

New developments in drug pricing policy in Canada

Virtual ISPOR 2020
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P M P R B
GUIDELINES
2019



Patented
Medicine Prices
Review Board

Conseil d'examen
du prix des médicaments
brevetés

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About the PMPRB and its regulatory framework

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About the PMPRB

- The PMPRB is an independent, quasi-judicial, consumer protection agency that carries out its 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:

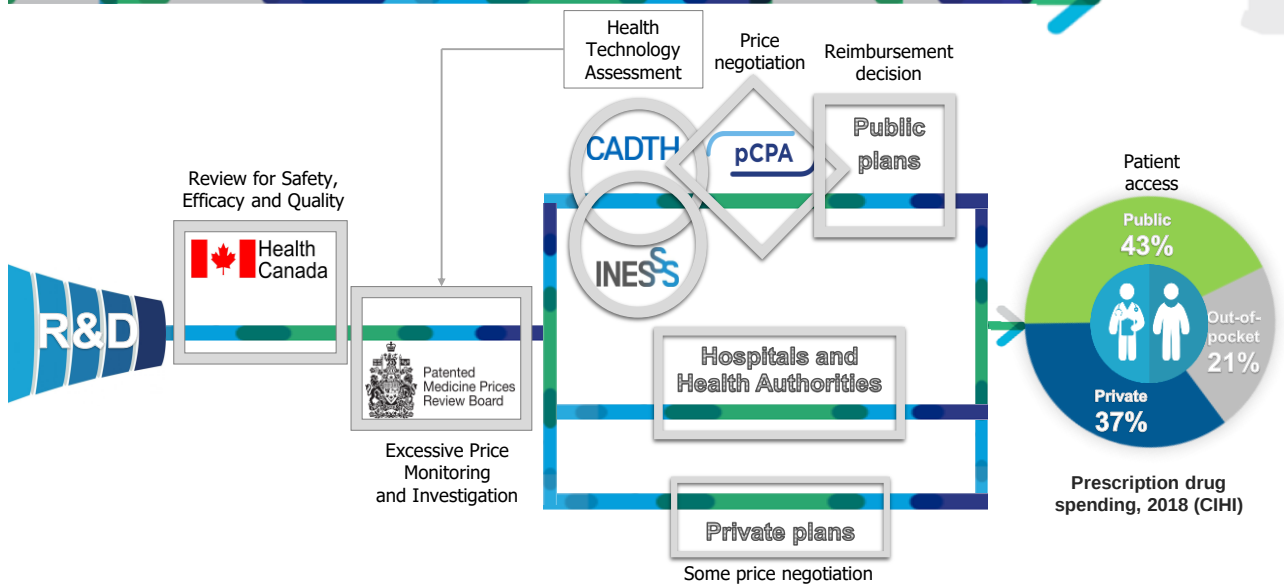
Guidelines (non-binding)	Scientific and price review process, price tests for new and existing drugs
Patented Medicines Regulations	Comparator countries and reporting requirements: e.g. prices of medicines, R&D investment
Patent Act Sections 79-103	Excessivity factors, mandate, jurisdiction, structure and powers of the Board

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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.

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The PMPRB is part of a complex regulatory and reimbursement ecosystem



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Canada's struggle with the affordability of new drugs

A collage of news articles highlighting the struggle with drug affordability in Canada:

- CBC News:** "Sky-high cost puts drug out of reach for adults with rare disease" (Posted: Apr 08, 2019 4:57 PM ET | Last Updated: Apr 08, 2019 4:57 PM ET). The article mentions a cost of more than \$700K for 1st year, Spin, which isn't an option for most adults with the disease.
- THE GLOBE AND MAIL:** "'Nobody can afford this' Olivia Little's parents wonder how they will treat maker tweaked the formula for eye drops, which cost a thousand dollars a year to \$103,272" (published: 2019-08-29, received: 2019-08-29 03:03 (EST)). The article is by Kelly Grant.
- CBC News:** "Patient with rare disease pleads for life-saving drug funding" (Top Stories, Local, The National, Opinion, World). The article features a photo of a man and a woman.
- THE GLOBE AND MAIL:** "Committee recommends against funding \$250,000-a-year Orkambi" (HEALTH REPORTER, PUBLISHED OCTOBER 4, 2018). The article mentions that Canadian governments should not pay for a \$250,000-a-year cystic fibrosis medication because the drug actually improves the condition.

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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 **20%** Percentage of Canadians without prescription drug coverage
- Almost 1 in 10 Canadians have had to forego filling a prescription drug in the past year for reasons related to cost **8.2%** Percentage of Canadians who had to forego filling a prescription because of cost
- Many Canadians who forego filling prescriptions seek additional health care services **374K** Canadians used additional health services as a result of foregoing a prescription drug in the past year
- The cost of paying for prescription drugs means that many Canadians must forego paying for basic necessities like food and heat **1.4M** Canadians had to forego other spending, including basic necessities, to pay for prescription drugs in the past year

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

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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**

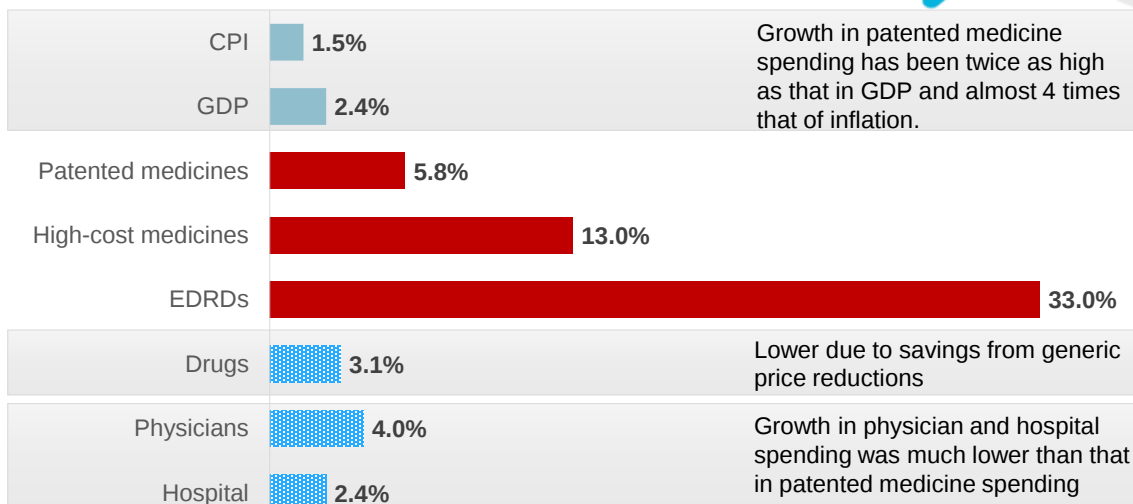
In the last 5 years, the fastest growing segment of the market is high cost drugs at **13%**, or which EDRDs are growing at **33%**

* 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.

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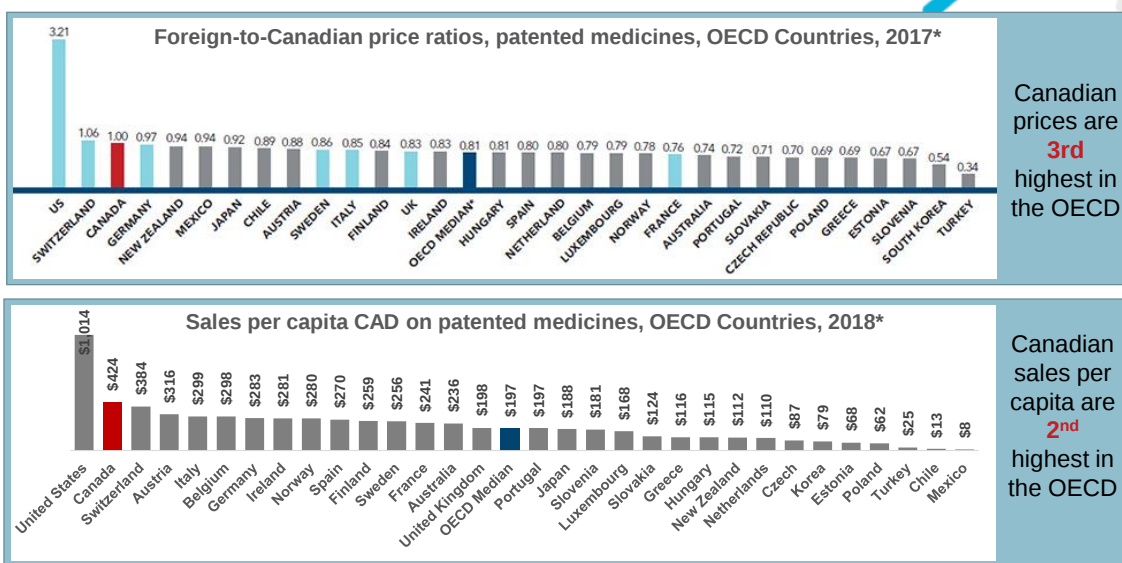
Spending on patented medicines is outpacing other healthcare categories and economic growth, 2013-2017



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



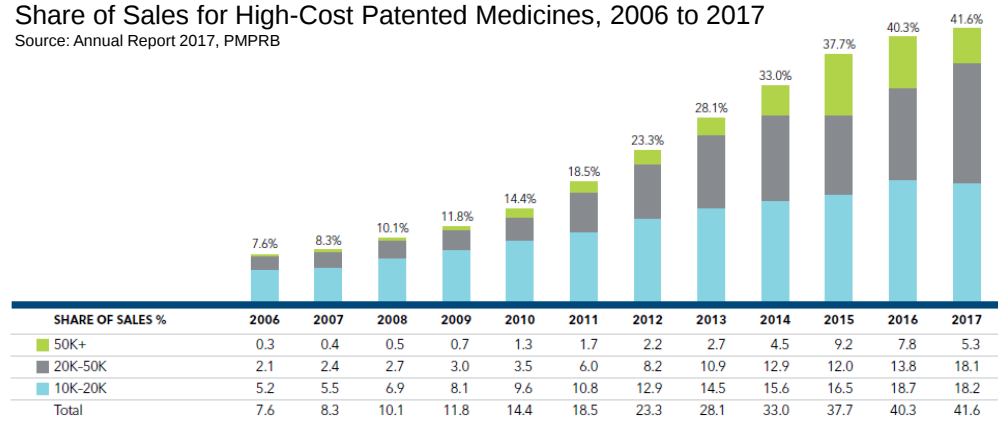
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Evolving pharmaceutical market – patented medicines

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

Source: Annual Report 2017, PMPRB



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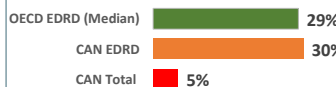
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Despite small patient populations, EDRDs are a rapidly growing market, gaining sizeable sales through high prices

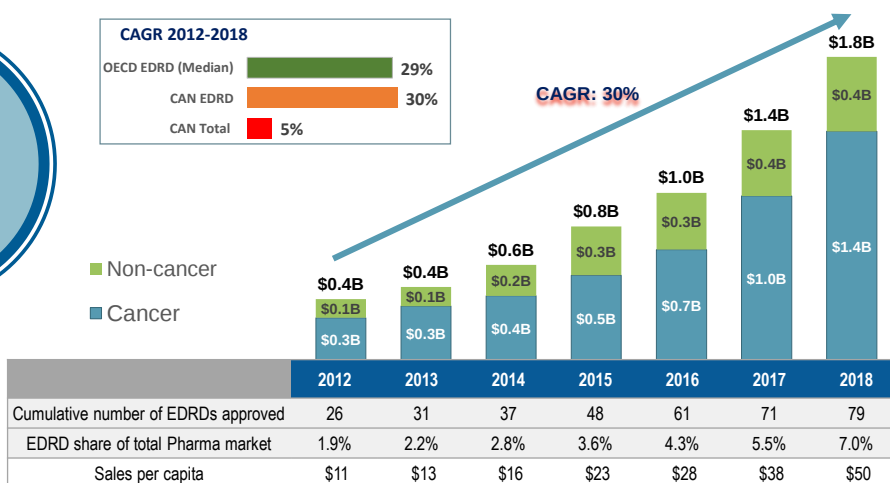
While EDRDs are rare by definition, collectively they represent a substantial portion of Canadian population

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

CAGR 2012-2018



■ Non-cancer
■ Cancer

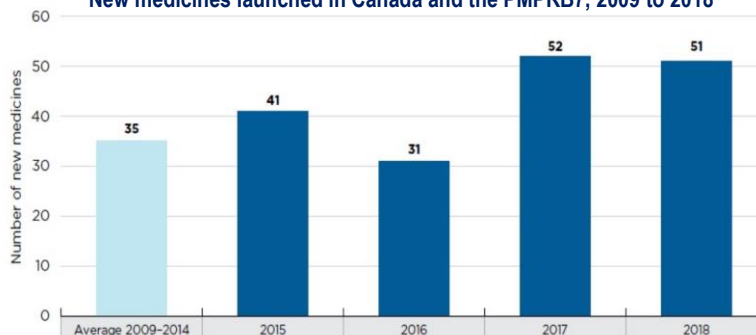


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Orphan medicines are increasingly dominating the market

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



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.

	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%

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.

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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

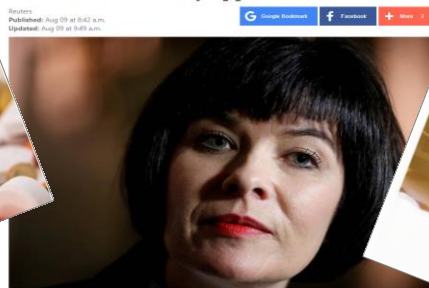
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Government has responded with "...biggest step to lower drug prices in a generation."

B.C. Applauds Federal Government For Modernizing Drug Pricing Regulations

Canada makes drug-price crackdown official over industry opposition



Government of Canada Announces Changes to Lower Drug Prices and Lay the Foundation for National Pharmacare
Health Canada says drug pricing changes will save Canadians billions

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

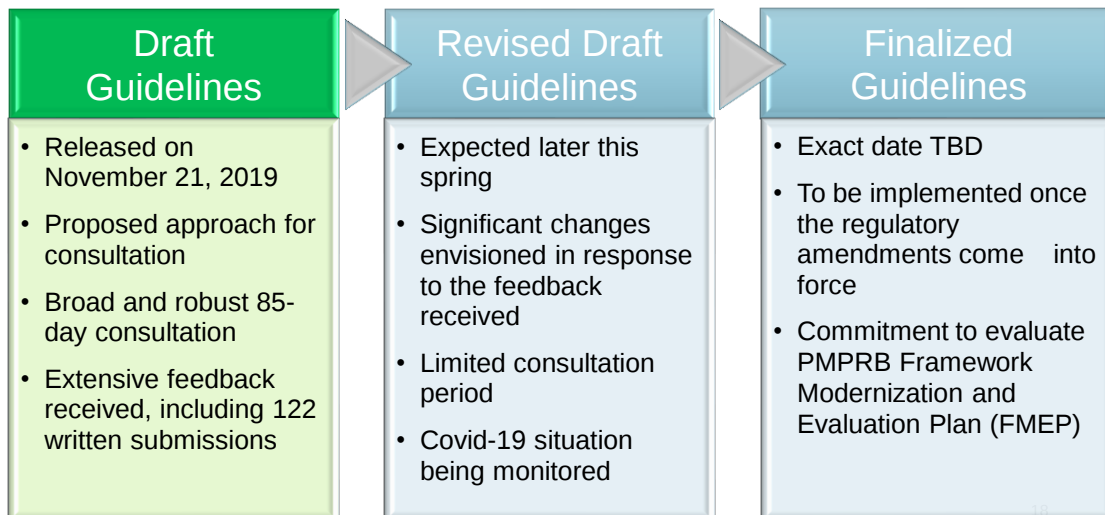
1. **Benchmarking prices against countries that are more like Canada** economically and from a consumer price protection standpoint.
2. **Considering the value and the overall affordability of a medicine** when setting the maximum price.
3. **Regulating at the level of the actual prices being paid in 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



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Are lower drug prices a barrier to access?



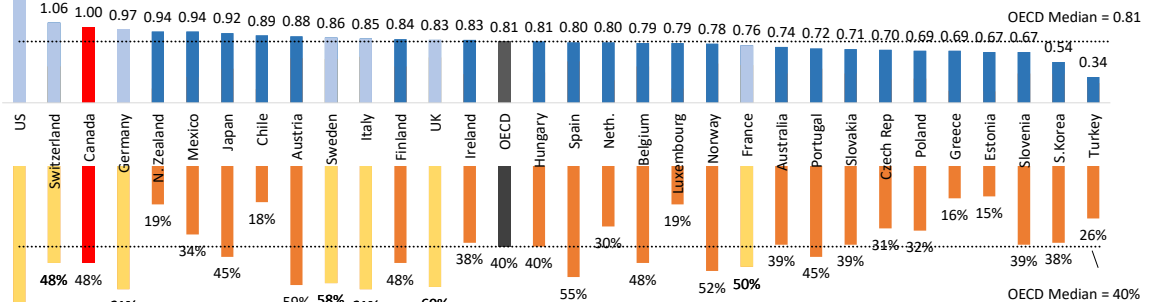
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Countries with lower patented drug prices than Canada have greater availability of new medicines

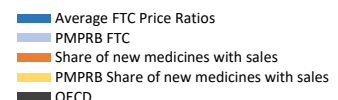
Despite higher drug prices prevailing in Canada, less than half (48%) of all new drugs have sales in Canada, lower than other major markets, many of which have lower average patented drug prices

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



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

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.



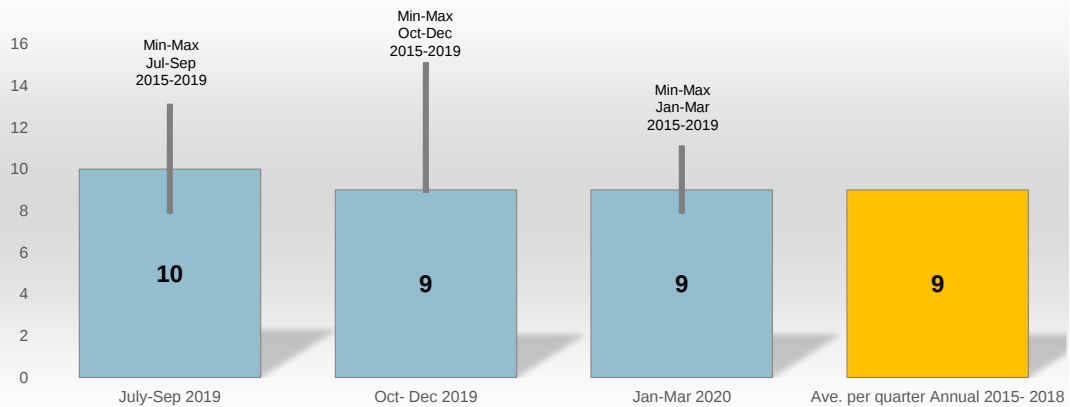
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Are there fewer drugs being launched in Canada since the announcement of the reforms on August 2019?

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

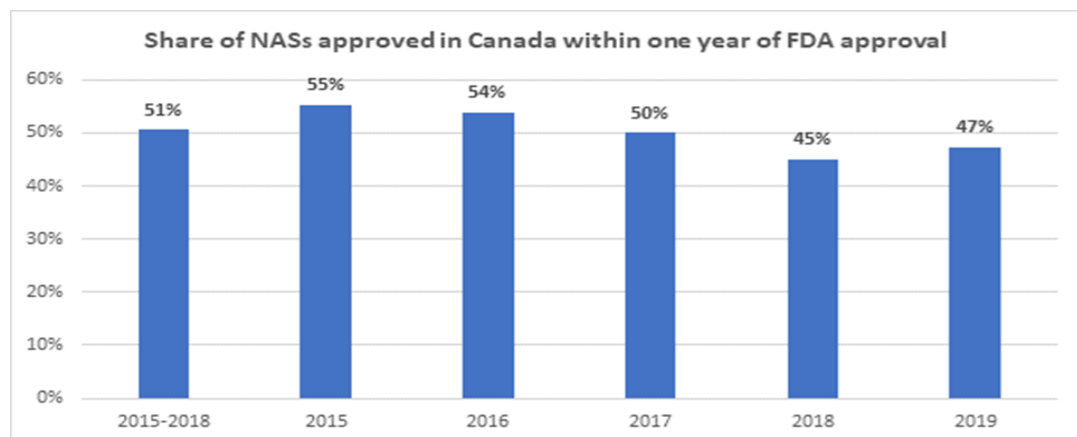


Data source: Health Canada Drug Product Database

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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.

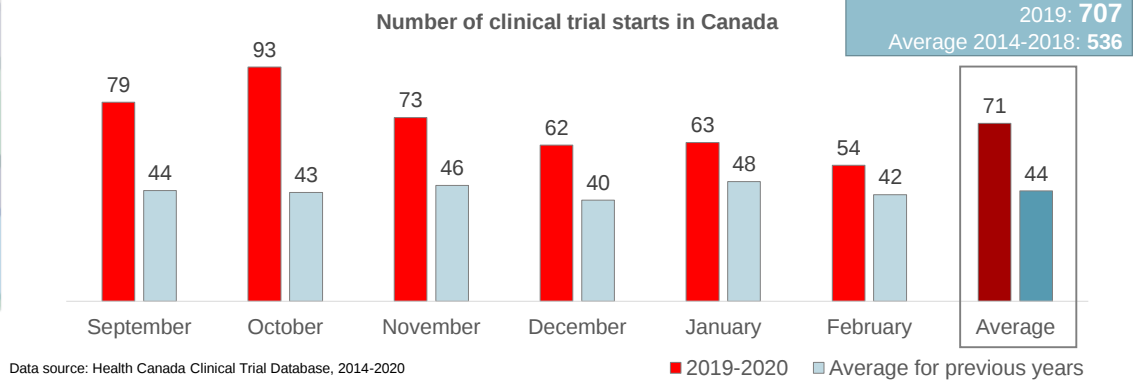


Data source: FDA and Health Canada Drug Product Database

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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 considered 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.



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Thank you

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