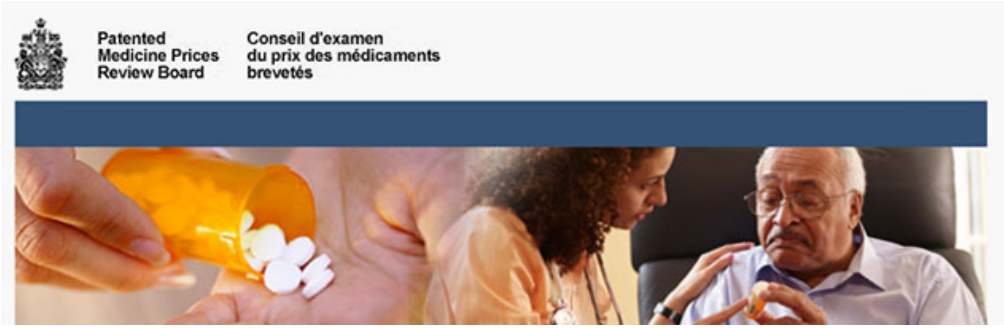

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PMPRB NEWSletter

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Notice to Readers

Updates

- Executive Director, Doug Clark spoke at the CARE Regional Congress on September 14, 2018, in Ottawa, ON.
- Executive Director, Doug Clark spoke at the CADTH Board of Directors Retreat on September 24, 2018, in Toronto, ON.
- Executive Director, Doug Clark spoke at the Advisory Council on Implementation of National Pharmacare's Information Day on October 17, 2018, in Ottawa, ON.

Upcoming Events

- Matthew Kellison, Director of Regulatory Affairs and Outreach, will be speaking at the Market Access Summit in Toronto on November 12, 2018 and at the Canadian Association for Healthcare Reimbursement's National Day on November 15, 2018.

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.

Canada

Update on Guideline Reform

Since June of this year, the PMPRB has been holding targeted consultations with its stakeholders on key aspects of a new, risk-based Guidelines framework which would operationalize Health Canada's proposed amendments to the *Patented Medicines Regulations* ("Regulations") and make patented drug prices more affordable for Canadians. This work has been carried out by a steering committee on Guidelines modernization and a technical working group composed mainly of experts in health technology assessment. Both groups have met in person and by conference call several times in the intervening months but progress on the issues under discussion has been slower than anticipated, owing to the complexity of the subject matter and conflicting views of participants on the merits of the underlying policy. The ultimate aim of both groups is to produce a report on their deliberations for consideration by the PMPRB's Board prior to the release of new draft Guidelines for broader public consultation. Originally slated to coincide with Health Canada's publication of final regulatory amendments, it is apparent that more time is needed for this work to be completed. As a January 2019 implementation date for the Regulations now appears to be unlikely, the PMPRB is in the process of revising the meeting schedule and timetable of deliverables for the steering committee and working group and will communicate that information to members shortly. Updates on past and future meetings as well as the status of the work of both groups will continue to be made available on the PMPRB website.

The PMPRB remains committed to an open and transparent consultation process as it readies itself operationally for the amended Regulations.

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NPDUIS update: Engagement activities

October 16 marked the annual face-to-face meeting of the NPDUIS Advisory Committee. The meeting was hosted in Ottawa to discuss upcoming projects and research priorities. The Advisory Committee is composed of representatives from Health Canada and public drug plans in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, Yukon and the Non-Insured Health Benefits program. It also includes observers from the Canadian Institute for Health Information (CIHI), the Canadian Agency for Drugs and Technologies in Health (CADTH), the Ministère de la Santé et des Services sociaux du Quebec, and the pan-Canadian Pharmaceutical Alliance (pCPA) Office.

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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New and upcoming publications

Poster publications for the Spring 2018 conference presentations are now available on the Analytical Studies webpage of the PMPRB website.

New Release:

CompassRx, 4th edition, 2016/17

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. The report found that increased spending on high cost drugs and reduced savings from generics was responsible for 6.3% average growth over 2 years.

Public drug plan expenditures increased by an additional 1.9% in 2016-17, following a notable growth of 10.8% in 2015-16, to reach a total of $10.7 billion. The increase in public plan drug costs in 2016-17 was driven by a greater use of higher-cost drugs combined with reduced generic savings and a decline in the use of direct-acting antiviral (DAA) drugs for hepatitis C. Higher-cost drugs (other than DAAs) continue to be the most pronounced driver, pushing costs upward by 4.4% in 2016-17.

CompassRx is a key resource for policy makers and researchers – highlighting factors relevant for understanding the sources of current cost pressures and potential future trends. The next edition, which will focus on public drug plan expenditures in fiscal year 2017-18, is due for release in the spring of 2019.

Coming soon in 2018:

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

The Market Intelligence Report series provides detailed information on specific therapeutic market segments of importance to Canadians. These targeted analyses are designed to inform policy discussions, aid in evidence-based decision making, and provide Canadians with insight into issues pertaining to pharmaceutical pricing, utilization, and sales trends in Canada and internationally.

The second study in the series explores the rapidly growing market of biologic anti-vascular endothelial growth factor (anti-VEGF) drugs. Biologic anti-VEGF drugs are used to treat wet age-related macular degeneration (AMD) and other retinal conditions. AMD is the leading cause of visual impairment in adults over 50, with the more serious "wet" form affecting over 100,000 Canadians. While anti-VEGF drugs offer substantial therapeutic improvements for these conditions, they have had a significant impact on pharmaceutical sales in Canada, accounting for 2.8% of the total market by 2017.

This analysis focuses on Lucentis (ranibizumab) and Eylea (aflibercept), the two anti-VEGFs indicated for retinal conditions, and also reports on Avastin (bevacizumab), an anti-VEGF drug approved for cancer treatment, and widely used off-label for retinal conditions.

Meds Entry Watch, 3rd edition

The Meds Entry Watch report explores the market entry dynamics of new medicines in Canadian and international markets. Closely following the recent release of the 2nd edition, the 3rd installment in this series offers a closer look at the new medicines launched in 2016, reporting on their availability, pricing, and uptake in sales as of Q4-2017, and provides a preliminary analysis of new launches from 2017 in Canadian and international markets.

This edition of the report also features a new section on biosimilars, with information on approvals, pricing, and uptake in use in Canada and internationally since 2006.

Meds Entry Watch informs decision makers, researchers, and patients of the evolving market dynamics of emerging therapies in the Canadian and international pharmaceutical environment. It is a companion report to the Meds Pipeline Monitor.

Meds Pipeline Monitor (previously the New Drug Pipeline Monitor)

The New Drug Pipeline Monitor is returning for 2018 with an enhanced methodology alongside its new title. This report highlights novel therapies in the late stages of clinical development that may significantly impact future drug expenditures in Canada. Selected medicines are reported by key therapeutic areas, including oncology, cardiovascular system diseases, blood diseases, Alzheimer disease and other neurological conditions, as well as rare diseases. The report also includes pipeline medicines that may not be novel but belong to high-growth or high-prevalence therapeutic areas and may impact market dynamics.

Meds Pipeline Monitor is a companion report to the Meds Entry Watch, which tracks the next stage in a product's life cycle, namely market entry. Together these reports provide decision makers, researchers, and patients with a broad overview of new and emerging drug therapies in the Canadian and international pharmaceutical environment.

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 Q2-2018 data to capture the impact of the most recent pCPA policy discounting the price of 70 commonly prescribed generic drugs at either 10% or 18% of their brand-name equivalents. The reporting highlights the extent to which generic prices have declined in Canada and provides an assessment of Canada's relative position internationally following these latest pricing policies. The results are presented for each of the market segments targeted by the policies.

Generics360 is an important resource for policy makers, the pharmaceutical industry, and patients.

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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2019 Human Drug Advisory Panel Meetings - Update

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 meeting date and submission deadlines for the first two meetings of the HDAP in 2019 are indicated below:

HDAP Meeting / Conference Call	**Requirements**	**Deadline**
Monday, February 25, 2019	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)	Thursday, November 1, 2018
	One electronic copy of patentee submission	Thursday, November 29, 2018
Monday, May 27, 2019	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)	Thursday, January 10, 2019
	One electronic copy of patentee submission	Thursday, February 14, 2019

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

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2019 CPI-Based Price-Adjustment Factors for Patented Medicines

The following table provides the CPI-Based Price-Adjustment factors for 2019. These factors were based on the actual rate of CPI inflation of 1.1% in 2015, 1.4% in 2016 and 1.6% in 2017.

CPI-Based Price-Adjustment factors for 2019

Benchmark Year	2016	2017	2018
Price-Adjustment Factor	1.042	1.030	1.016

Based on these factors, one can derive: (1) a maximum allowable cumulative price increase between 2016 and 2019 of 4.2% for patented medicines with Canadian sales in 2016; (2) a maximum allowable cumulative price increase between 2017 and 2019 of 3.0% for patented medicines with Canadian sales in 2017; and (3) a maximum allowable cumulative price increase between 2018 and 2019 of 1.6% for patented medicines with Canadian sales in 2018.

The year-over-year price increase cap for the 12-month period ending December 2019 is 2.4% (=1.5 x Actual Inflation in 2017).

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Summary of the Board's October 2018 Meeting

The Board held its third meeting of 2018 on October 11.

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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