Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

PMPRB Framework Modernization

16th Annual Market Access Summit

November 2017

Canada

30 years ago

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:

- Incentivize R&D expenditure through stronger patent protection;
- Mitigate the economic impact of stronger patent protection on the health system.

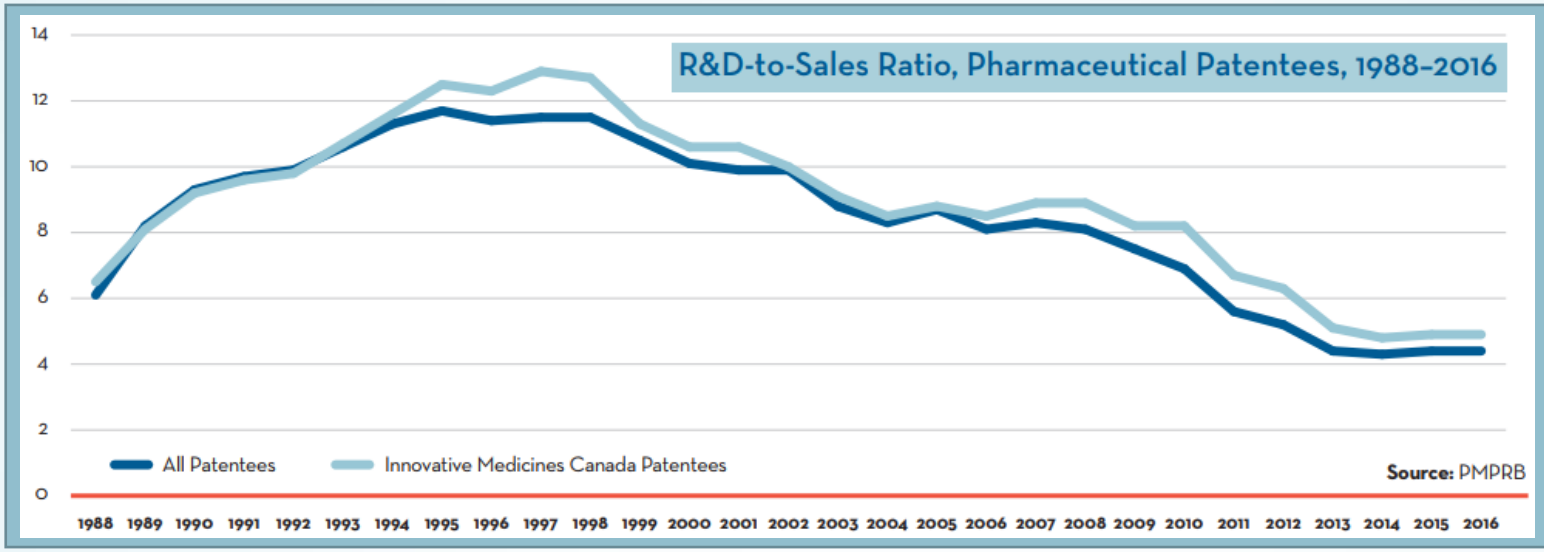
The PMPRB was conceived as C-22's "consumer protection pillar", to ensure that prices of patented drugs remain "reasonable" and "affordable".

The intent was to double R&D in Canada (to 10% of revenues) while keeping prices in line with high R&D countries (the "PMPRB7"*) on the assumption we would come to emulate them.

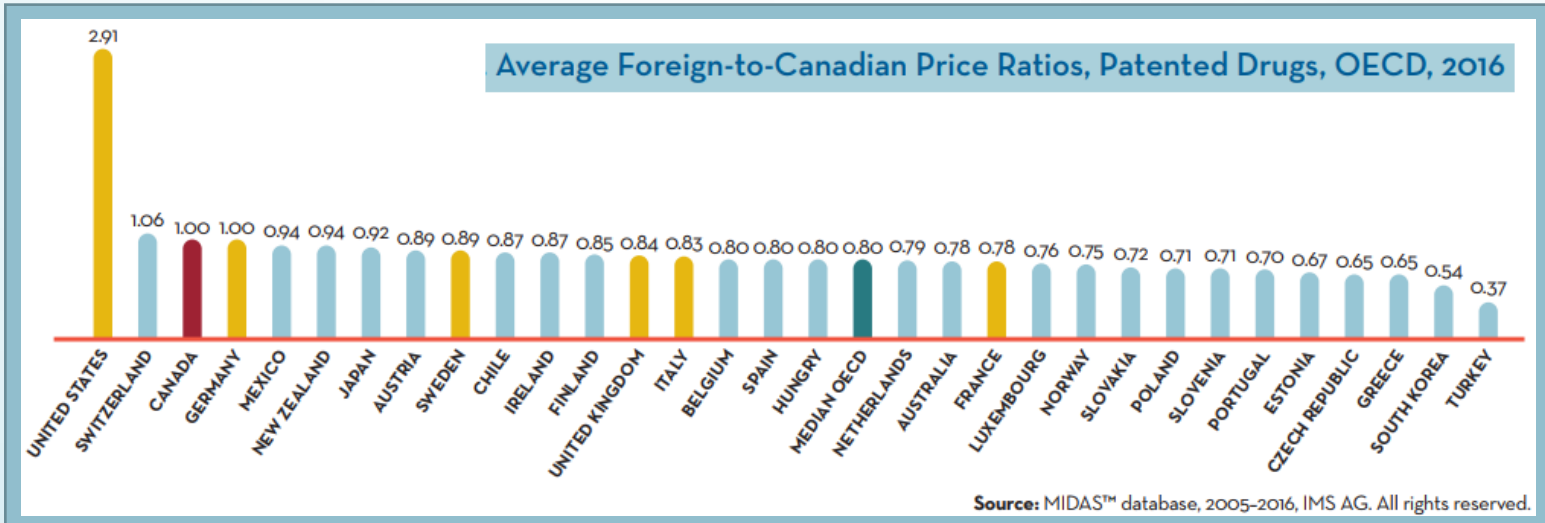
*Countries in the PMPRB7 are France, Germany, Italy, Sweden, Switzerland, the UK and the US.

Today

The policy objectives sought by Bill C-22 have not been met:



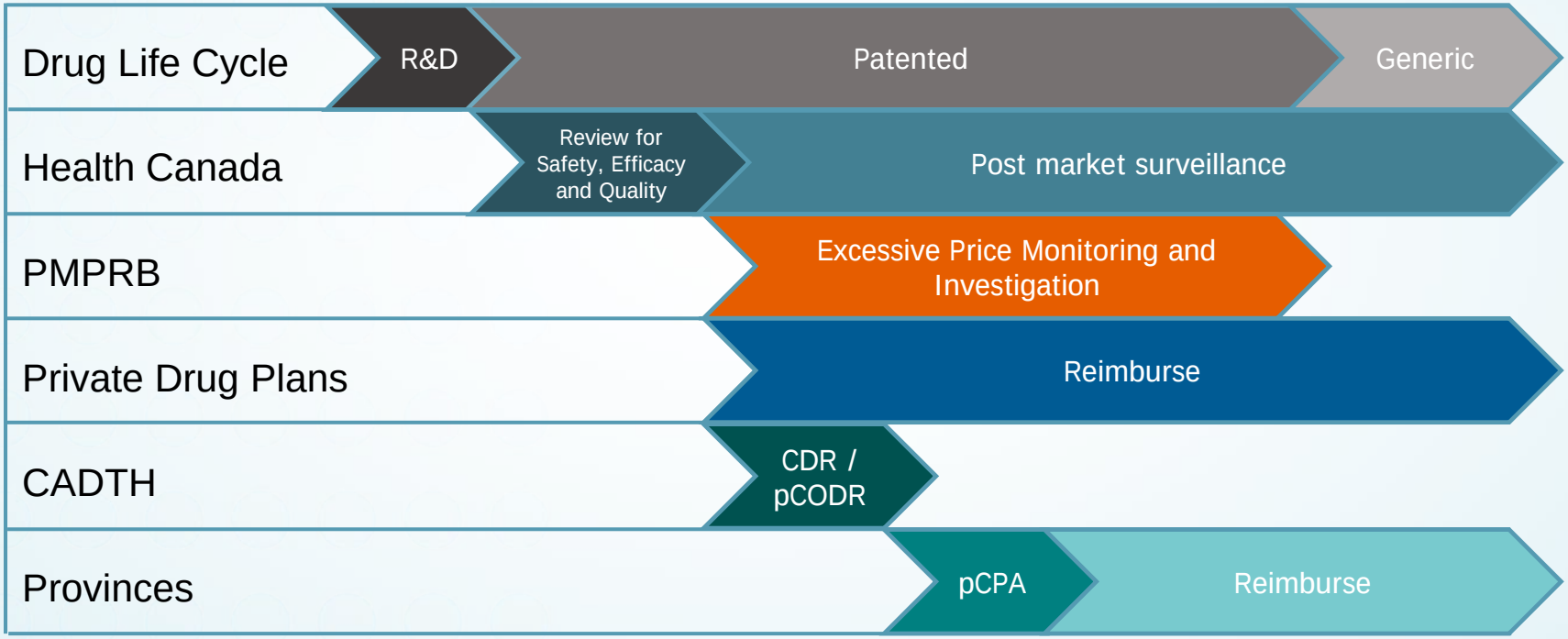
R&D is at historic low: 4.4%



Canadian prices are very high: (3rd in OECD)

PMPRB regulatory role in context

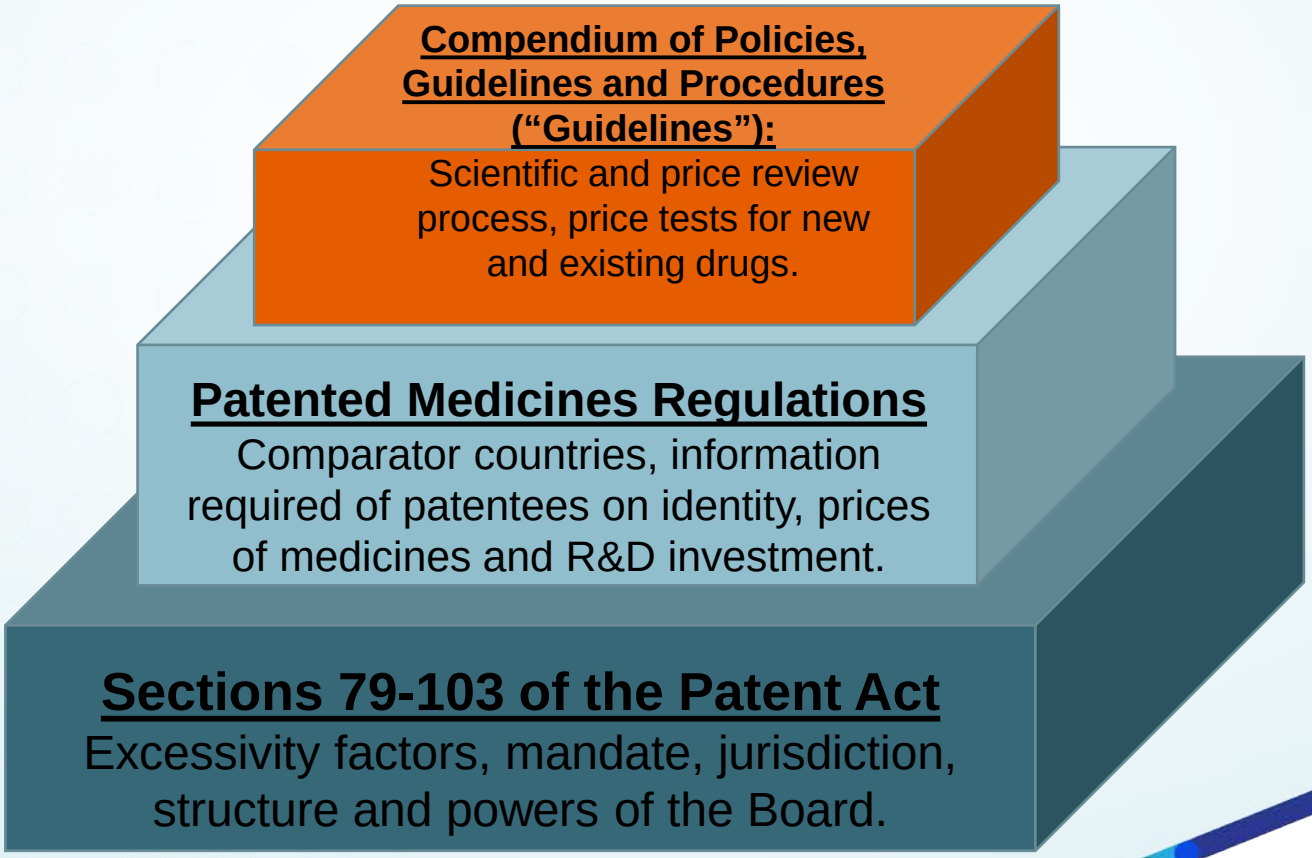
The PMPRB is part of a complex regulatory and reimbursement ecosystem



CADTH: Canadian Agency for Drugs and Technologies in Health
CDR: Common Drug Review
pCODR: pan-Canadian Oncology Drug Review
pCPA: Pan-Canadian Pharmaceutical Alliance

PMPRB regulatory framework

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



How PMPRB staff sets ceiling prices

New patented drugs are assessed for level of therapeutic benefit relative to existing therapies and assigned a ceiling price that is based on either:

1. The median international price;
2. The highest price in the domestic therapeutic class, or;
3. Some combination of the two.

After entering the market, the price of a drug can increase in keeping with CPI but never to the point of becoming highest of the **PMPRB7**.

Where PMPRB staff and a patentee disagree about whether a new or existing drug is excessively priced, a hearing may be held before PMPRB Board Members.

If Members decide a drug is excessively priced, they can order the patentee to reduce its price and/or pay back excess revenues.

Problems identified by stakeholders with current approach

Our basket of comparators is made up of premium priced countries and includes the US, an international outlier.

Our system focuses on rewarding therapeutic benefit (not the job of a price regulator) instead of policing the risk of abuse/excessive pricing.

All drugs are subject to the same level of regulatory scrutiny, regardless of price/cost and market dynamics.

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

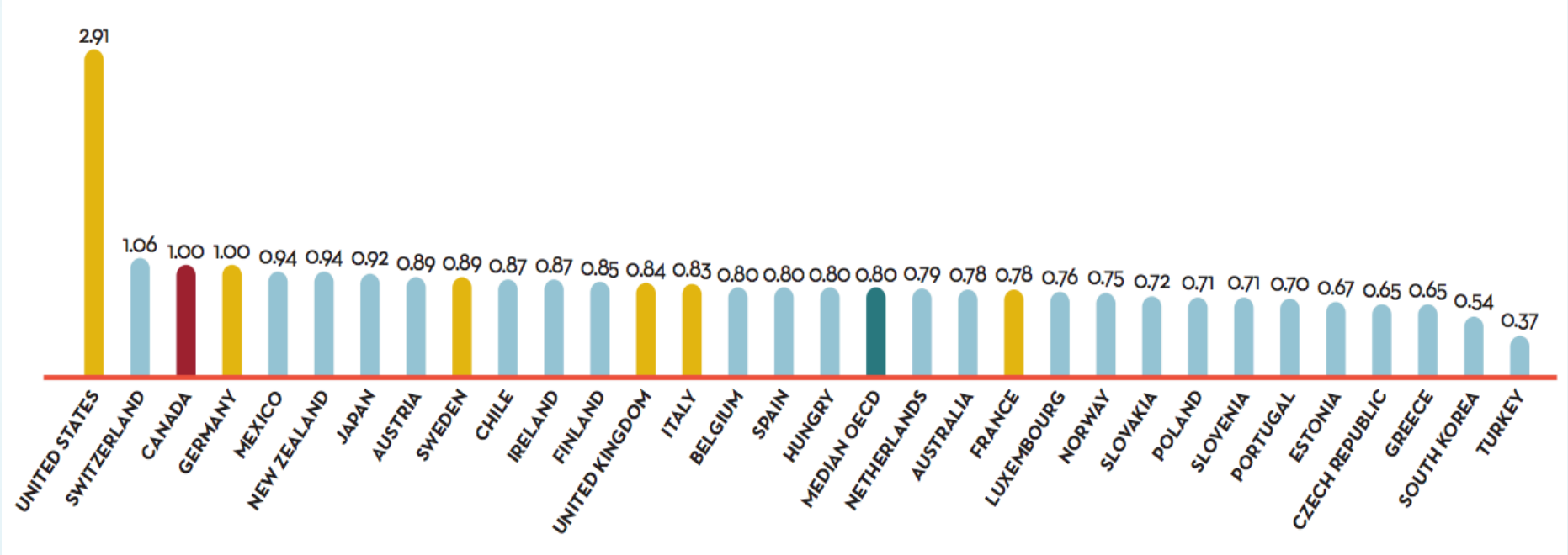
Me-too drugs can be priced at the top of the domestic therapeutic class.

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.

Canadian drug prices are high

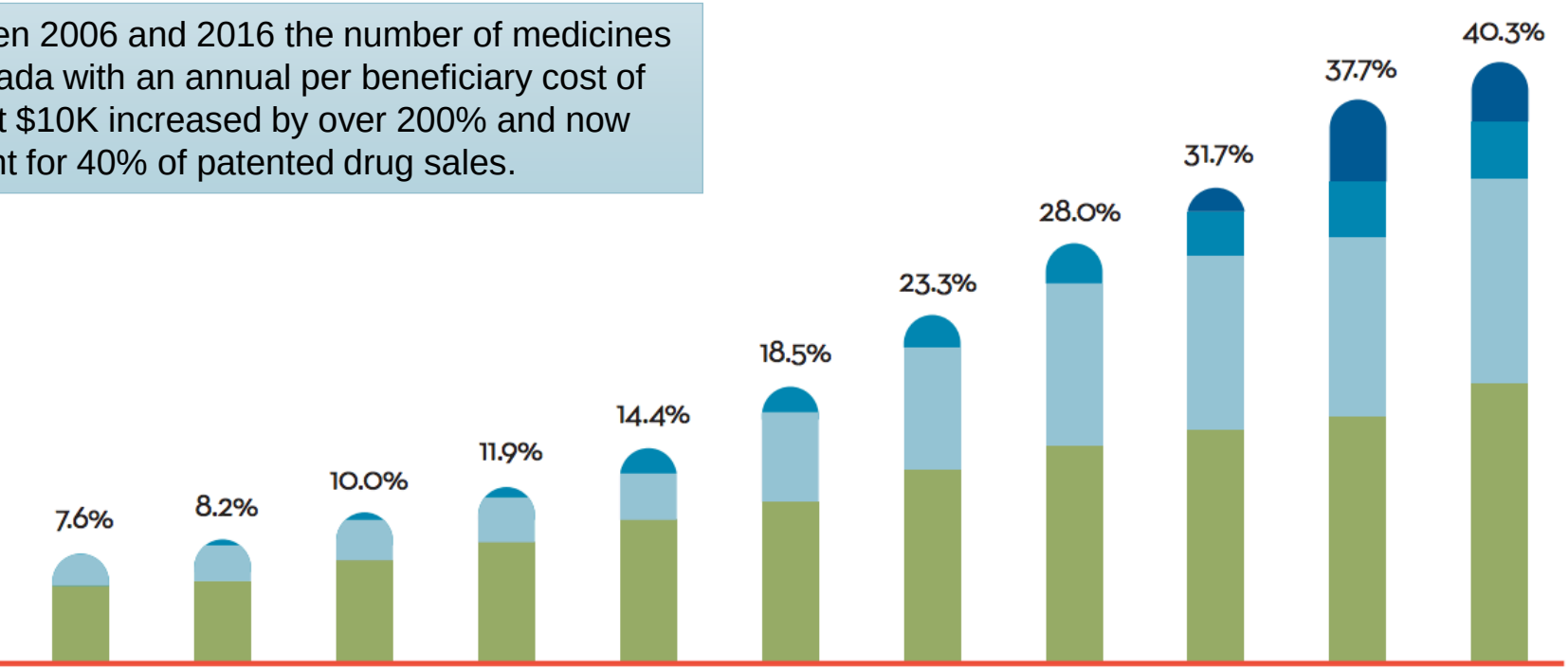
Average Foreign-to-Canadian Price Ratios, Patented Drugs, OECD, 2016



Source: PMPRB Annual Report, 2016

Number of high-cost drugs is rising

Between 2006 and 2016 the number of medicines in Canada with an annual per beneficiary cost of at least $10K increased by over 200% and now account for 40% of patented drug sales.



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
10k-20k	5.2%	5.5%	6.9%	8.1%	9.6%	10.8%	12.9%	14.5%	15.6%	16.5%	18.7%
20k-50k	2.1%	2.4%	2.7%	3.0%	3.5%	6.0%	8.2%	10.9%	11.6%	12.0%	13.7%
50k+	0.3%	0.4%	0.5%	0.7%	1.3%	1.7%	2.2%	2.7%	3.2%	3.7%	3.8%
Total HCD	–	–	–	–	–	–	–	–	1.3%	5.5%	4.0%

Source: PMPRB Annual Report, 2016
Data Sources: PMPRB & QuintilesIMS, Private Drug Plan Direct Drug Plan Database, 2006-2016

Pressure building for reform

Canada, like many countries, faces rising health care costs as payers struggle to reconcile finite budgets with patient access to costly 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 has growth in drug spending expenditures outstripping that on hospitals and physicians and is accounting for a disproportionate share of total pharmaceutical spending in Canada.

Making prescription drugs more accessible/affordable is a shared FPT priority.

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

Acces/affordability an FPT priority

"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."

Government of Canada / Gouvernement du Canada

Home → Budget 2017 → Budget Plan

Chapter 3 – A Strong Canada at Home and in the World

Prescription Medications and Health Innovation

To promote a more innovative health care system, Budget 2017 proposes measures that include:

- Improving access to prescription medications, lowering drug prices and supporting appropriate prescribing through an investment of $140.3 million over five years, starting in 2017–18, with $18.2 million per year ongoing, for Health Canada, the Patented Medicine Prices Review Board and the Canadian Agency for Drugs and Technologies in Health.

HEADLINE POLITICS

Jane Philpott at Economic Club of Canada

On May 16, 2017, Health Minister Jane Philpott delivers a speech to the Economic Club of Canada focusing on the cost of pharmaceuticals. Following her remarks, the minister responds to questions from reporters. (no interpretation)

HESA

Standing Committee on Health

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The Standing Committee on Health studies issues that relate to Health Canada, including bills and regulations. It also has oversig agencies, including the Canadian Food Inspection Agency and the Public Health Agency of Canada.

JUSTIN TRUDEAU,
PRIME MINISTER OF CANADA

Minister of Health Mandate Letter

- improve access to necessary prescription medications. This will include joining with provincial and territorial governments to negotiate common drug prices, reducing the cost Canadian governments pay for these drugs, making them more affordable for Canadians, and exploring the need for a national formulary;

Health ministers take on prescription drug costs going int federal meeting

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

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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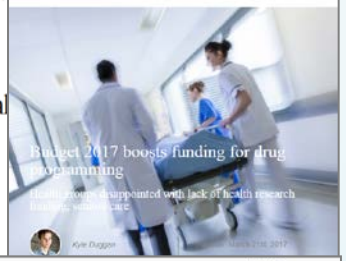
/POLITICS



Budget 2017 boosts funding for drug programming

Health groups disappointed with lack of health research

Government of Canada / Gouvernement du Canada

Home → Health → Health system and services → Health-related consultations → Consulting on Proposed Amendments to the Patented Medicines Regulations

Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations

THE COUNCIL OF CANADIANS / LE CONSEIL DES CANADIENS

ACTING FOR SOCIAL JUSTICE / AGIR POUR LA JUSTICE SOCIALE

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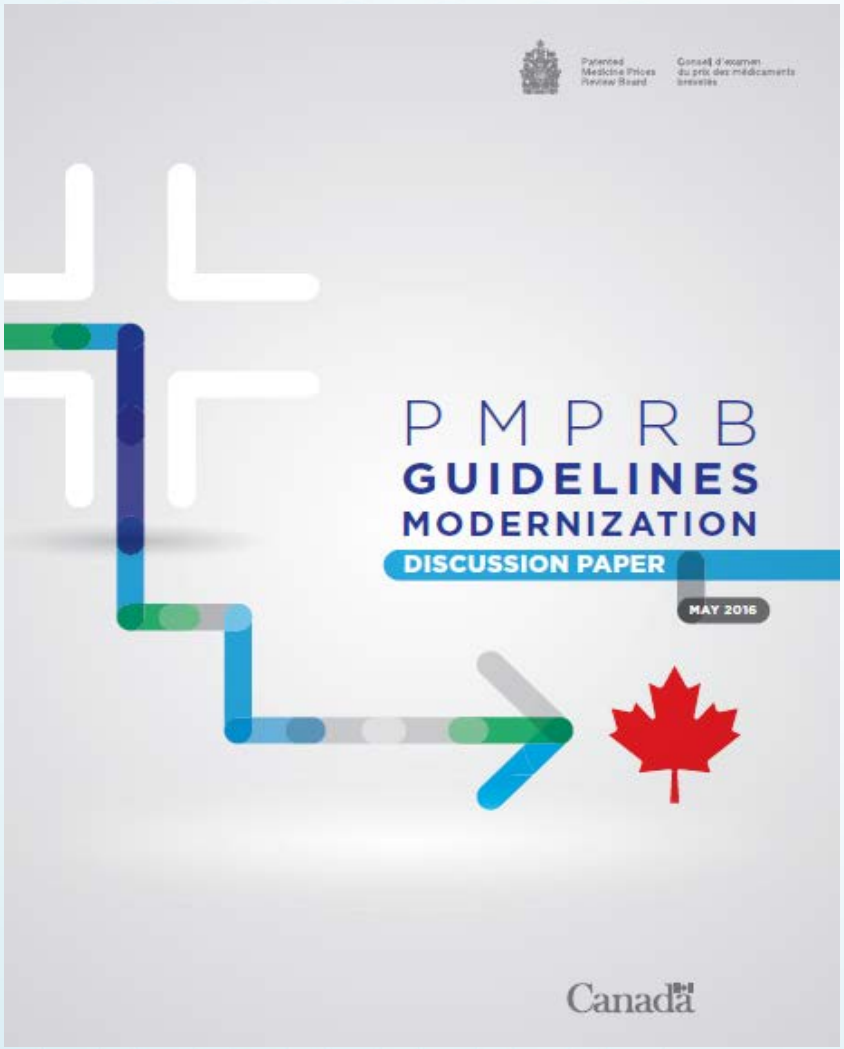
Council of Canadians disappointed by Budget 2017-18

March 22, 2017 - 8:33pm

Framework Modernization Step 1: PMPRB discussion paper on Guideline reform

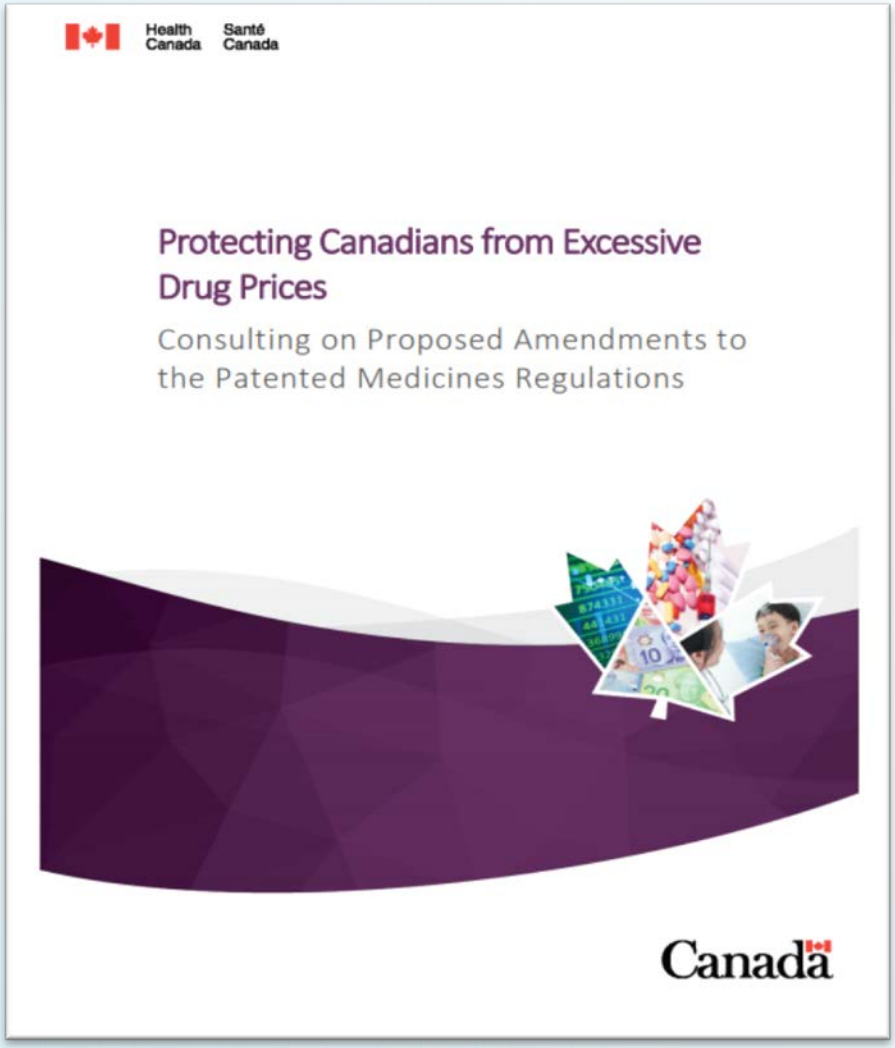


June 2016 discussion paper identified aspects of the Guidelines that are thought to be out of step with recent developments in the PMPRB's operating environment.

Stakeholder views sought on changes which would:

1. De-emphasize therapeutic benefit and international benchmarking;
2. Prioritize drugs at higher risk of monopoly pricing;
3. Revisit introductory price ceilings as market conditions change;

Step 2: Health Canada pre-consultation on regulatory amendments



On May 16, Minister Philpott announced pending changes to PMPRB regulations which would:

1. Enable the PMPRB to consider cost effectiveness and budget impact in setting ceiling prices;
2. Change the list of comparator countries;
3. Require patentees to disclose confidential rebates to third parties.

These changes are first of their kind in over twenty years and an integral part of the GoC's new federal pharmaceutical management strategy.

Next steps

"Pre-consultation" on Health Canada's proposed regulatory amendments closed on June 28.

Health Canada aims to pre-publish amendments in Canada Gazette, Part I later this year, followed by a 75-day consultation period.

Following pre-publication, the PMPRB will resume its consultation on Guidelines modernization and will solicit stakeholder feedback on how to operationalize the regulatory amendments.

The intention is to have a more robust, modern and risk-based approach to regulating patented drug prices in force by the end of 2018.

Key questions for stakeholders in 2018

In seeking to operationalize the regulatory amendments…

1. What considerations should inform PMPRB's screening of high risk drugs?
2. To what extent should low risk drugs be scrutinized?
3. How should a cost effectiveness threshold be established?
4. Should a different threshold apply depending on market size considerations?
5. How should re-benching work and when should it occur?
6. What price tests should the PMPRB apply to the proposed PMPRB12?
7. How should the PMPRB make use of confidential third party pricing information?