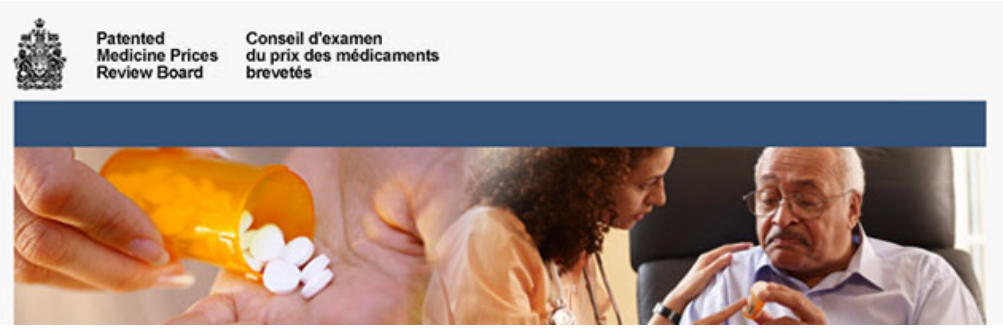

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PMPRB NEWSletter

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Notice to Readers

Updates

- Executive Director Doug Clark participated as a panelist at the Annual Care Congress on April 6, 2018 in Toronto, ON.
- Tanya Potashnik, Elena Lungu, and Nevzeta Bosnic participated as panelists at the Annual CADTH Symposium on April 16, 2018 in Halifax, NS.
- Doug Clark attended the Pharmaceutical Pricing and Reimbursement Information Network meeting on April 26 and 27, 2018, in Dublin.

Upcoming Events

- Doug Clark will participate as a panelist at the Canadian Society of Pharmaceutical Sciences Conference on May 23, 2018, in Toronto, ON.
- Doug Clark will be a discussion leader at Northwind's Annual Life Sciences Invitational Forum on May 24, 2018, in Cambridge, 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

Next steps on Guideline reform

As most of our readership will know, Health Canada recently consulted on a proposed comprehensive update to the Patented Medicines Regulations to curb excessive drug prices, ensure long-term sustainability, and align Canada's drug pricing policies with like-minded countries. Now that the comment period for the proposed amendments has closed, and in anticipation of final publication of the amendments in Canada Gazette Part II, the PMPRB will be resuming its parallel initiative to modernize its Guidelines by consulting stakeholders on the details of the framework described in its December 2017 Scoping Paper.

To that end, in June, the PMPRB will strike a multi-stakeholder Working Group on Guideline reform. The purpose of the Working Group will be to gather stakeholder input on key technical aspects of the new regime. Establishment of the Working Group will coincide with the release of more specific guidance on how the PMPRB foresees operationalizing the regulatory changes. Further information on the Working Group, including its composition, mandate and terms of reference, will be made available on the PMPRB website in the coming weeks. The report of the Working Group will be presented to the Board for consideration prior to the publication of draft Guidelines in the fall. This will be followed by a further period of consultation. The PMPRB will await gazetting of the regulatory amendments before finalizing its Guidelines, to accommodate the possibility of changes being made between prepublication and final publication which require adjustments in operational approach.

We look forward to constructive engagement with our stakeholders during this exciting and challenging period of reform and renewal.

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NPDUIS update: Engagement activities

Spring 2018 Conferences

NPDUIS team members are presenting their most recent analytical results as posters and oral presentations at the following noteworthy events this spring:

- The Canadian Agency for Drugs and Technologies in Health (CADTH) conference in Halifax, April 15-17;
- The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) conference in Baltimore, May 21-23; and
- The Canadian Association for Health Services and Policy Research (CAHSPR) conference in Montreal, May 29-31.

The presentations provide up-to-date information on a variety of key topics including: cost pressures in Canadian public and private drug plans; the Canadian and international availability and pricing of new drugs entering the market; the growth of high-cost drugs and beneficiaries in Canadian private plans; and the generic drug landscape in Canada. In addition, more detailed studies of the markets for age-related macular degeneration drugs and new oral antidiabetics will also be explored. Copies of the posters and/or slide presentations will be posted on the Analytical Studies webpage of the PMPRB website once the presentations are complete.

NPDUIS also organized two expert panels for the CADTH conference: one to debate the definition of "essential medicines" in the Canadian context; and another to discuss the sustainability of the increasingly high costs of oncology drugs.

Follow the PMPRB on Twitter for information on conference activities and to be notified of the release of upcoming publications, including the latest editions of Meds Entry Watch and CompassRx.

For future research topics, see the NPDUIS Research Agenda on the PMPRB website.

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New and upcoming publications

Coming soon in 2018:

Meds Entry Watch, 2nd Edition

The new drugs launched in Canadian and international markets are featured in this annual NPDUIS publication. This is the second edition in the series and provides up-to-date information on drugs launched in 2015 as well as preliminary listing and pricing information for drugs launched in 2016.

The analysis explores the availability and sales of new drugs in Canada and the PMPRB7; measures international uptake and price differentials; and reports on the level of therapeutic improvement, health technology assessments, price negotiation status and reimbursement decisions for new drugs available in Canada.

CompassRx, 4th edition

This annual NPDUIS report contains valuable information on the major factors driving prescription drug spending in public drug plans in Canada. It is a key resource for policy makers and researchers – highlighting factors relevant for understanding the sources of current cost pressures and potential future trends.

Potential Savings from Biosimilars in Canada

This analysis targets top-selling biologic biosimilars that are currently on the market or are expected to enter it within the next few years. The analysis will contribute important information to the discussion on the approval, pricing and reimbursement of biosimilar drugs.

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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 Guidelines. A VCU can also be submitted by a patentee after a Notice of Hearing is issued. 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.

Metoject Subcutaneous (methotrexate sodium)

Metoject Subcutaneous (methotrexate sodium) is indicated as a Disease Modifying Antirheumatic Drug (DMARD) for severe disabling psoriasis/psoriatic arthritis and severe disabling rheumatoid arthritis where standard therapeutic interventions fail.

On February 8, 2018, the Chairperson of the Board approved a VCU by Medexus Inc. (Medexus) regarding the price of Metoject Subcutaneous (Metoject). Medexus agreed to reduce the price of Metoject and to offset any remaining cumulative excess revenues as of December 31, 2017 by further reducing the 2018 price of one or more strengths of Metoject. Medexus also agreed to repay any remaining cumulative excess revenues as of December 31, 2018.

Finally, Medexus will ensure that the price of Metoject remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

Onreltea (brimonidine gel)

Onreltea (brimonidine gel, 0.33%) is indicated for the topical treatment of facial erythema of rosacea in adults 18 years of age or older.

On February 14, the Chairperson of the Board approved a VCU by Galderma Canada Inc. (Galderma) regarding the price of Onreltea. Galderma agreed to reduce the list price of Onreltea and to offset any excess revenues generated from January 1, 2017 to the date of implementation of the VCU.

Finally, Galderma will ensure that the price of Onreltea remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

Vectibix (panitumumab)

Vectibix 20 mg/mL (panitumumab) is indicated for the treatment of previously untreated patients with non-mutated (wild-type) RAS metastatic colorectal carcinoma in combination with FOLFOX (infusional 5-fluorouracil, leucovorin, and oxaliplatin). Vectibix is also indicated as monotherapy for the treatment of patients with non-mutated (wild-type) RAS mCRC after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

On February 28, the Chairperson of the Board approved a VCU by Amgen Canada Inc. (Amgen) regarding the price of Vectibix. Amgen agreed not to increase the price of Vectibix in any market while it remains under the PMPRB's jurisdiction and to repay any excess revenues generated during this period.

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Summary of the Board's April 2018 meeting

The Board held its second meeting of 2018 on April 17.

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, the future Guidelines consultations, the 2017 Annual Report, the 2018-19 PMPRB Budget and on NPDUIS activities.

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