidelines. 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.

Lynparza

Lynparza is an antineoplastic agent indicated for monotherapy use in the maintenance treatment of adult patients with platinum-sensitive relapsed BRCA mutated high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response to platinum-based chemotherapy.

On December 19, 2018, the Chairperson of the Board approved a VCU by AstraZeneca Canada Inc. (AstraZeneca) regarding the price of Lynparza. AstraZeneca agreed to reduce the list price of Lynparza and to offset any excess revenues received by AstraZeneca up to December 31, 2017.

AstraZeneca will also ensure that the price of Lynparza remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

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Summary of the Board's January 14, 2019 meeting

The Board held its first meeting of 2019 on January 14.

During this meeting, the Chairperson provided an update on Board operations. Board Members were also debriefed on the latest developments with respect to regulatory framework modernization and on NPDUIS activities.

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