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

PMPRB GUIDELINES MODERNIZATION

Canadian Institute's Pharma Symposium Canada

MAY 2016

Canada

Commitment to Modernization

Canada, like many countries, faces rising health costs as payers struggle to reconcile finite budgets with patient access to promising but costly new health technologies.

Canadian system is unique globally with a federal regulator tasked with policing abuse of patent-derived monopoly power but no mechanism to harness nationwide buying power to lower prices

Increasingly, the effectiveness of the PMPRB in carrying out its regulatory role within the Canadian system is being questioned.

PMPRB's 2015-2018 Strategic Objectives

1. Consumer focused regulation and reporting
2. Framework modernization
3. Strategic partnerships and public awareness
4. Employee Engagement

Origins of the PMPRB

Canada enacted a two-fold reform of its drug patent regime in 1987 (Bill C-22) that sought to balance competing industrial and social policy objectives:

- Strengthen patent protection for drug manufacturers to incentivize R&D
- Mitigate the financial impact of stronger pharmaceutical patent protection on payers

The PMPRB was conceived as C-22's "consumer protection pillar", to ensure patentees do not abuse their newfound statutory monopolies by charging excessive prices.

The intent was to double R&D in Canada (to 10% of revenues) while keeping prices in line with high R&D countries (the PMPRB-7"*) in order to pay our "fair share".

** France, Germany, Italy, Sweden, Switzerland, the UK and the USA.*

Impact of Policy

Prices are high and R&D is low

Although Canadian patented drug prices, on average, remain slightly below the median of the PMPRB7, this is because high US prices skew the median.

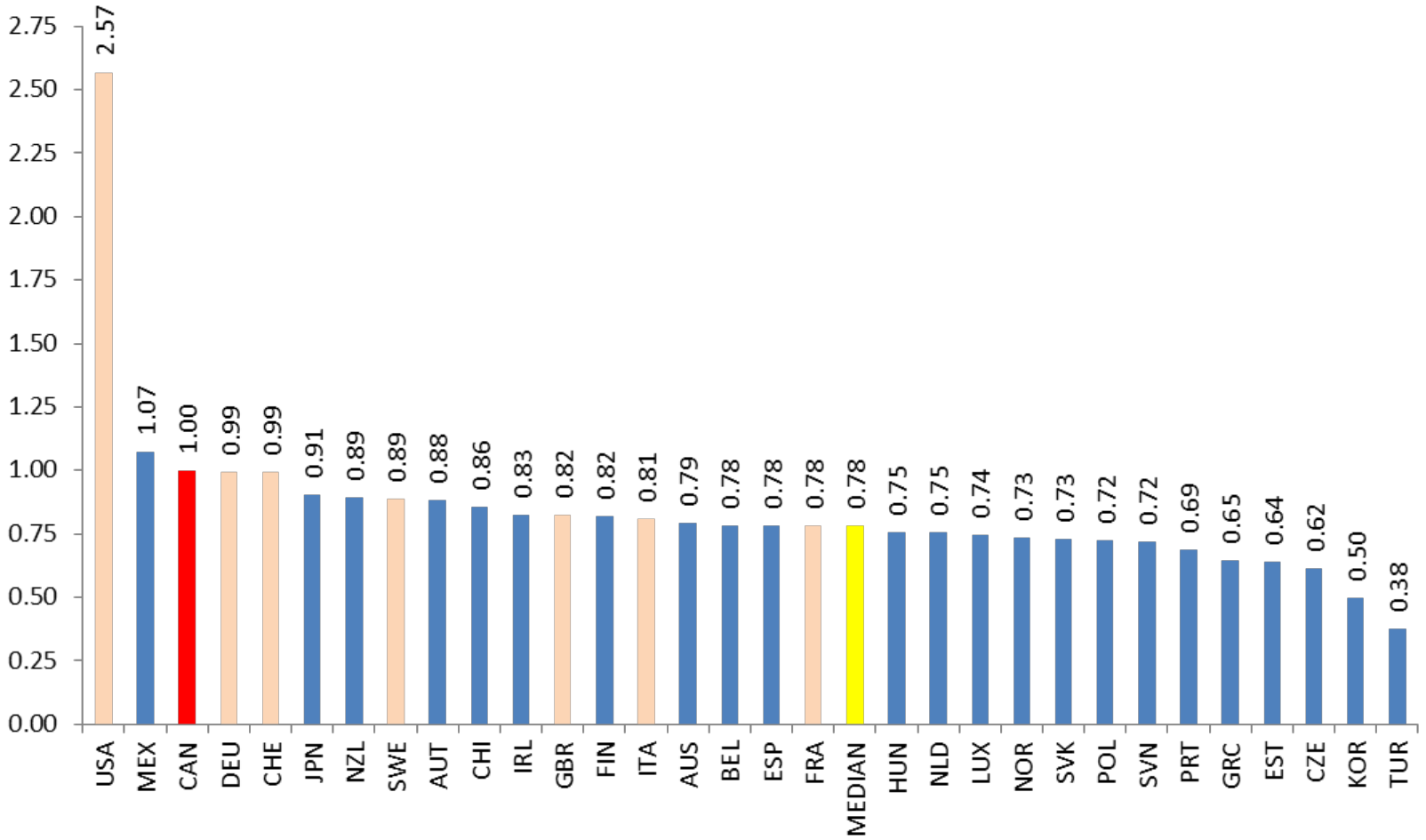
- Prices in France, Italy and the UK are 13-25% less than Canadian prices; Sweden and Switzerland are 3-4% less.
- Prices in Australia, Spain, the Netherlands and New Zealand are 14-34% less.

In 2005 only France and Italy had lower patented drug prices than Canada (among our comparators), today only Germany and the US are higher.

Conversely, R&D continues to decline, to 4.4% of revenues from sales of patented medicines in Canada for all patentees (5.0% for IMC members) – a fraction of the 22.8% average in the PMPRB7.

Prices are high

Average Foreign-to-Canadian price ratios paint a clear picture (Patented Drugs, 2015)

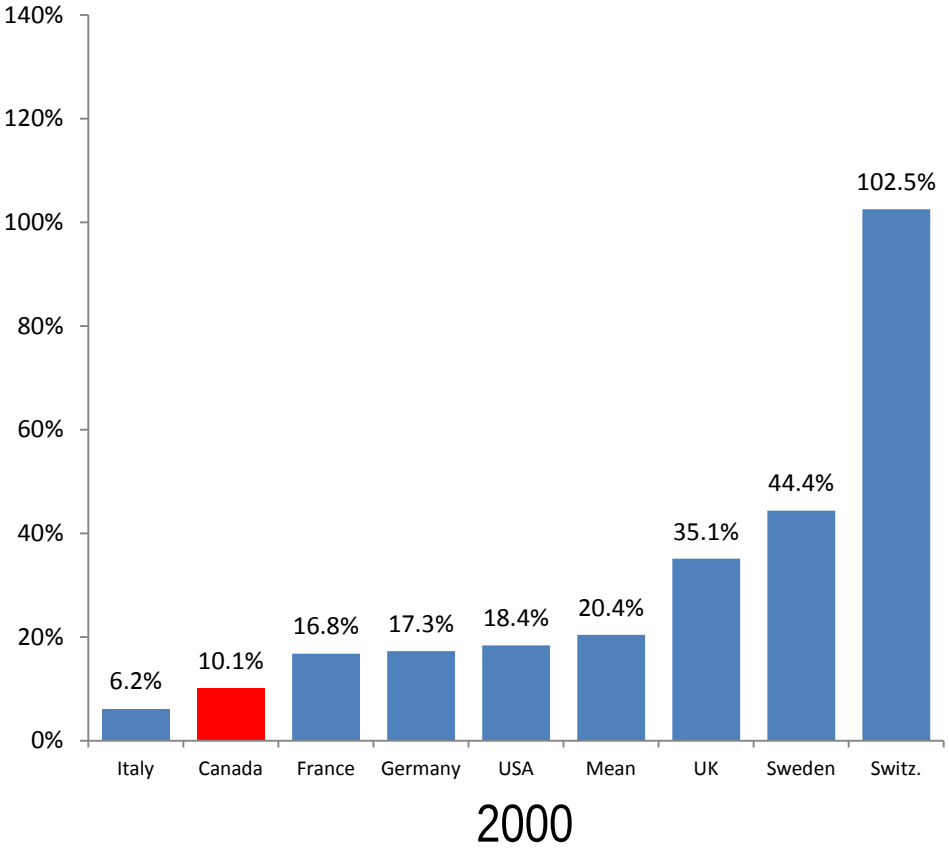


Source: IMS MIDAS database, 2005-2015, IMS AG.

R&D is Low

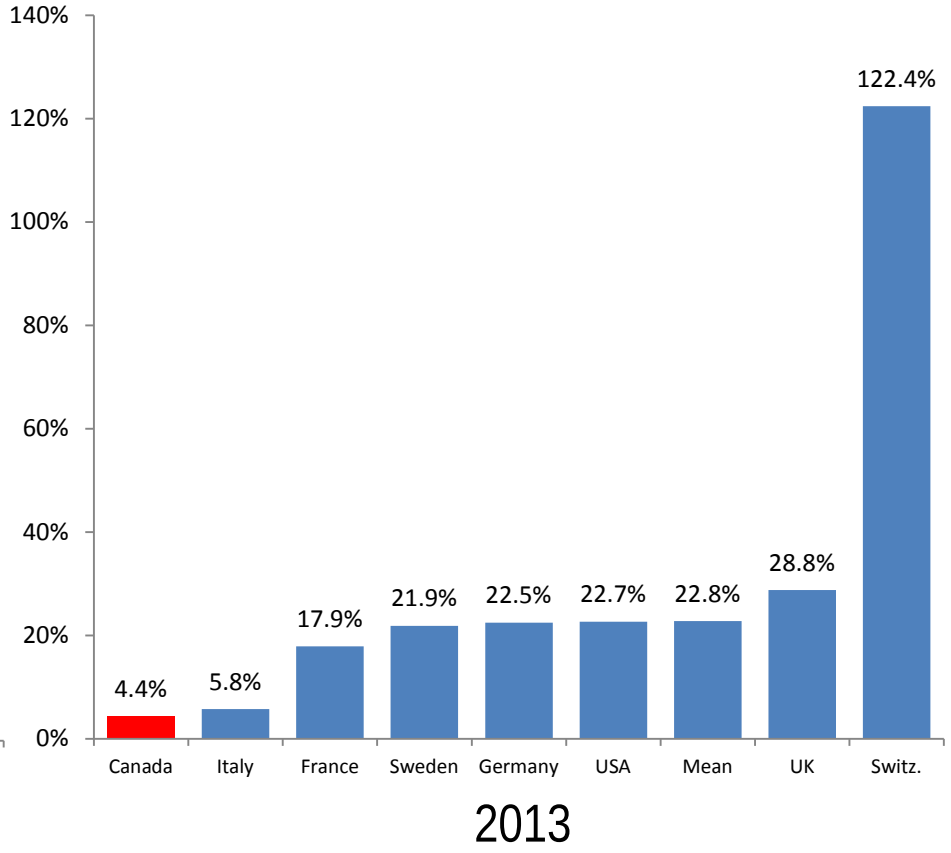
R&D-to-Sales ratios are even less favorable

In 2000, Canadian R&D was at its 10% target, but only half the PMPRB7 average.



2000

By 2013, R&D had increased in the USA, France, Germany and Switzerland but fell in Canada



2013

What's Changed?

A lot:

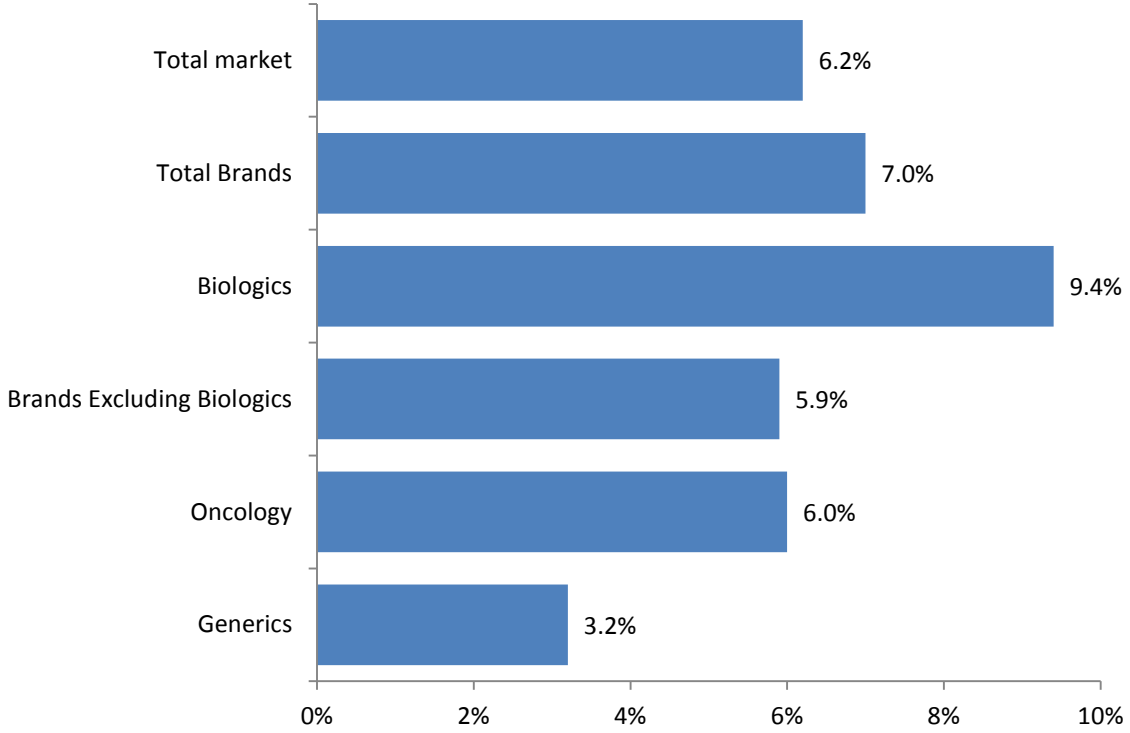
1. Influx of high cost specialty drugs (nichebusters vs. blockbusters)
2. International reform
3. Pan-Canadian Pharmaceutical Alliance
4. Confidential pricing/price discrimination
5. Government of Canada policy priorities

What's Changed?

High cost drugs

The era of mass-marketed "blockbuster" drugs is ending, as business models shift towards high cost specialty drugs at prices even the most well-funded payers struggle to afford.

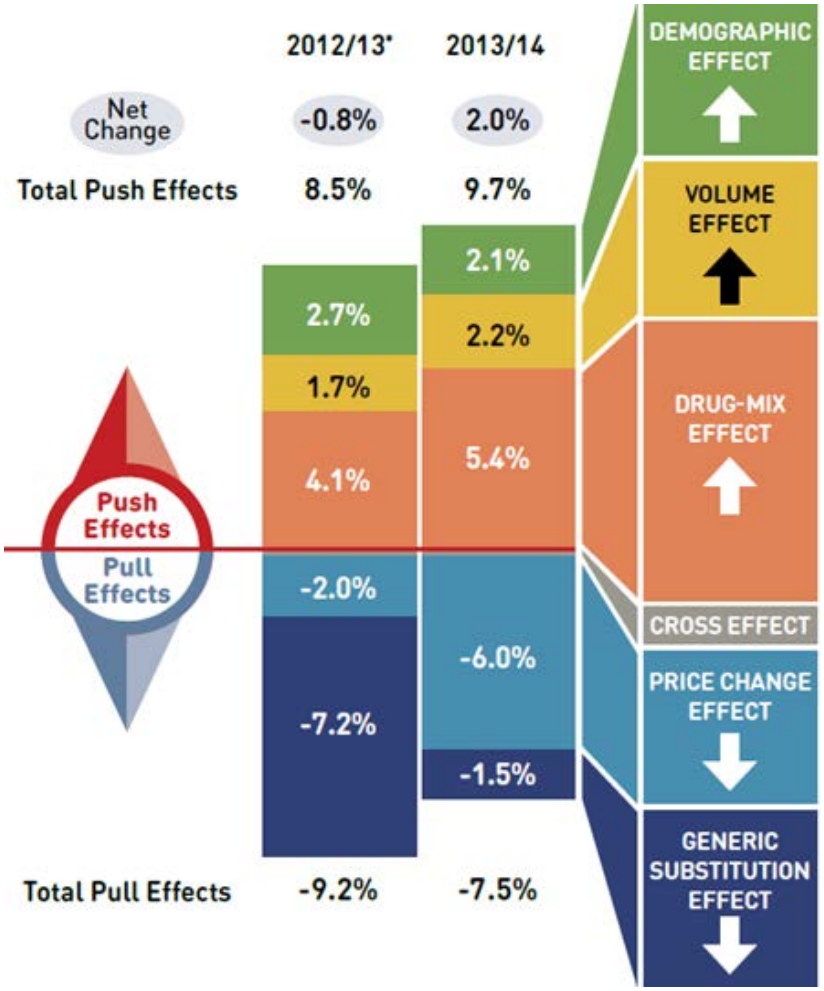
Segment Specific Spending Growth 2015



Source: IMS Brogan. Canadian Drug Stores and Hospitals Purchases, MAT December 2015

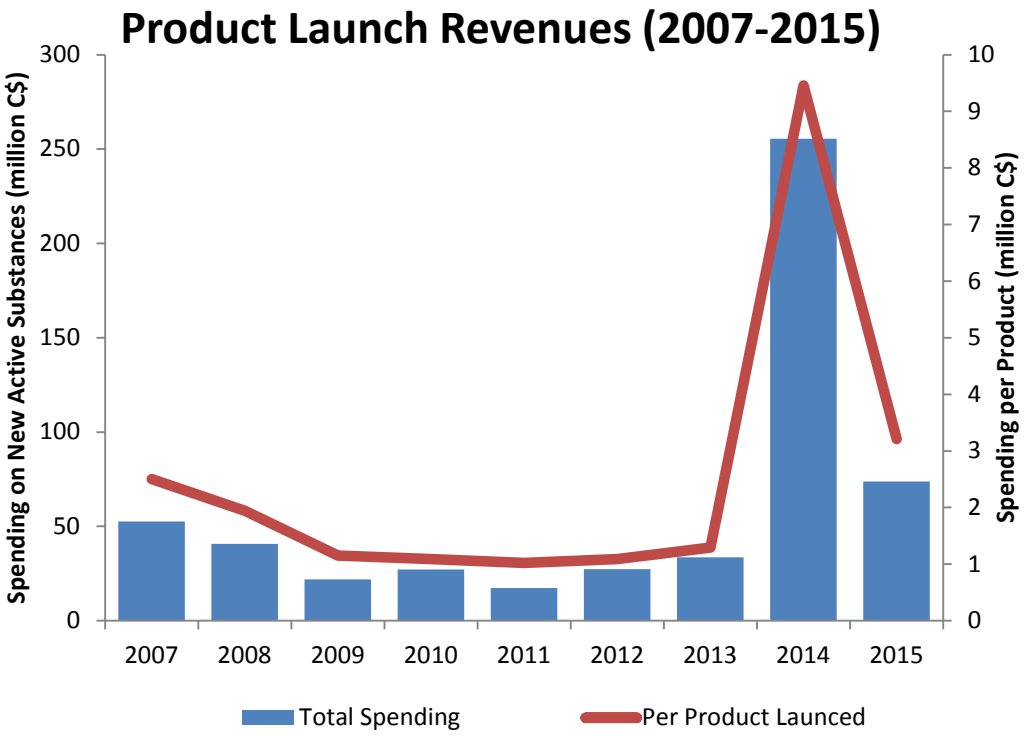
What's Changed?

Cost Drivers



Net growth in spending has been low recently because of the "pull" effects of generic substitution and generic price reductions.

The cost drivers behind "push" effects are growing and posing an increased challenge.



Source: IMS Brogan. Canadian Drug Stores and Hospitals Purchases, MAT December 2015

What's Changed?

International reform to pricing and reimbursement regimes

In 1987, price referencing was in its infancy, today, although it is widely practiced, it is increasingly an adjunct to other forms of price/cost control.

From 2010-2014 period, 23 European countries began planning or executed a major reform of their pharmaceutical price and cost regulatory framework.

Country	Year	Type of Reform
UK	2014	Annual, per company, public expenditure ceilings – 0% growth for next two years.
Sweden	2014	7.5% price reduction for drugs >15 years old not subject to generic competition.
Switz.	2013	Legislated negotiated price reduction of 2500 drugs.
Italy	2013	Expenditure ceiling, performance based reimbursement, 2-year price re-evaluation.
France	2012	Mandatory price review every 5 years, reimbursement rates cut for low innovation medicines, new stringent therapeutic evaluations.
Germany	2011	Consolidation of regulatory roles, mandatory rebates to public plans.

What's Changed?

Public payers collaborating on drug pricing

Provinces and territories have been able to improve their negotiating positions through the pCPA.

Quebec joined the pCPA in October 2015, for both brand and generic products.

Federal government joined the pCPA in 2016.

As of March 31, 2016, 100 joint negotiations have been completed under pCPA.

To date, joint negotiations on brand name drugs and generic price reductions are said to have resulted in more than $500 million in annual savings for public plans.

For first time ever, provinces are intervening in excessive price hearing before the PMPRB.

What's Changed?

Non-transparent pricing/price discrimination

To preserve the ability to price discriminate in a global market where price referencing is widespread, manufacturers began negotiating confidential discounts/rebates.

Savings from the pCPA currently benefit less than 45% of the market, and publicly insured consumers co-payments are based on list prices (not the confidential, rebated price).

Competition law concerns have so far prevented private insurers, responsible for the same portion of the market as provinces, from joint negotiation or purchasing.

Uninsured Canadians have no negotiating power and pay the highest (i.e., list) prices.

Payer	Share of drug costs
Public insurance	43%
Private insurance	35%
Out-of-pocket (deductible, co-pay + uninsured)	22%

What's Changed?

Priorities

"A Liberal government's… priorities for a new Health Accord will include:

We will consult with industry and review the rules used by the Patented Medicine Prices Review Board to ensure value for the money governments and individual Canadians spend on brand name drugs."

https://www.liberal.ca/realchange/investing-in-health-and-home-care

MINISTER OF HEALTH MANDATE LETTER

Office of the Prime Minister / Cabinet du Premier ministre

Ottawa, Canada K1A 0A2

Dear Dr. Philpott:

I am honoured that you have agreed to serve Canadians as Minister of Health.

In particular, I will expect you to work with your colleagues and through established legislative, regulatory, and Cabinet processes to deliver on your top priorities:

- Engage provinces and territories in the development of a new multi-year Health Accord. This accord should include a long term funding agreement. It should also:
  - support the delivery of more and better home care services. This includes more access to high quality in-home caregivers, financial supports for family care, and, when necessary, palliative care;
  - advance pan-Canadian collaboration on health innovation to encourage the adoption of new digital health technology to improve access, increase efficiency and improve outcomes for patients;
  - improve access to necessary prescription medications. This will include joining with provincial and territorial governments to buy drugs in bulk, reducing the cost Canadian governments pay for these drugs, making them more affordable for Canadians, and exploring the need for a national formulary; and

Health ministers take on prescription drug costs going into federal meeting

Justin Trudeau's Liberals have promised a new health accord with the provinces

CBC News Posted: Jan 20, 2016 2:47 PM PT | Last Updated: Jan 20, 2016 5:55 PM PT

ERIC HOSKINS

Why Canada needs a national pharmacare program

ERIC HOSKINS

Contributed to The Globe and Mail

Published Tuesday, Oct. 14, 2014 9:59AM EDT

Last updated Tuesday, Oct. 14, 2014 10:00AM EDT

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Hoskins is Ontario's Minister of Health and Long-Term Care

HESA

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Implications for the PMPRB

Since the PMPRB's price ceilings are based on public list prices, rather than the price net of confidential rebates and discounts, at introduction patented drug prices are 20% below our price ceilings on average.

As a result, patentees have considerable latitude to price discriminate between different market segments.

The PMPRB's guidelines do not place any particular emphasis on high-cost specialty drugs even though these are the products that tend to have few if any competitors and are arguably at greatest risk of abuse of statutory monopoly.

Despite its consumer protection origins, the reality is that the PMPRB's current framework offers very little protection to those Canadians who are least able to pay, as well as to public and private insurers in circumstances where they have little to no countervailing power.

Strategic Objective 2

Framework modernization

"The Canadian regime has remained essentially unchanged since 1987, while other countries have undergone significant reform. In this light, the PMPRB will examine whether and to what extent changes to its regulatory mandate are warranted to ensure that Canadians pay a "fair share" for patented drugs. This entails examining options to modernize and simplify Board guidelines, but also engaging with and assisting federal, provincial and territorial partners in any future discussions on broader reform."

Guidelines Modernization

The PMPRB will be issuing a discussion paper entitled “Rethinking the Guidelines”

Section 85 of the Patent Act contemplates intervention only where a patented drug price is considered “excessive”, which is undefined and determined based on a set of broadly expressed factors.

Many of the core concepts which give effect to s.85 have been developed through the Guidelines, which the Board is authorized to make, subject to consulting first with stakeholders

While the s.85 factors can only be amended by Parliament, their open ended nature allows for a flexible and contextually driven interpretation of “excessive” that evolves with time and circumstances.

The discussion paper will highlight aspect of the Guidelines that are thought to be potentially in need of reform, including:

1. How therapeutic benefit is assessed and applied
2. How and when therapeutic class/comparators is assessed and applied
3. International and domestic price tests
4. How CPI is applied
5. “Any market” price review

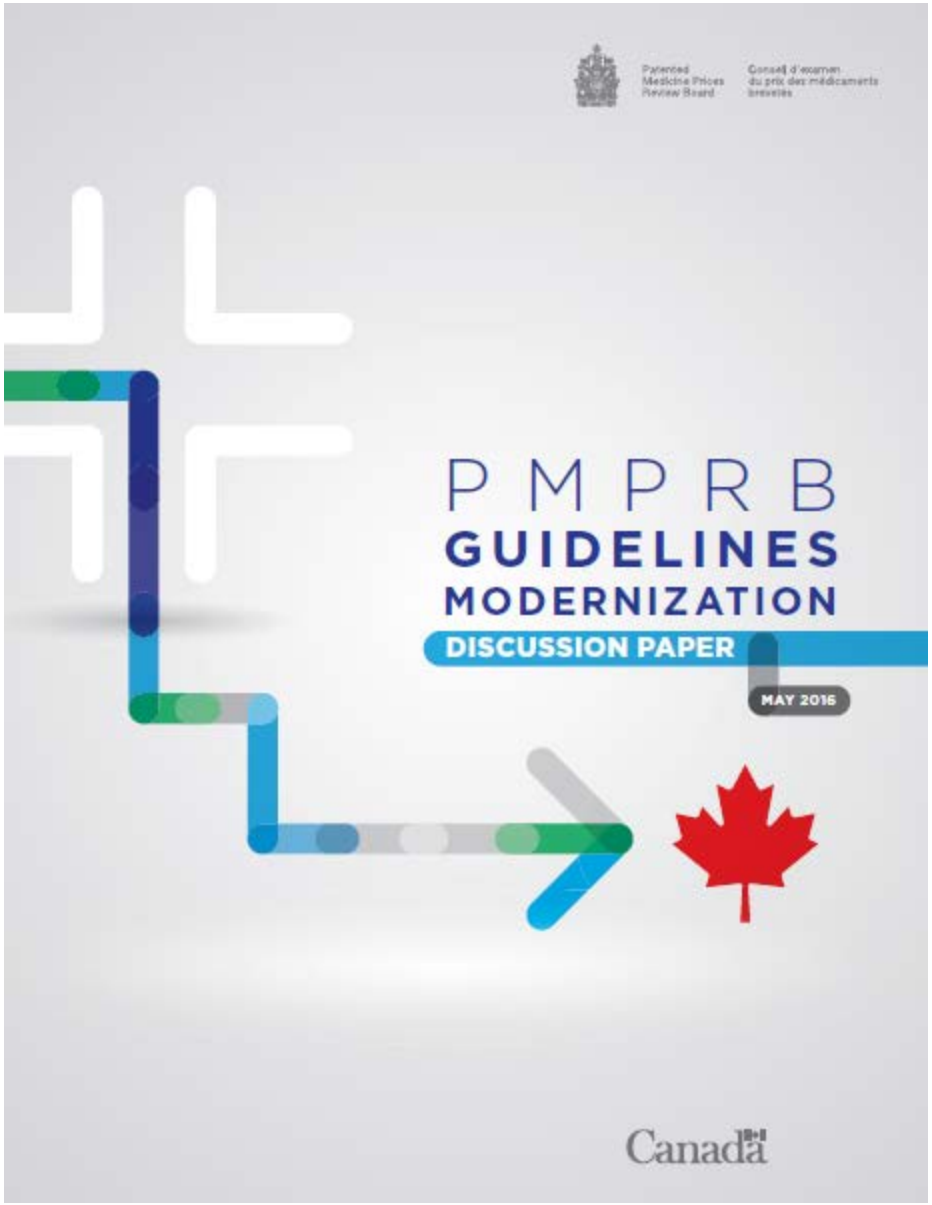
Next steps

The first stage of the consultation process will seek public and stakeholder feedback on a series of broadly framed questions on big picture issues.

The feedback so received will shape the second stage, when specific Guideline changes will be proposed for notice and comment.

Phase	Steps	Proposed Timelines
1 – Consult on discussion paper	• Publish Discussion Paper • Meeting with stakeholder groups across Canada • Obtain written comment from stakeholders and the public on issues raised in Discussion Paper • Analyze results from Phase 1	Spring - Fall 2016
2 –Public policy hearings	• Board to host public policy hearings to provide audience to stakeholders who wish to speak to their written submissions	Fall/Winter 2017
3 – Consult on proposed Guideline changes	• Publish proposed Guidelines through Notice and Comment process • Strike multi-stakeholder working groups on specific issues	Spring/Summer 2017

Stay tuned!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