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

PMPRB: DRUG PRICING 101

Benefits^3 2017 Conference
Generation everyone

April 2017

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.*

Canadian drug policy

Canada is the only wealthy country with a publicly funded health care system that does not include universal drug coverage.

Federally, the PMPRB sets ex-factory price ceilings for patented drugs.

Provinces pool buying power under the pan-Canadian Pharmaceutical Alliance (pCPA) to negotiate rebates off of the list price.

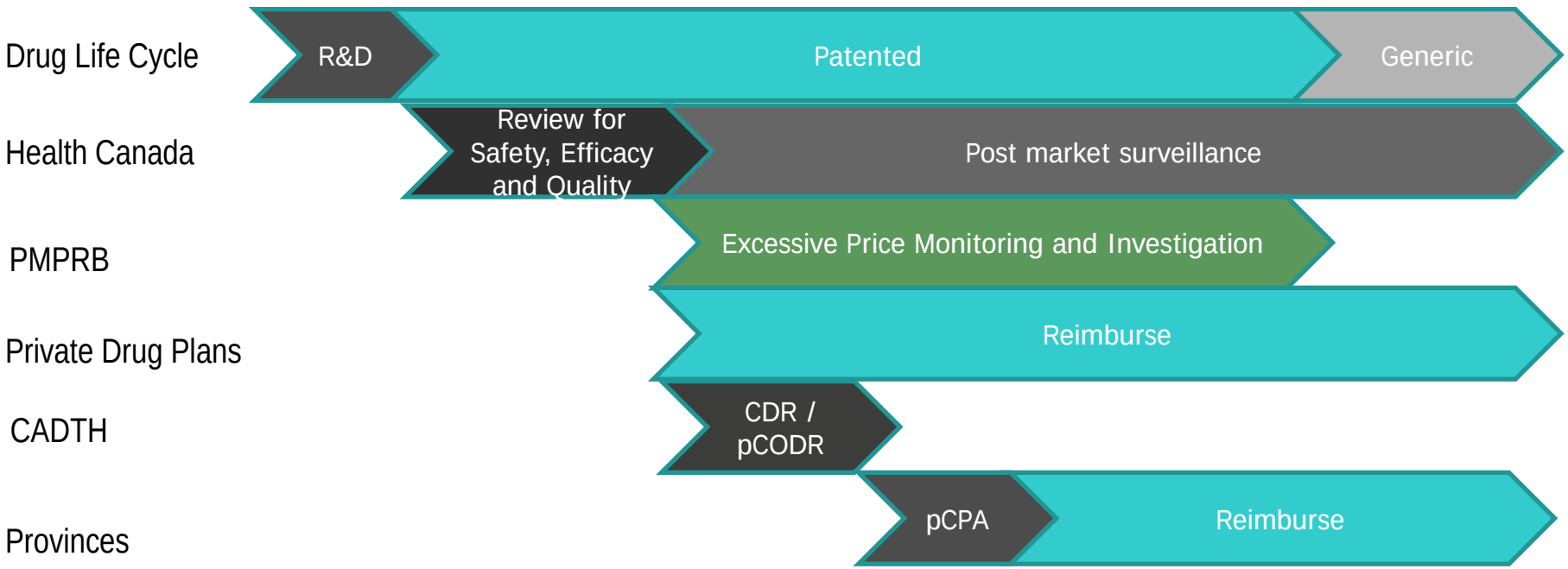
Private insurers have only recently started to negotiate prices for drugs, and then for a small percentage of new drugs. As such they pay much higher prices than provinces.

The uninsured pay the highest (that is, list) prices for drugs.

Payer	Prescription Drug Costs Share (2015)
Public Insurance	43%
Private Insurance	35%
Out-of-pocket	22%

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

A new drug is given a ceiling price based on its level of therapeutic benefit, its price in other countries and the Canadian price of other drugs in the same therapeutic class.

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 is 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 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 instead of policing the risk of abuse/excessive pricing.

All drugs are subject to the same level of regulatory scrutiny, regardless of cost.

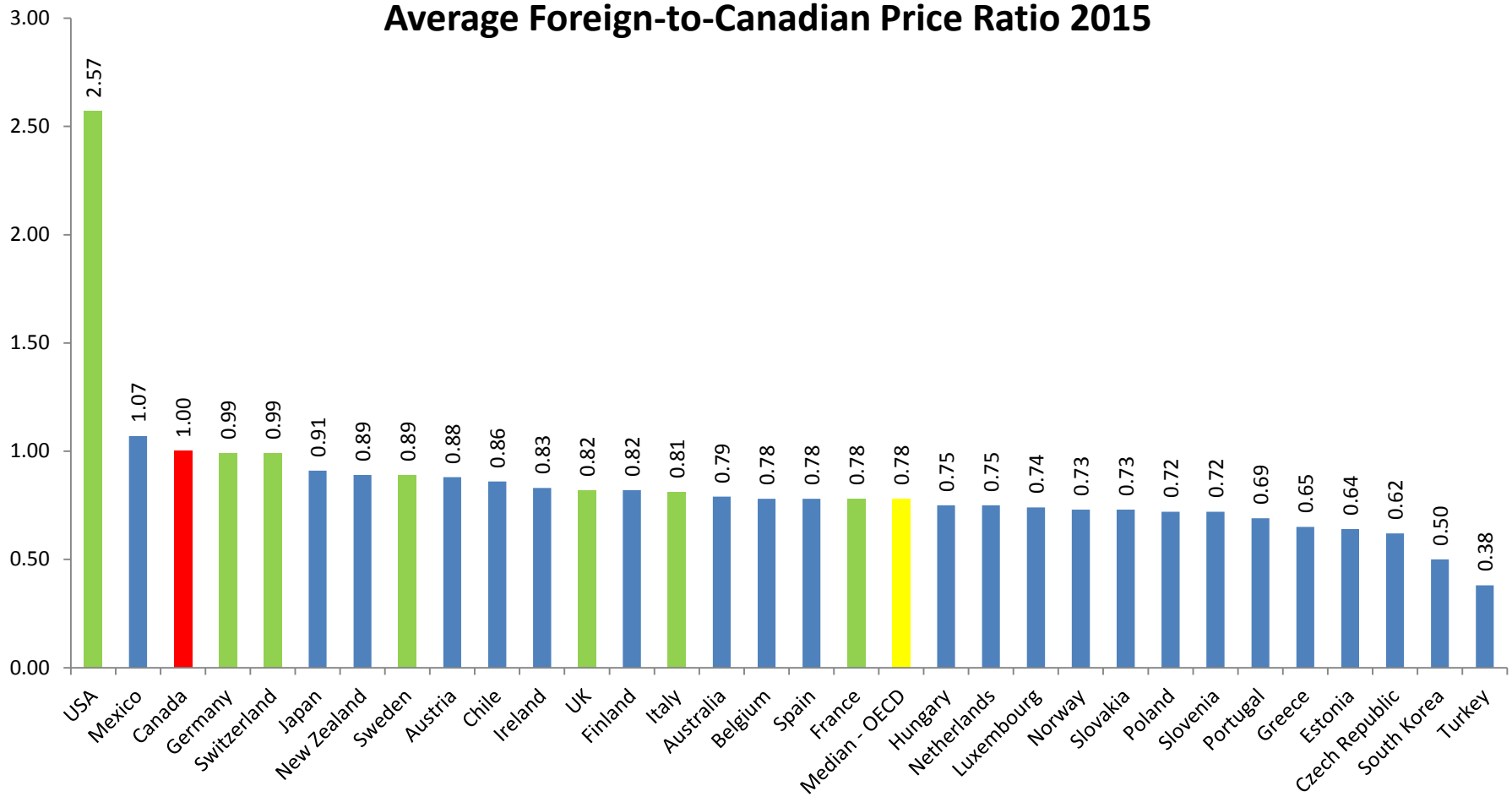
Our only absolute ceiling for existing drugs is *highest* international price.

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.

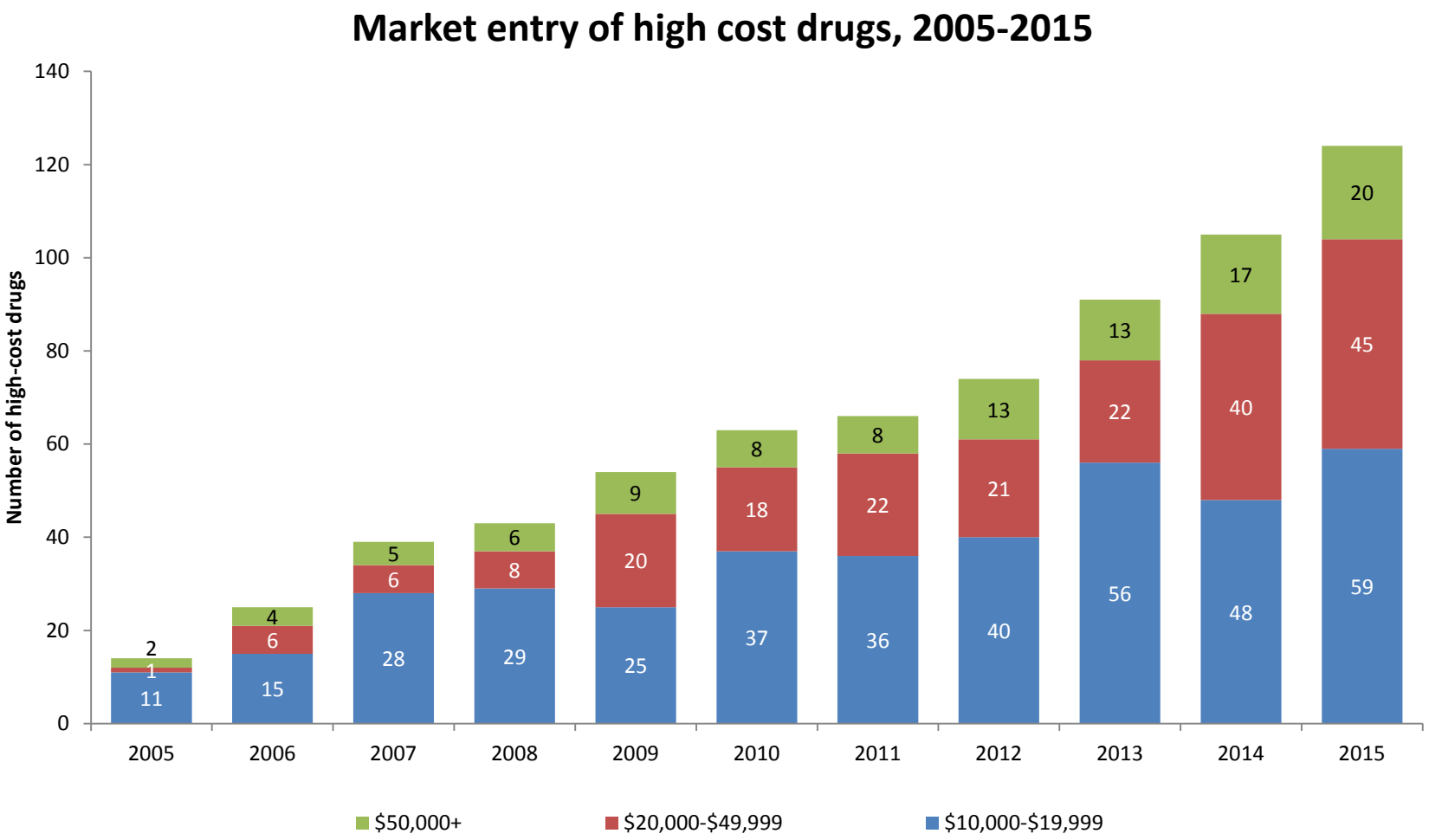
It is not working: prices are high and R&D is low.

Canadian drug prices



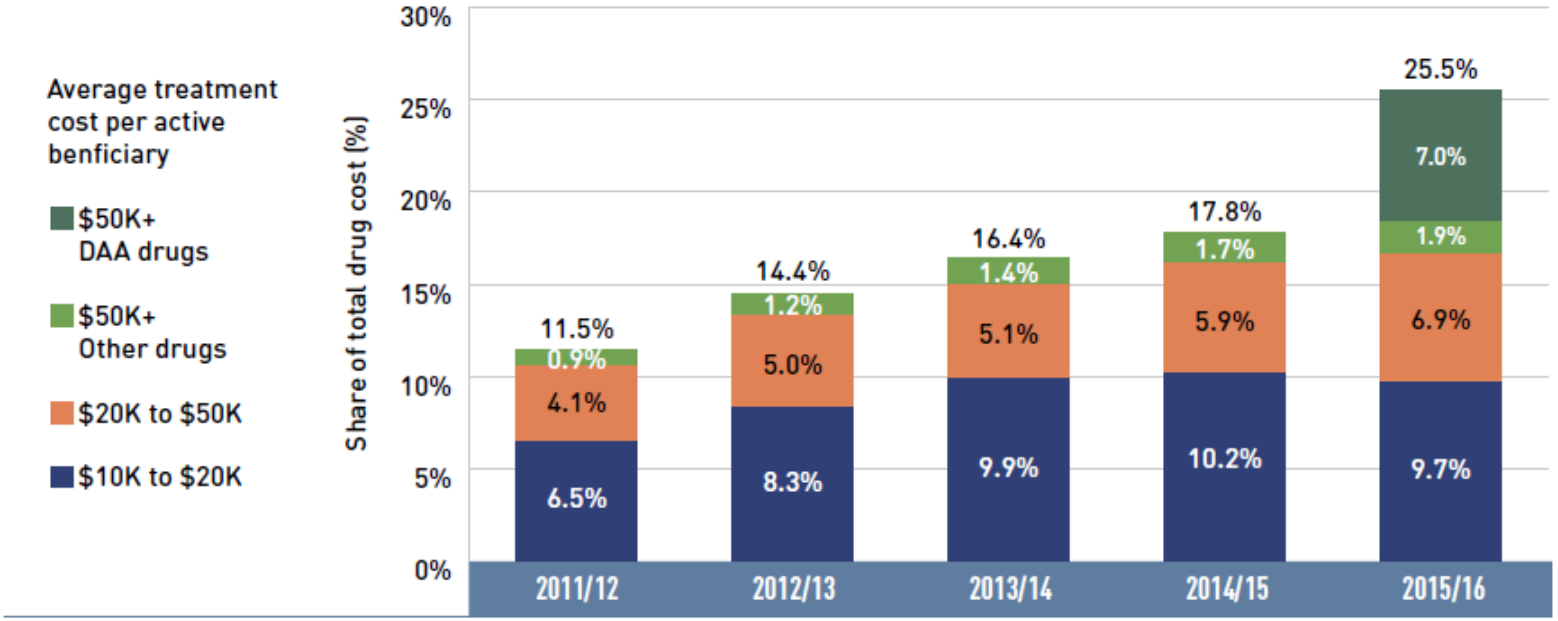
Sources: PMPRB Annual Report 2015; National Prescription Database Utilization Information System

Increase in number of high cost drugs



IMS-Brogan Pay-Direct Private Drug Database, 2015

Figure 3.6 Trends in the number and cost of high-cost drugs* NPDUIS public drug plans†, 2011/12 to 2015/16



	2011/12	2012/13	2013/14	2014/15	2015/16
Total no. of molecules	42	54	58	72	81

Note: These results are underestimated, as some high-cost drugs are reimbursed through special public drug plan programs that are not captured in the NPDUIS data.

* Average annual drug costs per active beneficiary exceeding $10,000.

† British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and the Non-Insured Health Benefits Program.

‡ New direct-acting antiviral (DAA) drugs used in the treatment of hepatitis C; forms part of the $50K+ band.

Data source: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

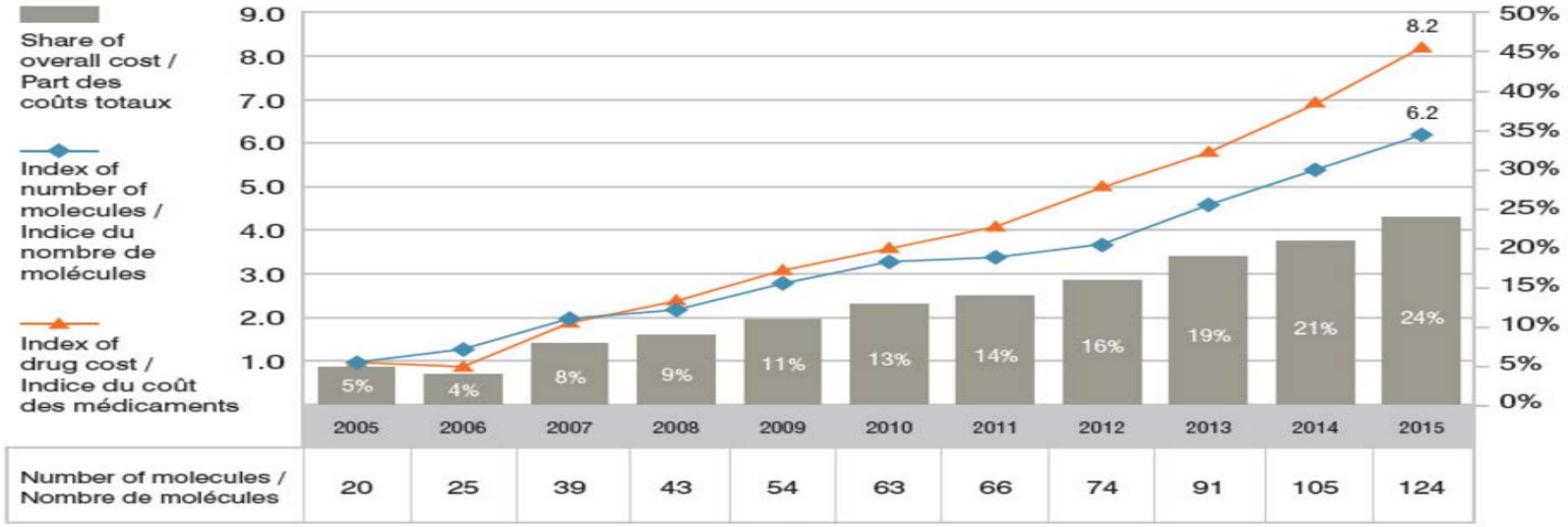
Private spending on high cost drugs

TRENDS IN THE NUMBER AND THE COST OF HIGH-COST DRUGS*

Private drug plans†, 2005 to 2015

TENDANCES RELATIVES AU NOMBRE ET AU COÛT DES MÉDICAMENTS À COÛTS ÉLEVÉS*

Régimes privés d'assurance-médicaments†, de 2005 à 2015



	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Number of molecules / Nombre de molécules	20	25	39	43	54	63	66	74	91	105	124

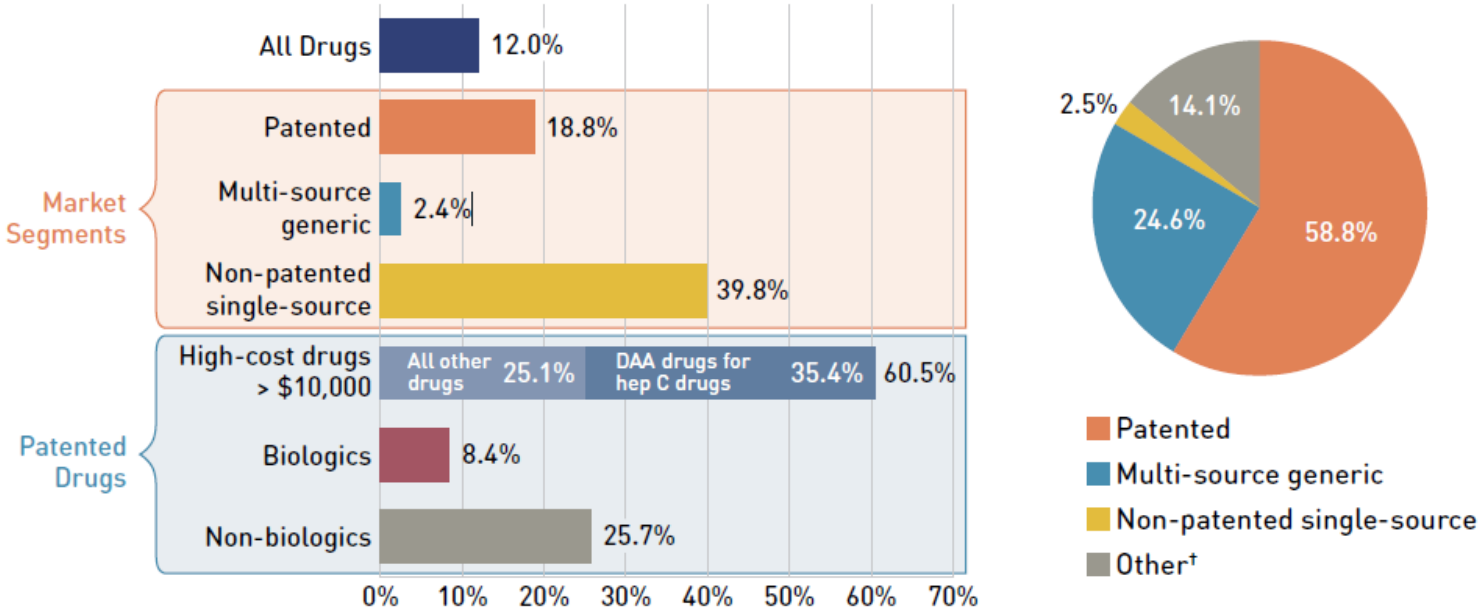
*Molecules with an annual average cost per active beneficiary of $10,000 or more. /
*Molécules ayant un coût moyen annuel par bénéficiaire actif de 10 000 $ ou plus.

Source: 2016 –(PMPRB-NPDUIS), Private Drug Plans in Canada: High-Cost Drugs and Beneficiaries, 2005 to 2015 - Poster, IMS Brogan®

Public spending on high cost drugs

Total public spending on high cost drugs doubled in 2015

Figure 2.7 Annual rates of change in drug costs by market segment, NPDUIS public drug plans*, 2014/15 to 2015/16



Note: High-cost drugs have an average annual treatment cost of greater than $10,000, and include both biologics and non-biologics.

* British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador, and the Non-Insured Health Benefits Program.

† This market segment includes devices, compounded drugs, and other products that are reimbursed by public drug plans but do not have a Health Canada assigned Drug Identification Number (DIN).

Data source: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

Impetus for 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.

FPT priorities

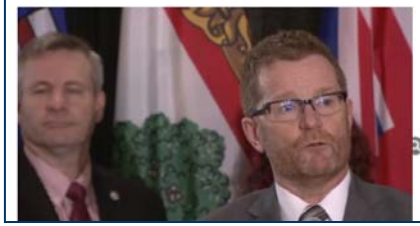
"A Liberal government's… priorities for a new Health Accord will include:

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."

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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HESA

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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.

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

Government of Canada / Gouvernement du Canada

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

Prescription Medications and Health Innovation

While Canadians are rightly proud of their universal public health care system, international assessments from such organizations as the Commonwealth Fund and the Organisation for Economic Co-operation and Development show that our system lags behind other major peer countries in several areas. For example, the costs Canadian families pay for prescription medications are too high and too few Canadians have access to digital health care.

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.

LIFE AND HEALTH INSURANCE

Government aims to lower price of prescription drugs

by Susan Yellin March 23, 2017 01:00 p.m.

The federal government says Canadians pay too much for prescription medications and announced in its budget on Wednesday that it wants to take steps to lower them.

The budget proposed improving access to prescription medications, lowering drug prices and making an investment of $140.3 million over five years to Health Canada, the Patented Medicine Prices Review Board and the Canadian Agency for Drugs and Tec

POLITICS

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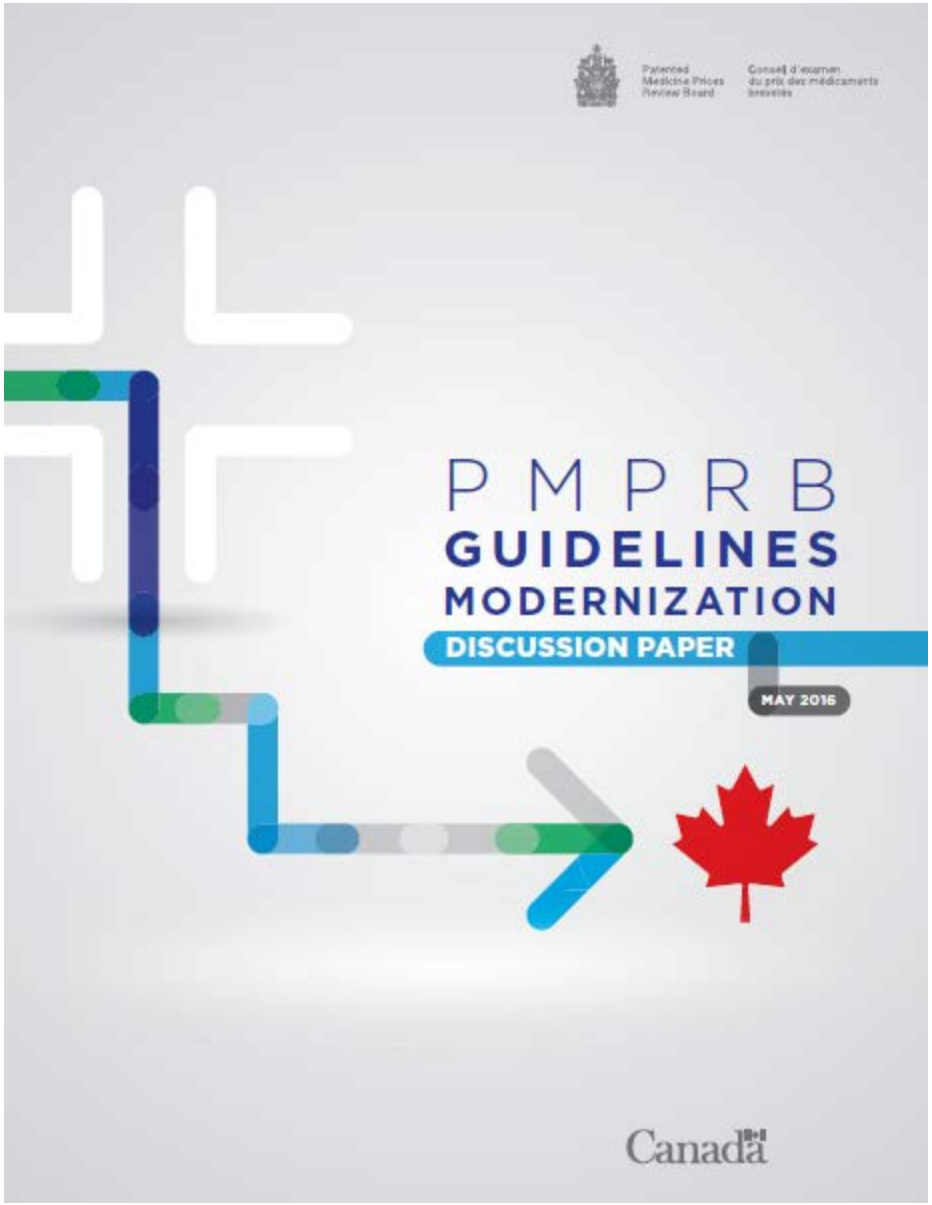
Council of Canadians disappointed by Budget 2017-18

March 22, 2017 - 8:33pm

Guidelines reform



Consultation on Guidelines reform

Last 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. International and domestic price tests
3. How CPI is applied
4. “Any market” price review/price discrimination

Over 65 submissions were received from a wide array of stakeholder groups.

The feedback received in response to the discussion paper will inform the second phase of consultations, when specific changes to the Guidelines will be proposed.

Public feedback on Guideline reform

Areas of relative agreement:

- 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;
- Legislative and/or regulatory change should precede Guideline reform.

And disagreement:

- 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;

Closing Remarks

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.