Patented Medicine Prices Review Board Canada

Conseil d'examen du prix des médicaments brevetés Canada

PMPRB GUIDELINES REFORM

15th Annual Market Access Summit

Canada

Background

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

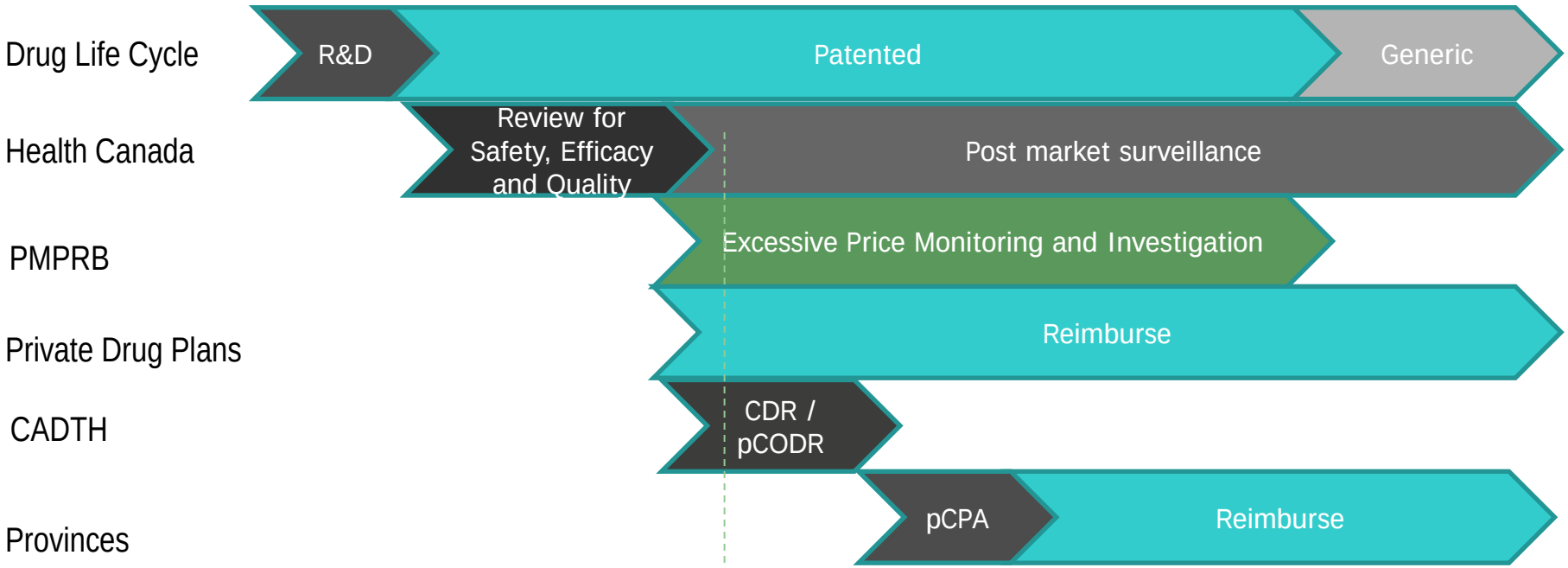
The PMPRB was conceived as C-22's "consumer protection pillar", to ensure patentees do not abuse their newfound statutory monopolies by charging excessive prices.

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")* on the assumption we would come to emulate them.

**Countries in the PMPRB-7 are Italy, France, Germany, Sweden, Switzerland, the UK and the US.*

PMPRB regulatory role in context

The PMPRB is part of a complex regulatory and reimbursement ecosystem



CADTH: Canadian Agency for Drugs and Technologies in Health
pCPA: Pan-Canadian Pharmaceutical Alliance

PMPRB regulatory framework

The PMPRB's authority to regulate patented drug prices reposes on three legal instruments:

- Sections 79-103 of the *Patent Act*: excessivity factors, mandate, jurisdiction, structure and powers of the Board;
- *Patented Medicines Regulations:* comparator countries, information required of patentees on identity, prices of medicines and R&D investment;
- Compendium of Policies, Guidelines and Procedures ("Guidelines"): scientific and price review process, price tests for new and existing drugs.

How the PMPRB sets ceiling prices

Breakthrough	Substantial Improvement	Moderate Improvement	Slight/no Improvement		New Presentation of an Existing Drug
No comparator	Drug products over which drug under review brings substantial improvement	Drug products over which drug under review brings moderate improvement	Drug products over which drug under review brings slight/no improvement		Same active ingredient Same indication /use Same or comparable dosage form
MIPC	**Higher of** - **Top of TCC** - **MIPC**	**Higher of:** **- Mid point (Average of top of TCC and MIPC)** **-Top of TCC**	Comparable drug products: **Top of TCC**	No comparators; only "superior" **Lower of:** - **Bottom of TCC**	**RR test if same dosage regimen** **TCC if different dosage regimen**
	If cannot derive dosage regimen or price of comparator(s) is excessive: MIPC test				
Highest International Price Comparison (HIPC) test					

Problems with current approach

Our basket of comparators includes the US, an international outlier.

Our system focuses on rewarding therapeutic benefit instead of policing the risk of abuse/excessive pricing.

Our only absolute ceiling for existing drugs is *highest* international price.

Me-too drugs can be priced at the top of the domestic therapeutic class.

It is based on publicly available list prices, which are increasingly divorced from the true price net of confidential rebates/discounts.

It is not working: prices are high and R&D is low.

Framework modernization

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

In addition to relatively high utilization, Canada pays among the highest prices in the world for patented and generic drugs.

A surge in high cost drugs is driving public drug plan spending back into double digit growth and is accounting for a disproportionate share of total pharmaceutical spending in Canada.

Making prescription drugs more affordable is a shared FPT priority

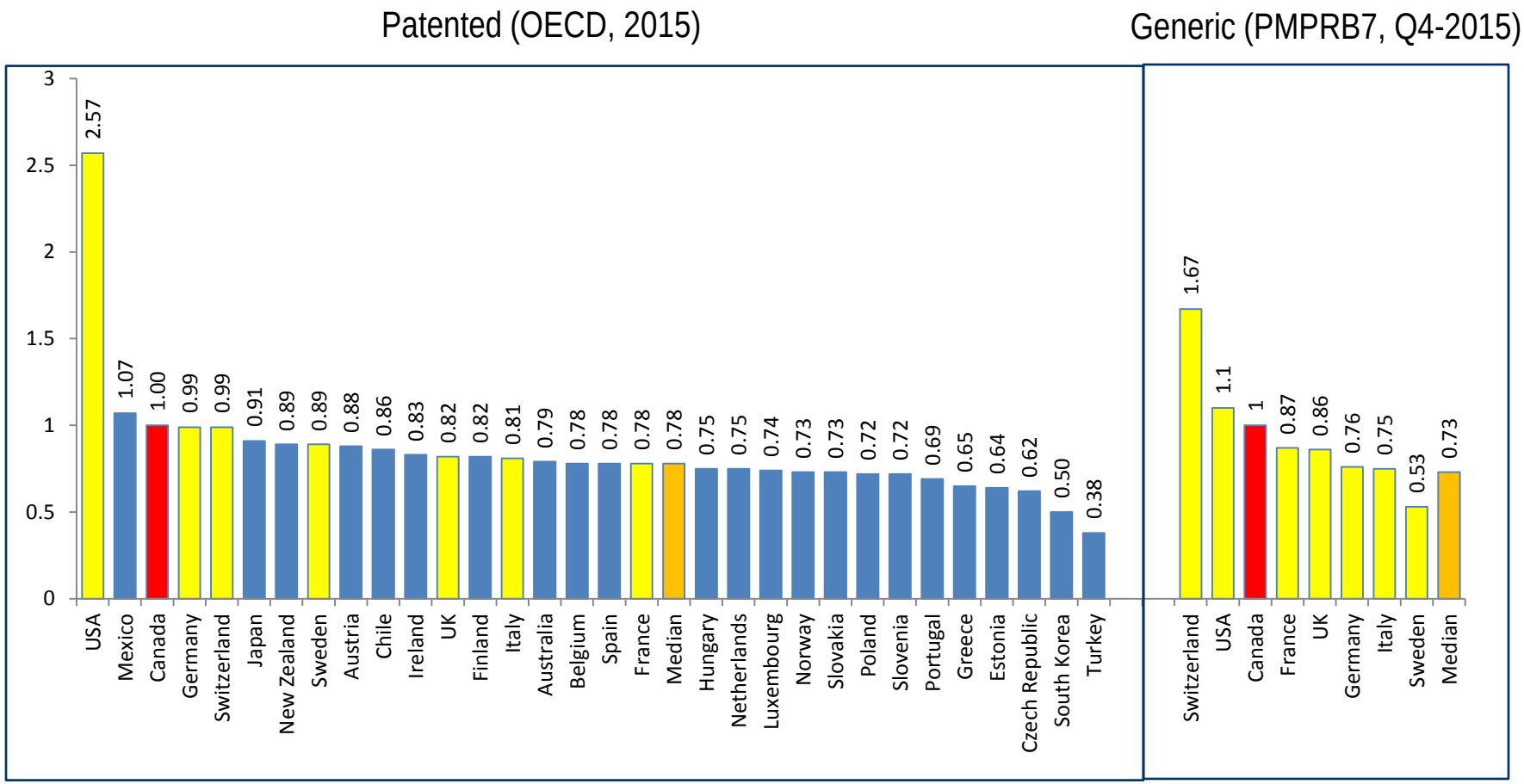
Framework modernization is one of the PMPRB's 2015-2018 strategic priorities.

As a first step, PMPRB is currently consulting on Guideline reform.

Canadian drug prices

In addition to relatively high pharmaceutical utilization, Canada pays among the highest prices in the world for both patented and generic drugs.

Foreign-to-Canada price ratios

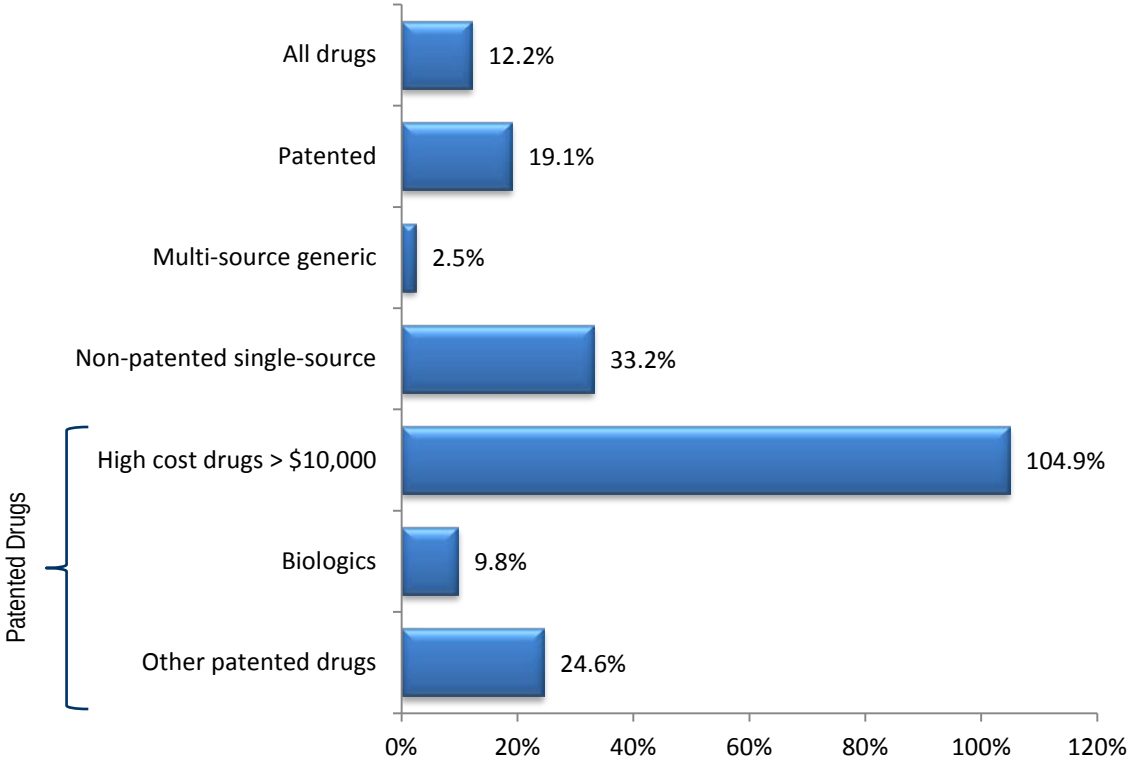


Sources: PMPRB Annual Report 2015; National Prescription Drug Utilization Information System Database

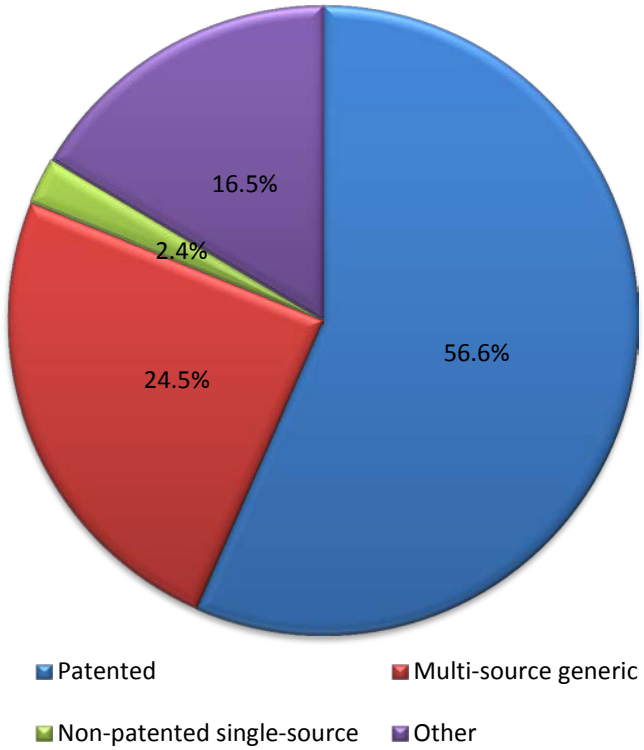
High cost drugs

Total public spending on high cost drugs doubled in 2015.

Public plan drug cost annual change by market segment



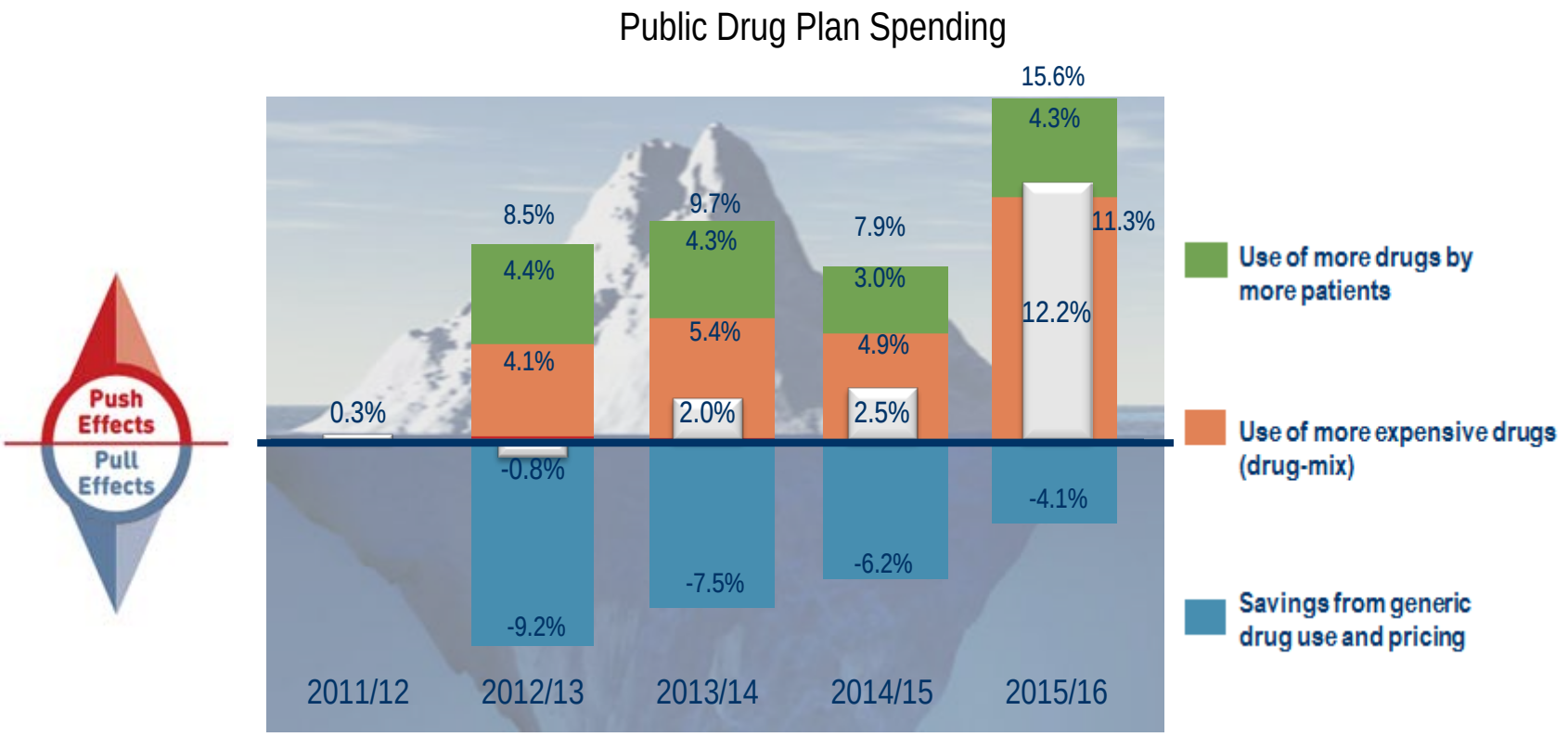
Expenditure share by market segment



Source: National Prescription Drug Utilization Information System Database

High cost drugs

Growth in public drug plan spending has returned to double digits.



Source: National Prescription Drug Utilization Information System Database

FPT priorities

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

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1K 186 58 G+1 8 AA

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

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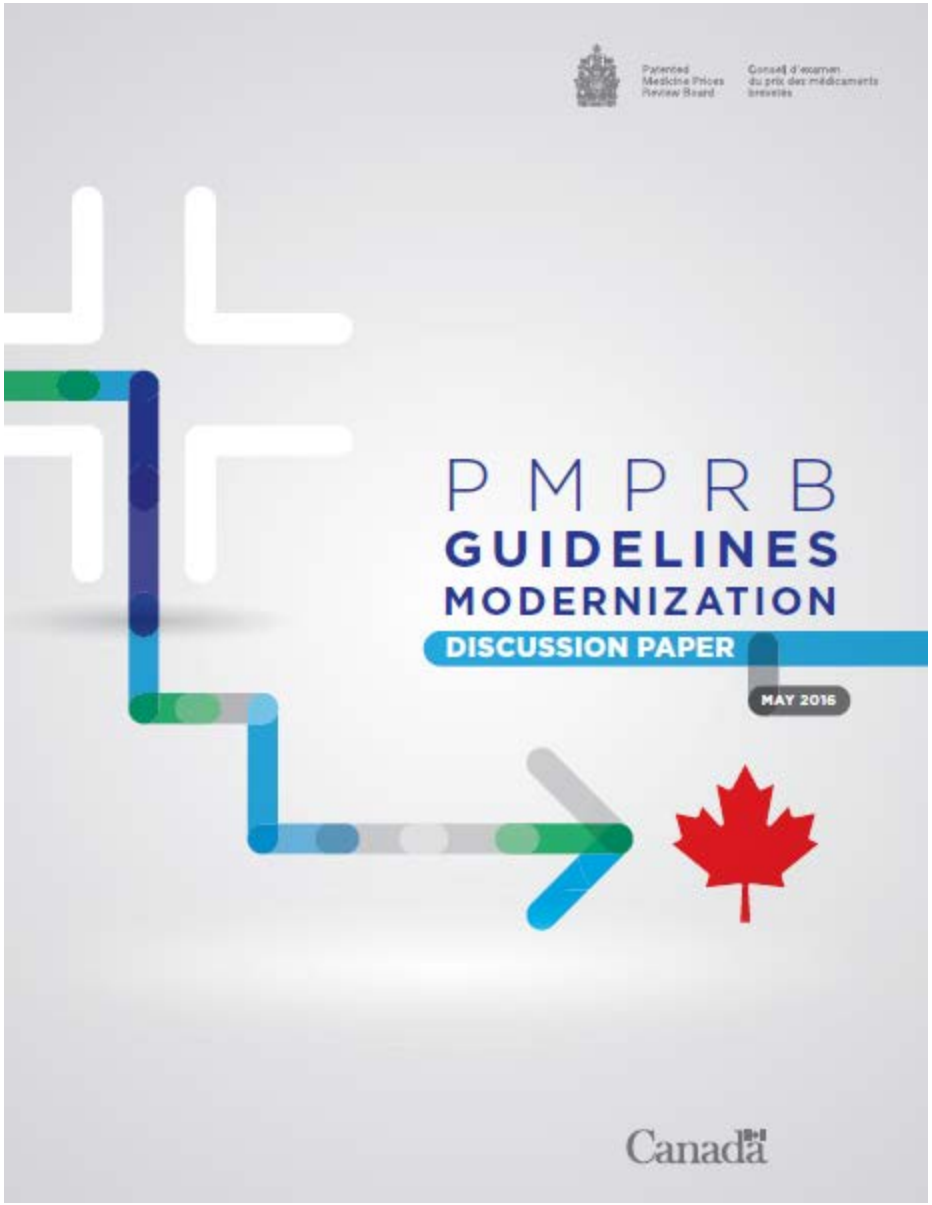
Guidelines reform



Consultation on Guidelines reform

In June, the PMPRB commenced consultations by issuing a discussion paper on Guidelines reform.

The paper encourages stakeholders and the public to take a fresh look at how the PMPRB interprets and applies the Act and Regulations in light of recent changes in its operating environment.

It also highlights aspects of the Guidelines that are thought to be particularly outdated, including:

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

Feedback received to the questions in the paper will inform the second phase of consultations, when specific changes to the Guidelines will be proposed.

Public feedback on Guideline reform

To the extent there is common ground (relatively) among a disparate group of stakeholders, it is mainly with respect to the following points:

- The PMPRB is relevant and has a distinct role to play by protecting consumers from excessive prices;
- The PMPRB should complement and not duplicate the role played by other participants in the Canadian pharmaceutical system (e.g., CADTH, pCPA);
- The PMPRB should prioritize drugs based on risk factors of abuse;
- The PMPRB should adopt “bright line” rules that are informed by international best practices and provide predictability and certainty to stakeholders;
- “Value” is an important consideration in assessing whether a price is excessive
  - Continued belief in the idea that patents and value-based-pricing encourage the “right” kind of innovation
- Legislative and/or regulatory change should precede Guideline reform.

Public feedback on Guideline reform

To the extent there is disagreement (relatively), it is mainly with respect to the following points:

- Whether “affordability” and excessivity are related concepts;
- What countries Canada should compare itself to and how ceilings should be set;
- What risk factors should be considered in prioritizing drugs;
- Whether, how and when to “rebench”
- Whether price disparities between different types of payers can be considered excessive;
- Temporal application of revised Guidelines

Closing Remarks

Canada and the developed world is signaling a need to find solutions to ever increasing drug budget pressures.

The “patent cliff” savings from the era of mass-marketed, so-called “blockbuster” medicines are not expected to continue to finance innovation.

The drug pipeline is increasingly moving towards specialty drugs that target less common, untreated, and severe illnesses but at a price even the most well-funded payers struggle to afford.

Growing concern over sustainability has led other countries to introduce measures to address affordability, maximize value for money and keep pace with a rapidly evolving market.

PMPRB reform needs learn from international best practices and adapt regulation to the Canadian drug approval, economic assessment and reimbursement landscape context.

All stakeholders, including industry, stand to win from a price regulator that contributes to the long term sustainability of Canada’s health care system.

Next steps

Phase	Steps	Timelines
Phase 1: Consult on Discussion Paper	• Publish Discussion Paper and meet with stakeholders • Obtain written comments on the Discussion Paper • Gather and analyze all results from Phase 1 of consultation	Summer/Fall 2016
Phase 2: Public policy hearing	• Invite stakeholders to appear before the Board and make representations in support of their written submissions	Winter/Spring 2017
Phase 3: Consult on draft revised Guidelines	• Publish proposed changes to Guidelines for public comment • Strike multi-stakeholder forum(s) on specific issues and explore options for specific changes to the Guidelines	Fall 2017