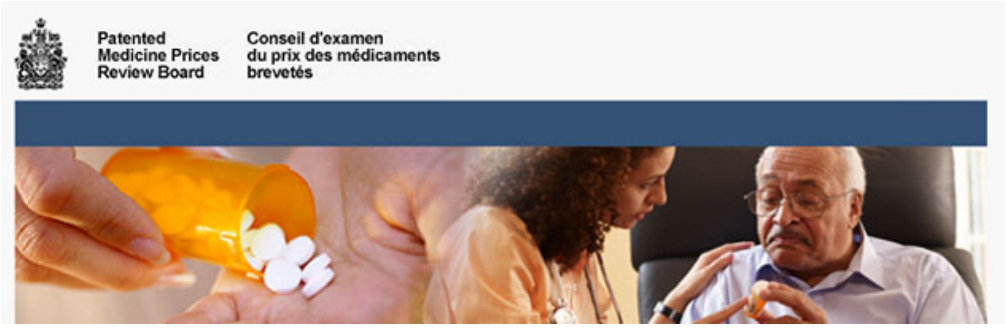

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PMPRB NEWSletter

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Notice to Readers

Updates

- Director Regulatory Affairs and Outreach, Matthew Kellison spoke at the CAHR Market Access 201 conference on June 19.

Upcoming Events

- Executive Director, Doug Clark will be a speaker at the CARE Regional Congress on September 14, 2018, in Ottawa, ON.

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

New Board Members Appointed

I am pleased to welcome Dr. Ingrid Sketris and Mr. Matthew Herder as the newest members of the Board, as announced by the Honourable Ginette Petitpas Taylor, Minister of Health, on June 29, 2018.

Dr. Ingrid Sketris is a licensed pharmacist and professor at the College of Pharmacy at Dalhousie University, with appointments to Medicine and Health Services Administration. She is a leader in pharmacy, and has served as President of the Association of Faculties of Pharmacy of Canada and as a board member of the Canadian Council for Accreditation of Pharmacy Programs.

Mr. Matthew Herder is an Associate Professor with the Health Law Institute and the Faculties of Medicine and Law at Dalhousie University. Professor Herder's research focuses on biomedical innovation policy, with a particular emphasis on intellectual property law.

The appointment of such highly regarded and knowledgeable members to the Board will serve us well as we undertake the final phase of modernizing our regulatory framework. I look forward to working with them during this exciting time in the PMPRB's history.

Dr. Mitchell Levine

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Update on Guideline Reform

On Tuesday, June 26, 2018 the PMPRB hosted the first meeting of the newly established Steering Committee on Modernization of Price Review Process Guidelines.

The one-day meeting provided members with an opportunity to review the terms of reference for the Steering Committee and to discuss timelines for implementation of the proposed changes to the PMPRB's regulations and guidelines. PMPRB Staff presented an outline of how the new Guidelines might work, to generate discussion and help identify key questions and issues for stakeholders. Members also discussed the mandate of the Technical Working Group and the possibility that other matters might warrant expert review by additional such groups.

The first meeting of the Technical Working Group on the Modernization of Price Review Process Guidelines took place in Ottawa on Thursday July 26, 2018. The Technical Working Group will inform the work of the Steering Committee by examining issues that would benefit from the review of experts in health technology assessment and other economic and scientific matters.

Discussions during the one-day meeting focused on the following issues:

- Options for determining what drugs fall into 'Category 1';
- Application of supply-side cost effectiveness thresholds in setting ceiling prices for Category 1 drugs;
- Drugs with multiple indications;
- Options for using the CADTH and/or INESS reference case analyses to set a ceiling price;
- Perspectives; and
- Application of the market size factor in setting ceiling prices.

Reference documents for the work of both the Steering Committee and the Technical Working Group are available online. Further meetings are planned and will be discussed in future editions of the NEWSletter.

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Supreme Court Declines to Grant Leave to Review Decision Reiterating Constitutional Validity of the PMPRB

In a decision dated June 28, 2018 (37949), the Supreme Court of Canada dismissed Alexion Pharmaceutical Inc.'s application for leave to appeal arising from the December 7, 2017 Federal Court of Appeal's (2017 FCA 241) decision related to the constitutional validity of the PMPRB. The Federal Court of Appeal's decision dismissed an appeal of a Federal Court decision striking an application for judicial review seeking a declaration that the excessive price provisions of the Patent Act were unconstitutional.

The judicial review application was originally brought in September 2015 by Alexion Pharmaceuticals Inc., which sells the patented medicine Soliris (eculizumab)whose price was, at the time, the subject of a hearing before the Board. The Attorney General of Canada moved to strike the application on the grounds that it was "bereft of any chance of success" in view of the Federal Court of Appeal's decision in the Sandoz case (2015 FCA 249) that confirmed the constitutionality of the excessive price provisions of the Patent Act. The motion to strike was granted by Prothonotary Aalto based on stare decisis (2016 FC 716) and later upheld by Justice Simpson (2017 FC 22). Alexion then appealed to the Federal Court of Appeal alleging that the Sandoz decision was not binding authority.

The Federal Court of Appeal upheld the decision of the Federal Court. In addition, on its own motion, the Court addressed the issue of whether it was appropriate for Alexion to launch an application for judicial review before putting the arguments before the Board. In this regard, the Court found that "by bypassing the Board, the application has undermined its position as the first instance forum for decisions of fact and of law within its mandate, and deprived the reviewing court of the Board's insights on the purpose and operation of the challenged provisions." While the Court would have dismissed Alexion's appeal on this ground alone, it proceeded to address the issues raised in the appeal in the interest of judicial economy.

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NPDUIS update: Engagement activities

A teleconference was held with the NPDUIS Advisory Committee on June 20 to discuss current and upcoming projects and priorities. 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, the Canadian Agency for Drugs and Technologies in Health, the Ministère de la Santé et des Services sociaux (MSSS) du Québec and the pan-Canadian Pharmaceutical Alliance (pCPA) Office. The annual face-to-face meeting between the NPDUIS group and its advisory committee will be hosted in October.

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, academics and consumer and industry groups.

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: Meds Entry Watch, 2nd Edition

This annual NPDUIS publication features the new medicines launched in Canadian and international markets. The second edition in this series, published June 26th, identifies new active substances launched in 2015 and 2016, and analyzes their availability, pricing, and sales as of the end of 2016.

Important new medicines have been launched since 2009, accounting for nearly one quarter of brand-name medicines sales in Canada by 2016. In line with trends observed from 2009 to 2014, the study found that high-priced speciality medicines such as those used to treat rare diseases, biologic medicines and oncology medicines, continue to dominate the new drug landscape in 2015 and 2016, both in Canada and internationally. The report also found that while Canada launched more new medicines than most OECD countries, it launched fewer than all PMPRB comparator countries, including many with lower average patented medicine prices.

Coming soon in 2018:

CompassRx, 4th edition

Public drug plan expenditures account for a significant portion of the overall health-care budget. Through its flagship CompassRx report, the PMPRB monitors and analyzes the evolving pressures driving these expenditures including changes in the beneficiary population, the amount of medicines used, use of lower- and higher-priced medicines, medicine prices and use of brand-name and generic or biosimilar options. Since peaking in 2015/16, the growth in medicine costs has returned to historic levels. High-cost medicines remain a significant factor as the impact of generic price reductions declines.

Market Intelligence Reports

The Market Intelligence Report series provides detailed information on specific therapeutic market segments of importance to Canadians. Two targeted analyses from this series are scheduled for release by the end of the 2018.

Medicines for Age-related Macular Degeneration

Age-related macular degeneration (AMD) is the leading cause of irreversible blindness in Canada, affecting approximately 2 million Canadians. While new anti-vascular endothelial growth factor (anti-VEGF) medicines have improved therapy outcomes for these conditions, they come with a high price tag. By 2017, sales of these medicines accounted for 2.8% of the total Canadian pharmaceutical market. This analysis focuses on two major contributors, ranibizumab (Lucentis) and aflibercept (Eylea), to provide insight into the sales, uptake and prices of anti-VEGF medicines.

Diabetes Medicines

Diabetes is one of the leading causes of death in Canada, and its growing prevalence has fueled the development of new treatment options for diabetic patients. Non-insulin treatments, used as first line therapies for patients suffering from type 2 diabetes, currently capture more than half the sales in the anti-diabetic market. Over the past decade, dipeptidyl peptidase-4 inhibitors (DPP-4) and sodium-glucose cotransporter-2 inhibitors (SGLT-2) have stirred the market. This report provides insight into these two new classes of diabetes medicines with an analysis of their uptake and sales in Canada and

internationally.

Meds Entry Watch, 3rd edition

Closely following the recent release of the second edition, the third installment in this series offers a closer look at the new active substances launched in 2016, reporting on availability, pricing and sales as of Q4-2017, and provides a preliminary analysis of new medicines launched in 2017 in Canadian and international markets.

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First Quarter 2019 Human Drug Advisory Panel Meeting

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 meeting 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

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

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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 medicine sold in Canada appears to have exceeded 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.

Quinsair (levofloxacin) is indicated for the management of cystic fibrosis ("CF") in patients aged 18 years or older with chronic pulmonary Pseudomonas aeruginosa infections.

On June 26, 2018, the Chairperson of the Board approved a VCU by HZNP Canada Limited regarding the price of its medicine sold under the brand name of Quinsair. HZNP agreed to reduce the price of Quinsair and to ensure that its price remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

Repatha (evolocumab) is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD) who require additional lowering of low density lipoprotein cholesterol (LDL-C).

On May 10, 2018, the Chairperson of the Board approved a VCU by Amgen Canada Inc. (Amgen) regarding the price of the medicine sold under the brand name Repatha 120 mg/mL. Amgen agreed to reduce the price of Repatha 120 mg/mL and to ensure that its price remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction. Amgen also agreed to offset excessive revenues of $40,070.73 by making a payment to the Receiver General of Canada.

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