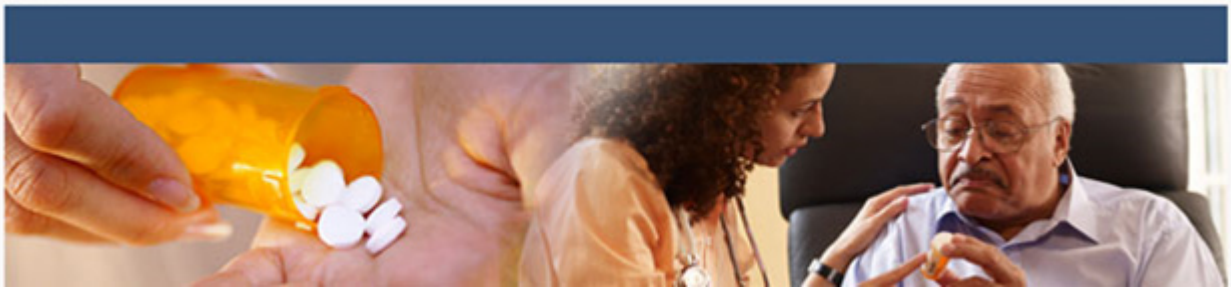
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés



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PMPRB *NEWSletter*

Update on the PMPRB framework modernization

On May 16, 2017, the Honourable Jane Philpott, Minister of Health, outlined a comprehensive plan to improve access, affordability and appropriate prescribing of pharmaceuticals in Canada. As a key part of that plan, the government is proposing changes to the way patented drug prices are regulated in Canada. From May 16 to June 28, 2017, Health Canada solicited feedback on proposed amendments to the *Patented Medicine Regulations* from provincial and territorial governments, consumer groups, patients, industry, academics, private drug plans and interested members of the public.

The stakeholder feedback received from this consultation will allow for refinement of the regulatory proposal prior to its pre-publication in the *Canada Gazette*, Part I (CGI) later this year. The Regulatory Impact Analysis Statement, which will accompany the pre-publication of the proposed regulations in CGI, will summarize the results of the current consultations and also include a cost-benefit analysis of the proposed amendments that estimates the impact of each element of the proposal on patented medicine expenditures in Canada. At that time, there will be a substantive consultation lasting 75 days.

Once the proposed regulations are in the CGI, the PMPRB will resume the Guidelines consultation process and will solicit input on how the proposed new factors and information could be applied in practice by Board Staff.

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Block 5 Filing Requirements for Patentees

Patentees are reminded that the *Patented Medicine Regulations* (Regulations) require them to file the publicly available ex-factory prices for each dosage form, strength, and package size in which their product is sold to each class of customer in each country set out in the schedule.

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Notice to Readers

Updates

- PMPRB Executive Director Doug Clark attended the Public Policy Forum roundtable discussion Balancing Innovation, Affordability and Outcomes: A New Model for Accessing Innovative Drugs on June 22, 2017 in Ottawa, ON.

Upcoming Events

- Doug Clark will be speaking at a seminar organized by Johnson Insurance Services in Fredericton, NB on **August 11, 2017**.

It is the responsibility of the patentee to ensure that Block 5 information accurately reflects the outcome of the patentee's own independent inquiry into the price of the product in each country. The information published on the PMPRB's website pertaining to how Board Staff verify prices submitted by patentees in their Block 5 filings, including the sources used, is for information purposes only and is not intended to serve as a substitute or shortcut for a patentee's own due diligence in seeking to comply with the Regulations. As each product may ultimately be assessed on a case-by-case basis, patentees are encouraged to contact Board Staff for guidance in specific cases of uncertainty regarding information that should be filed.

Additional information regarding filing requirements is available in the Patentee's Guide to Reporting on the PMPRB website.

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PMPRB bids farewell to Board Member Normand Tremblay

The PMPRB has bid a fond farewell to Normand Tremblay, who completed his term as a member of the Board on May 31, 2017.

Mr. Tremblay was appointed to the Board in May of 2012. His hard won record of achievement in business development, depth of knowledge in operational planning and down to earth, plain spoken manner brought a unique and welcome perspective to Board deliberations. Although his personal and business commitments did not afford him the time to serve a second term on the Board, Mr. Tremblay's enthusiasm and vision for the PMPRB will have a lasting impact on the organization's ongoing efforts to reform and modernize how it carries out its consumer protection mandate.

An open, transparent and merit-based Governor-in-Council selection process is underway to fill current vacancies on the Board.

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2018 Human Drug Advisory Panel schedule

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 HDAP meets four times a year. Meeting dates and deadlines for 2018 submissions are indicated below:

Reminders

- 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

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2018 Human Drug Advisory Panel schedule

HDAP Meeting / Conference Call	Requirements	Deadline
Tuesday, February 27, 2018	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)	November 7, 2017
	One electronic copy of patentee submission	December 12, 2017
Monday, May 7, 2018	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)	January 11, 2018
	One electronic copy of patentee submission	February 15, 2018
Monday, September 24, 2018	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)	May 10, 2018
	One electronic copy of patentee submission	June 7, 2018
Monday, November 26, 2018	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)	July 26, 2018
	One electronic copy of patentee submission	August 23, 2018

The 2018 HDAP meeting schedule and more information on requirements for filing electronic submissions are available on the PMPRB website.

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NPDUIS update: Engagement activities

NPDUIS Advisory Committee

An NPDUIS Advisory Committee teleconference was held in June 2017 to discuss the NPDUIS research agenda and the latest

developments at the jurisdictional level. The PMPRB is pleased that representatives from the Ministère de la Santé et des Services sociaux du Québec and the pan-Canadian Pharmaceutical Alliance Office are now regular observers on the Committee.

The next Advisory Committee meeting will be held in Ottawa in October 2017. This annual face-to-face meeting is co-organized by the Canadian Institute for Health Information (CIHI).

Conferences

The NPDUIS team presented the results of several analytical studies as posters and oral presentations at the Canadian Association for Health Services and Policy Research conference in Toronto, from May 22 to 26, 2017.

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New and upcoming publications

New

CompassRx, 3rd edition – 2015/16 **(May 2017)**

The latest edition of the PMPRB report on prescription drug expenditures in Canada's public drug plans was released on May 24, 2017. This issue focuses on the 2015/16 fiscal year and provides a retrospective review of trends in prescription drug expenditures since 2011/12.

The report found that prescription drug expenditures for Canadian public drug plans reached $11.3 billion in 2015/16, up $1 billion over the previous year. The increase was mainly driven by a 12% growth in drug costs. Patented drugs, which represented the largest market segment in terms of expenditures, accounted for the highest growth rate at 18.8%. While new and curative treatments for hepatitis C were major contributors to this growth, other high-cost drugs continued to put upward pressure on drug plans.

This relatively high growth rate signals a shift from a sustained period of low growth, as expenditures related to new, higher-cost drugs significantly outstripped savings from generic price reductions and generic competition to drugs that recently lost patent protection.

The findings from this series of reports aid stakeholders in anticipating and responding to the evolving cost pressures affecting Canada's public drug plans.

Upcoming

Report on public formularies in Canada – Part I[i]

The first report in a new three-part series on **Canadian public drug plan formularies** is slated for publication in the fall of 2017. This series explores the current overlaps and gaps among Canadian public drug plan formularies: Part I provides insight on

the degree of alignment among the general public drug plan formularies in 2015; while Parts II and III focus exclusively on newer drugs and oncology drugs, respectively.

In addition to a high-level comparison of the formulary listings, the first report unpacks specific market segments including single- and multi-source drugs, high-cost drugs, and a list of essential medicines. The alignment between public formularies is also analyzed by comparing the bilateral agreement rates for each of the 55 public plan pairs.

The information contained in these reports will be of interest to a wide variety of stakeholders and will shed light on issues related to national health initiatives.

Generics360

This series focuses on generic drug pricing and markets in Canada and compares them to other industrialized countries. The upcoming edition features an expanded international scope that includes Organization for Economic Co-operation and Development (OECD) countries in the 2016 analysis.

Potential savings from biosimilars in Canada

This report explores the potential cost impact of biosimilars on the Canadian market, targeting biologic drugs with biosimilars currently available on the market, as well as top-selling biologic drugs that are expected to lose market exclusivity over the next few years. This analysis will contribute key information to the discussion on the approval, pricing and reimbursement of biosimilar products.

Meds Entry Watch, 2nd Edition

Top new drugs launched in Canadian and international markets are featured in this annual PMPRB publication that explores market entry dynamics from the perspective of availability, sales, launch sequence, market penetration, and price comparisons.

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Summary of the Board's May 2017 meeting

The Board held its first quarterly meeting of 2017 on May 18.

The Vice-Chairperson provided an update on Board operations and Board members were briefed on recent policy and regulatory developments. The Board Members were updated on recent and upcoming NPDUIS research initiatives. Board members were also presented with information on trends in pharmaceutical pricing and investment in research and development, which will be published in the PMPRB 2016 Annual Report.

The Board's next meeting is scheduled for September 2017.

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[i] Previously appeared in the Research Agenda as the *Canadian Drug Reimbursement Landscape.*