Presenters Disclosure

- We have no current or past relationships with commercial entities
- We have received no speakers fee for this learning activity

NEW DEVELOPMENTS IN HTA AND DRUG PRICING POLICY IN CANADA:

ARE THEY DESIGNED TO MANAGE ACCESS AND AFFORDABILITY, OR ARE THEY A BARRIER TO ACCESS?

ISPOR 2020
MAY 19, 2020

Moderator:

- Mitch Moneo, Assistant Deputy Minister, Pharmaceutical Services Division, BC Ministry of Health

Presenters:

- Brent Fraser, Vice President, Pharmaceutical Reviews, CADTH
- Sang Mi Lee, Senior Manager, pan-Canadian Pharmaceutical Alliance
- Tanya Potashnik, Director, Policy and Economics Branch, PMPRB

Presenter One

Brent Fraser, B.Sc. in Pharmacy; MBA

Vice-President Pharmaceutical Reviews

CADTH

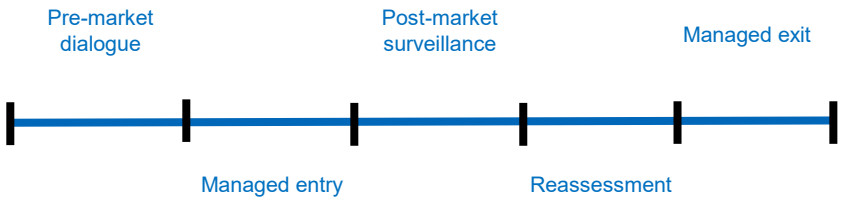
The Perfect Storm for Health Systems

1. Robust pipelines of promising and disruptive technologies
2. Increased demand for early and equitable access to promising technologies
3. Regulatory acceleration
4. An affordability crisis

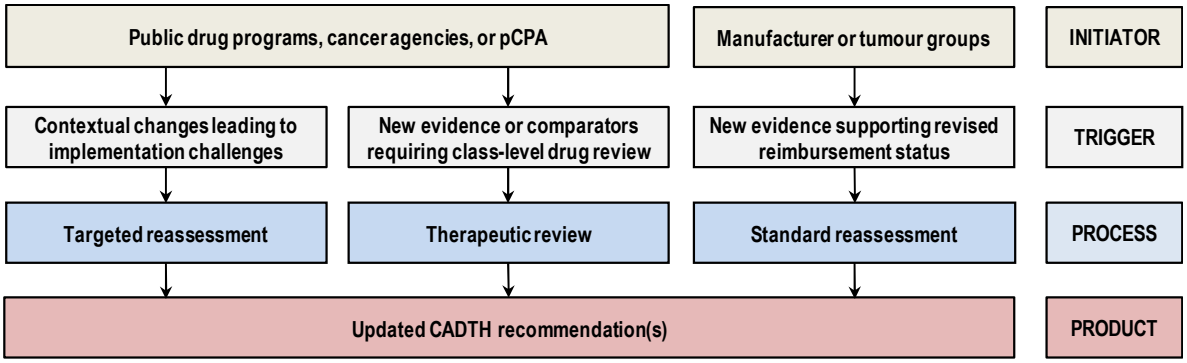
Fostering a Shift from HTA to Health Technology Management (HTM)

1. **Early identification of disruptive technologies**
2. **Strengthened engagement with stakeholders**
3. **Life cycle HTA (in collaboration with regulators)**
4. **Evidence-informed implementation**

Life cycle HTA



CADTH Reassessment Processes



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CADTH Reassessment Processes

CADTH aims to conduct its reviews in the most efficient manner:

- A **standard reassessment** is conducted to address questions related to comparative clinical benefit and/or cost-effectiveness of a single drug that is currently reimbursed by the drug programs for the indication(s) of interest.
- **Targeted reassessment** is conducted to address changes in contextual factors that may affect the ability of the drug programs to implement existing recommendations from CADTH.
- **Therapeutic review:** Questions regarding the comparative safety, clinical effectiveness, and cost-effectiveness of multiple drugs.

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Triggers for Reassessment

Regulatory activity	• Revised indications (e.g., changes that could alter coverage) • Conversion from NOC/c to NOC (if concern in initial review)
Coverage activity	• Required component of funding arrangement • Utilization issues (e.g., perceived overuse) • Manufacturer proposes changes to existing criteria
Clinical/cost-effectiveness questions	• Emergence of new comparators • Availability of new clinical data (e.g., new RCTs or RWE) • Uncertainty of the magnitude of benefit
Contextual changes	• Clinical practice considerations (new guidelines that do not align with CADTH recommendation)

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Challenges (Drug Plan Perspective)

- Plans have significant challenges attempting to implement recommendations with reassessment conditions
- Unclear who is responsible for generating the evidence, funding analyses, and paying for the drug during the study
- Lack of tools to require manufacturers to comply
- Concern that the evidentiary bar is lowered by reimbursing in the absence of sufficient evidence

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Challenges (CADTH Perspective)

- Committees unable to provide detailed guidance as to the type data that would be required for reassessment
- Confidentiality of listing agreements (e.g., conditions and pricing) could create a barrier to conducting a meaningful and transparent reassessment of the drug
- Limited resources could require prioritization of drugs for reassessment

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Presenter Two

Sang Mi Lee, B.Sc. in Pharmacy

Senior Manager

pan-Canadian Pharmaceutical Alliance (pCPA)

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Sang Mi Lee, Sr. Manager, pCPA Office

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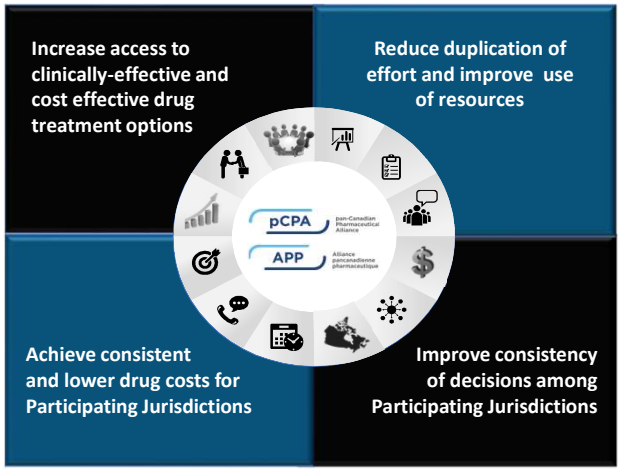
The pCPA is an alliance of the provincial, territorial and federal governments that collaborates on a range of public drug plan initiatives and conducts negotiations on brand name drugs in Canada to:



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Prior to a negotiation:

- CADTH shares "pre-submission" materials (manufacturer's discretion) with the pCPA to facilitate timely product awareness, preparation, and to reduce duplication of effort.
  - Relevant information from INESSS is incorporated into pCPA process as required.

During Negotiation:

- During an active negotiation: CADTH and INESSS formulary listing recommendations are both used as a guide for pCPA negotiations
  - CADTH recommendations guide drug negotiations by British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland & Labrador, Yukon Territory, Nunavut, and Northwest Territories.
  - INESSS recommendations guide drug negotiations by Québec's

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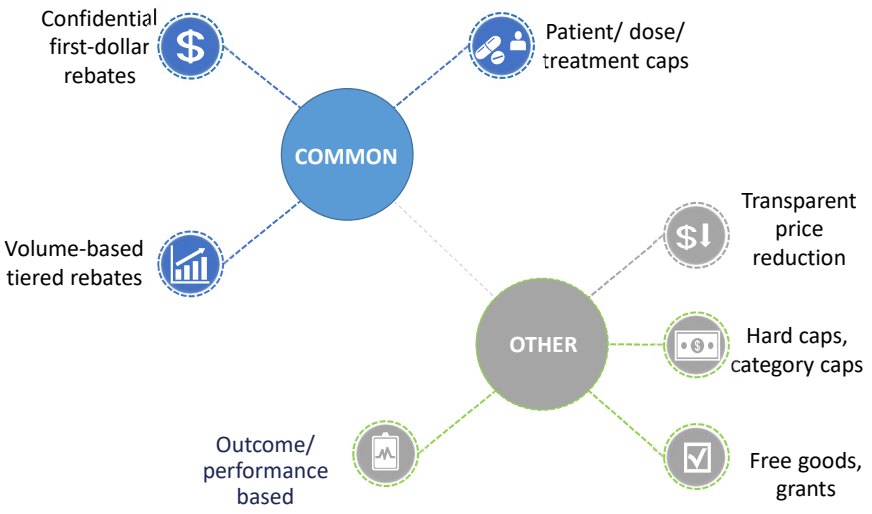

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Consensus based decisions with 14 different participating jurisdictions

Wide gap in perception of appropriate value between manufacturer and payor (appropriate cost-effectiveness?)

Pay per performance or outcomes-based proposals

Uncertainty of budget impact

Value vs. Timeliness of Negotiations & Access

Manufacturer proposed criteria vs. Notice of Compliance indication vs. CADTH/INESSS recommendation

Gene therapy specific

Early products have uncontrolled trials (very high clinical uncertainty), unclear long-term efficacy and cost-effectiveness, as well as issues around availability of sites, capacity, unique set of payors, interprovincial billing, etc.

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Presenter Three

Tanya Potashnik, MA

Director, Policy and Economics Branch

Patented Medicine Prices Review Board

Outline

1. About the PMPRB and its regulatory framework
2. Canada's struggle with the affordability of new drugs
3. Are lower drug prices a barrier to access?

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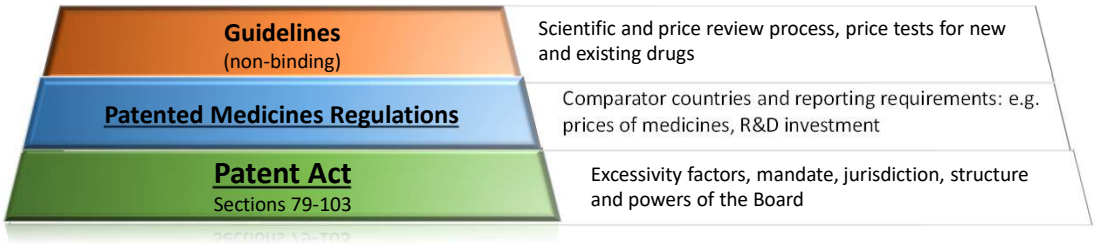
1 About the PMPRB and its regulatory framework

PMPRB

About the PMPRB

- The PMPRB is an independent, quasi-judicial, consumer protection agency that carries out it's mandate at arm's length from the Minister of Health.
- It was established by Parliament in 1987 under the Patent Act (Act), to ensure that the prices of patented medicines sold in Canada are not excessive.
- PMPRB is a "consumer protection pillar" established as a counter-balance to the market exclusivity afforded to patent medicines through the Act, which eliminated compulsory licensing, giving patentees a statutory monopoly power.
- The PMPRB regulatory framework reposes on three legal instruments:



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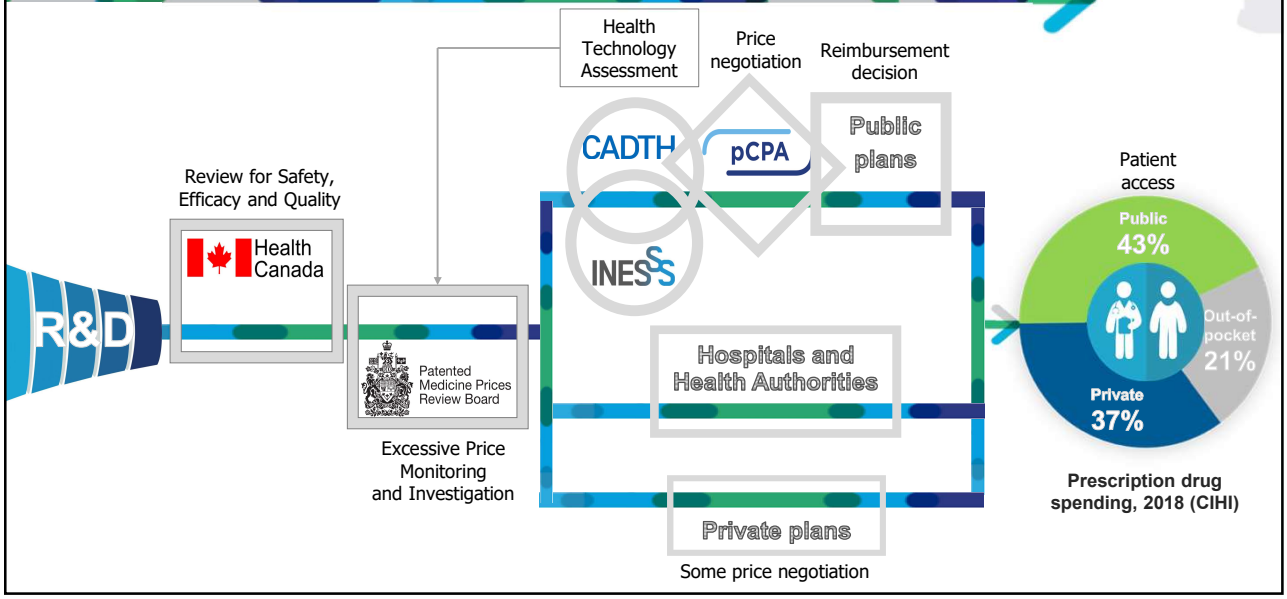
- Despite a number of minor changes to these legal instruments, the regulatory framework has remained virtually unchanged since the PMPRB's founding.

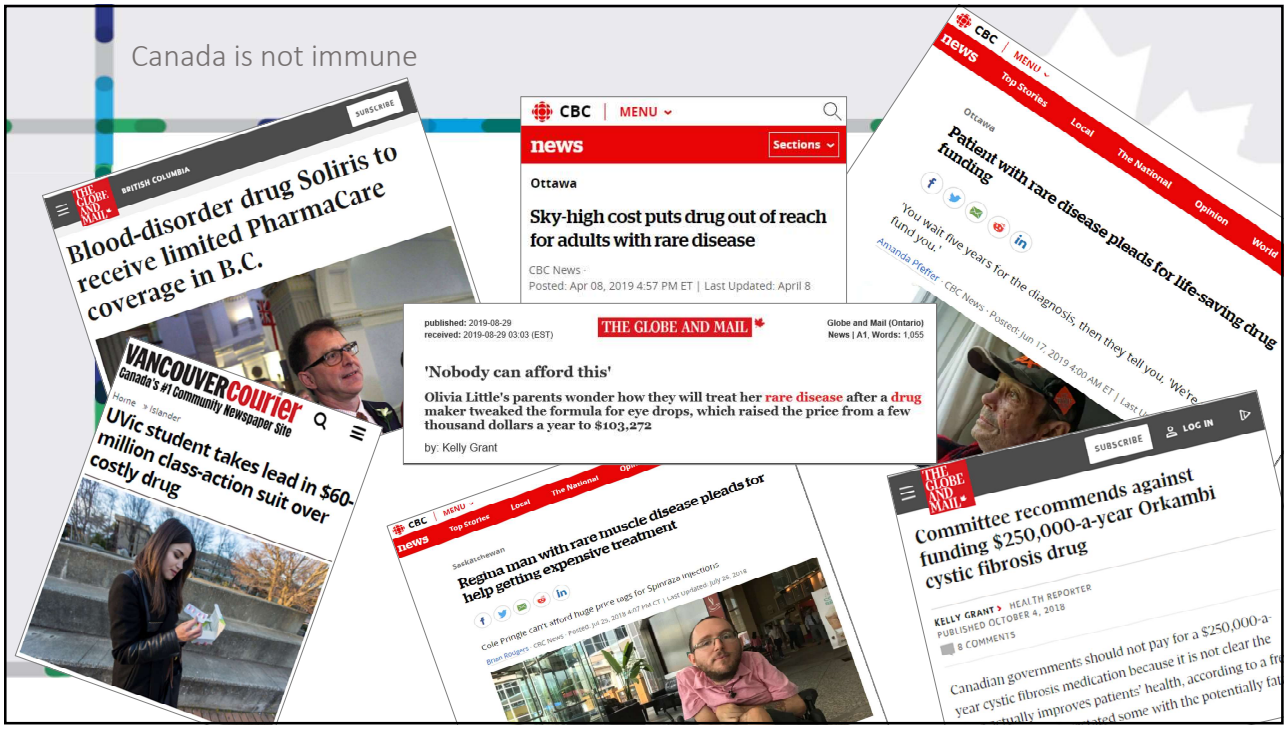
The PMPRB is part of a complex regulatory and reimbursement ecosystem



2 Canada's struggle with the affordability of new drugs

Drug affordability has become a global issue, even for the richest countries

Canada is not immune



For many Canadians, prescription drugs are unaffordable

- 21% of the prescription drug sending in 2018 was out-of-pocket
- About 1 in 5 Canadians report having no prescription drug coverage while many more are underinsured or face high deductibles or co-pays
- Almost 1 in 10 Canadians have had to forego filling a prescription drug in the past year for reasons related to cost
- Many Canadians who forego filling prescriptions seek additional health care services
- The cost of paying for prescription drugs means that many Canadians must forego paying for basic necessities like food and heat

20% — Percentage of Canadians without prescription drug coverage

8.2% — Percentage of Canadians who had to forego filling a prescription because of cost

374K — Canadians used additional health services as a result of foregoing a prescription drug in the past year

1.4M — Canadians had to forego other spending, including basic necessities, to pay for prescription drugs in the past year

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Sources: CIHI
The Impact of Out-of-Pocket Prescription Drug Costs, *The consequences of patient charges for prescription drugs in Canada: a cross-sectional survey*, University of British Columbia, 2016

Rapid growth in high-cost* drugs is accounting for an increasingly significant share of spending but covers only a small minority of claimants

High-cost patented drug are used by only **1%** of Canadians but accounted for **30%** *of 2017* sales, up from only **8%** in 2006

In 2017, 5 of top 10 selling drugs had an average annual treatment cost exceeding **$10K**

In the last 5 years, the fastest growing segment of the market is high cost drugs at **13%**, or which EDRDs are growing at **33%**

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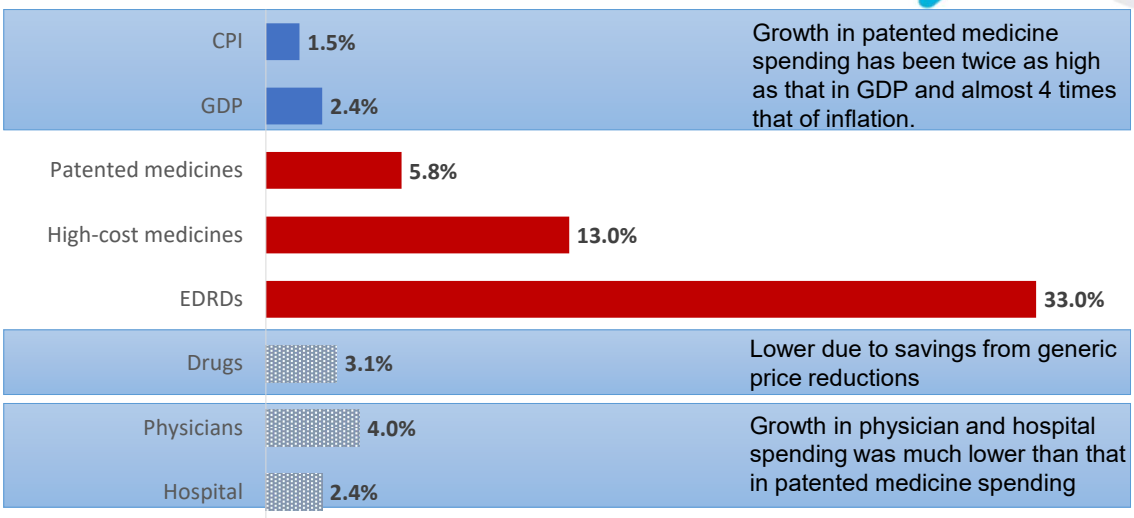
* High-cost is defined as average annual cost exceeding $10,000
Data source: 1. PMPRB Annual Report 2017; 2. PMPRB CompassRx, 5th edition; 3. IQVIA™ Private Pay Direct Drug Plan Database.

Spending on patented medicines is outpacing other healthcare categories and economic growth, 2013-2017



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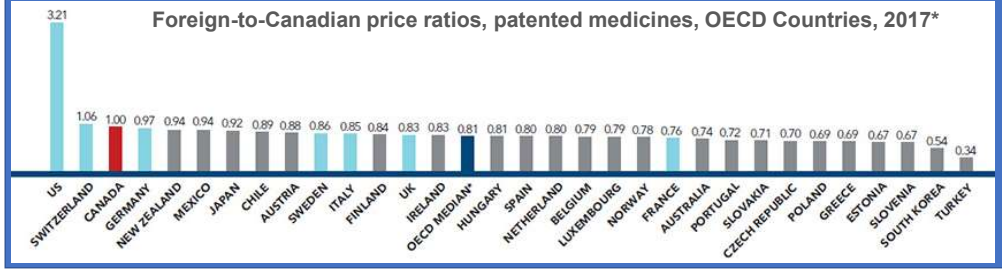
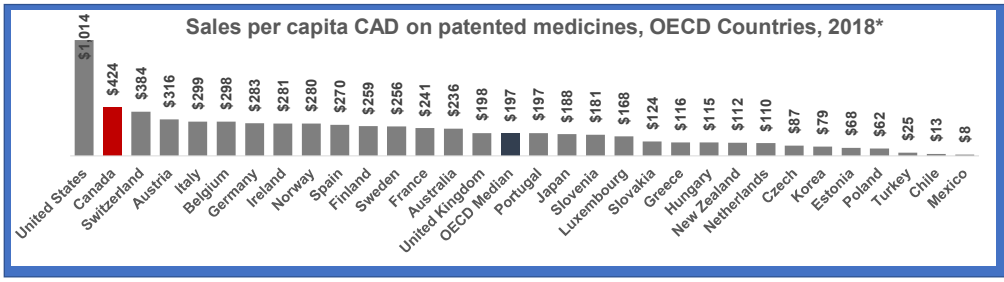
Canada pays third-highest list prices on patented medicines in OECD and has the second-highest sales per capita



Canadian prices are **3rd** highest in the OECD

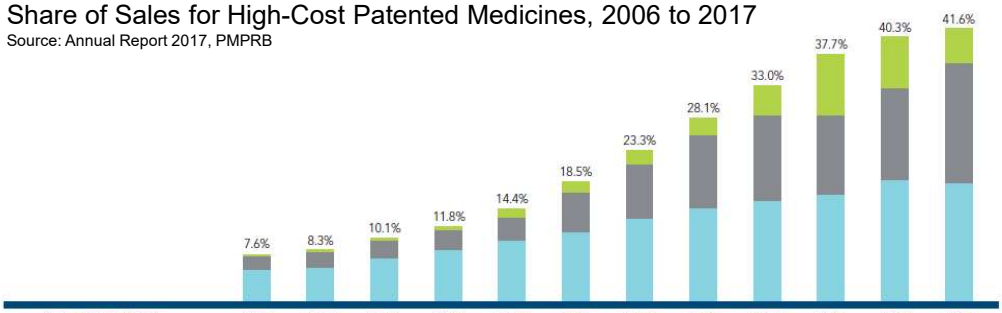


Canadian sales per capita are **2nd** highest in the OECD

Evolving pharmaceutical market – patented medicines

Share of Sales for High-Cost Patented Medicines, 2006 to 2017

Source: Annual Report 2017, PMPRB

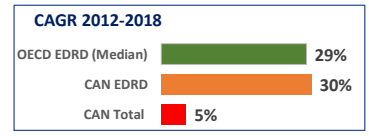


SHARE OF SALES %	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
50K+	0.3	0.4	0.5	0.7	1.3	1.7	2.2	2.7	4.5	9.2	7.8	5.3
20K-50K	2.1	2.4	2.7	3.0	3.5	6.0	8.2	10.9	12.9	12.0	13.8	18.1
10K-20K	5.2	5.5	6.9	8.1	9.6	10.8	12.9	14.5	15.6	16.5	18.7	18.2
Total	7.6	8.3	10.1	11.8	14.4	18.5	23.3	28.1	33.0	37.7	40.3	41.6

Despite small patient populations, EDRDs are a rapidly growing market, gaining sizeable sales through high prices

While EDRDs are rare by definition, collectively they represent a substantial portion of Canadian population

"Rare diseases affect one in 12, or approximately 2.8 million Canadians" (CORD)



	2012	2013	2014	2015	2016	2017	2018
Cumulative number of EDRDs approved	26	31	37	48	61	71	79
EDRD share of total Pharma market	1.9%	2.2%	2.8%	3.6%	4.3%	5.5%	7.0%
Sales per capita	$11	$13	$16	$23	$28	$38	$50

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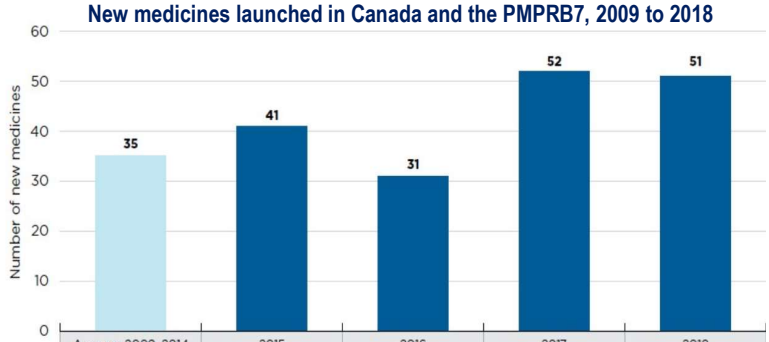
Orphan medicines are increasingly dominating the market

New medicines launched in Canada and the PMPRB7, 2009 to 2018



	Average 2009–2014	2015	2016	2017	2018
Share of orphan medicines	33%	54%	42%	46%	59%
Share of oncology medicines	20%	34%	16%	33%	29%

U.S. FOOD & DRUG ADMINISTRATION

CDER New Drugs Program: 2018 Update

In CY 2018 so far*, CDER has approved 55 NMEs, including 31 orphan drugs

– For the first time ever, the majority of NMEs approved are orphan drugs to treat rare diseases

- Data source: PMPRB Meds Entry Watch
- IQVIA MIDAS® Database, 2009 to 2014 (all rights reserved); US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

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Main problems with current framework

- Our basket of comparators – the PMPRB7 – is made up of premium priced countries and includes the US, an international outlier.
- PMPRB price review is based on publicly available list prices, which are increasingly divorced from the true price net of confidential rebates/discounts.
- Internal and external price referencing are ineffective tools to regulate the prices for many high-cost medicines.
- All medicines are subject to the same level of regulatory scrutiny, regardless of risk of abuse of market power.
- PMPRB sets ceiling prices for medicines at introduction and does no reassess over time to ensure that the prices continue to remain non-excessive

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Government has responded with "…biggest step to lower drug prices in a generation."

Amendments to the Patented Medicine Regulations provide the PMPRB with modern tools and information it needs to protect Canadians :

1. **Benchmarking prices against countries that are more like Canada** economically and from a consumer price protection standpoint.
2. **Considering the value and the overall affordability of a medicine** when setting the maximum price.
3. **Regulating at the level of the actual prices being paid in Canada** and not just the non-transparent manufacturer list prices.

These proposals will bring Canada in line with the policies and practices of most other developed countries

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Recent and next steps in the implementation of the regulatory changes

Draft Guidelines

- Released on November 21, 2019
- Proposed approach for consultation
- Broad and robust 85-day consultation
- Extensive feedback received, including 122 written submissions

Revised Draft Guidelines

- Expected later this spring
- Significant changes envisioned in response to the feedback received
- Limited consultation period
- Covid-19 situation being monitored

Finalized Guidelines

- Exact date TBD
- To be implemented once the regulatory amendments come into force
- Commitment to evaluate PMPRB Framework Modernization and Evaluation Plan (FMEP)

3

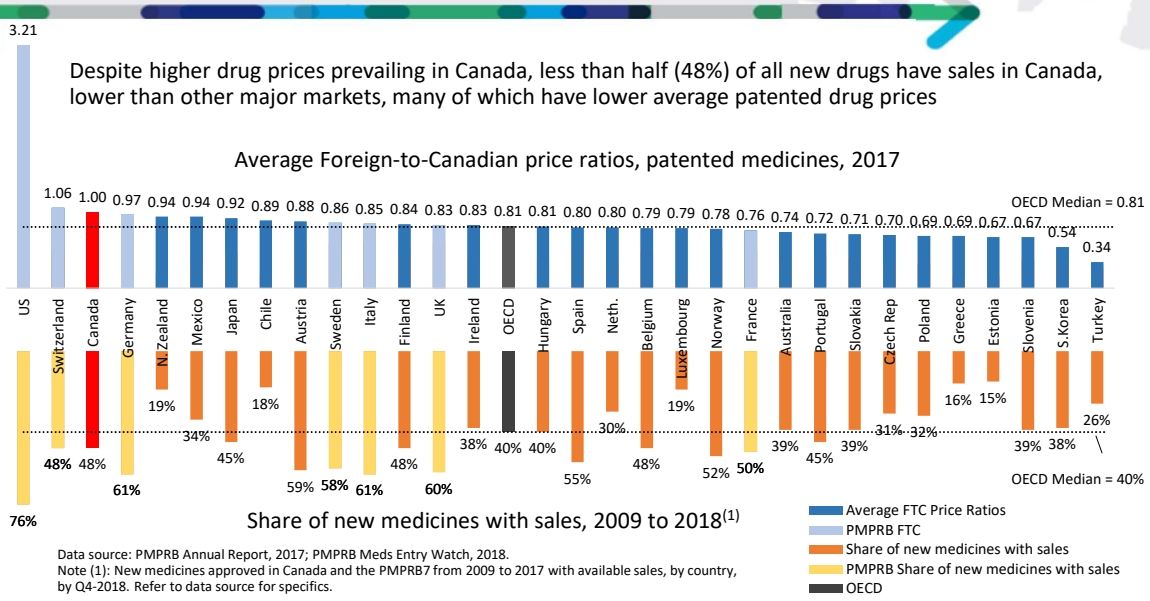
Are lower drug prices a barrier to access?

PMPRB

Countries with lower patented drug prices than Canada have greater availability of new medicines

Despite higher drug prices prevailing in Canada, less than half (48%) of all new drugs have sales in Canada, lower than other major markets, many of which have lower average patented drug prices

Average Foreign-to-Canadian price ratios, patented medicines, 2017



Share of new medicines with sales, 2009 to 2018(1)

Average FTC Price Ratios
PMPRB FTC
Share of new medicines with sales
PMPRB Share of new medicines with sales
OECD

Data source: PMPRB Annual Report, 2017; PMPRB Meds Entry Watch, 2018.
Note (1): New medicines approved in Canada and the PMPRB7 from 2009 to 2017 with available sales, by country, by Q4-2018. Refer to data source for specifics.

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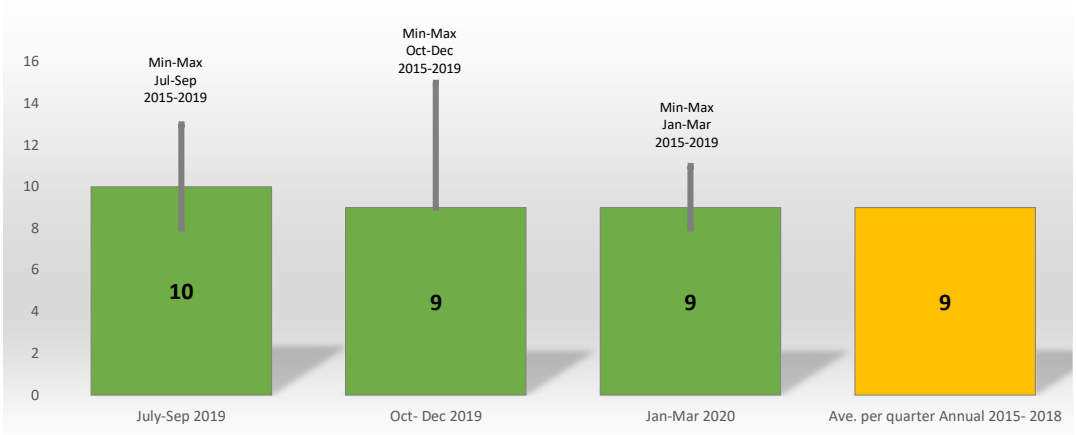
Are there fewer drugs being launched in Canada since the announcement of the reforms on August 2019?

The number of new medicines approved over the most recent three quarters are in line with past trends

Number of new medicines approved in Canada per quarter, 2015 - 2020



Data source: Health Canada Drug Product Database

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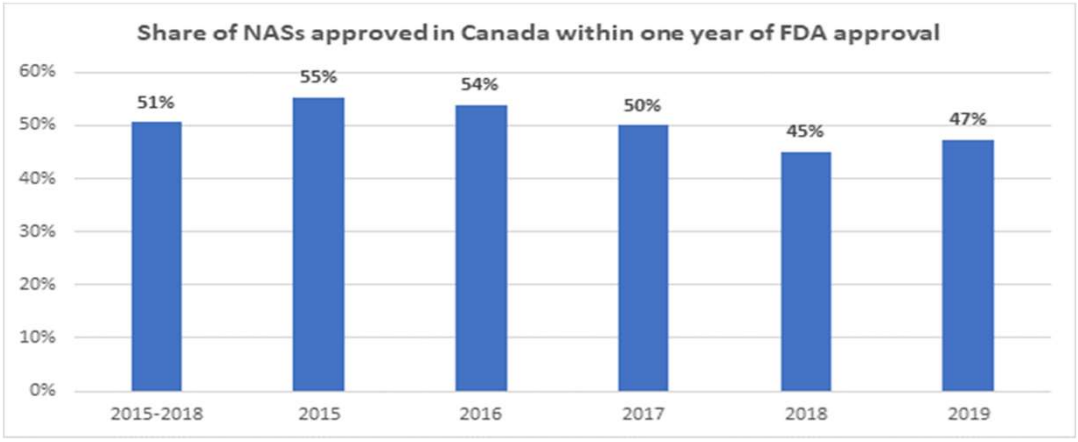
Are there delays in Canadian drug launches since the announcement of the reforms on August 2019?

- Critics of the reforms claim so, however, just under 50% of new medicines approved by Health Canada in 2019 received that approval within one year of United States approval, higher than in 2018.



Data source: FDA and Health Canada Drug Product Database

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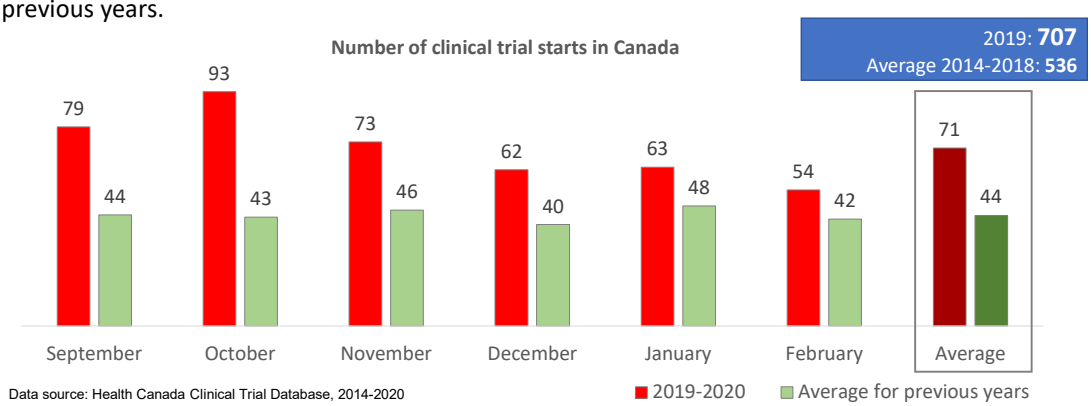
Is the number of new clinical trials being started in Canada declining since the announcement of the reforms on August 2019?

- Studies that say yes, are based on information in the Health Canada Clinical Trial Database that is incomplete and inappropriate to be consider in this context (e.g. "No Objection Letter")
- In fact, the number of new clinical trials being started in Canada has been markedly higher since the announcement of the amendments to the Patented Medicine Regulations, than the average of previous years.



Data source: Health Canada Clinical Trial Database, 2014-2020

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