Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

Revised PMPRB Guidelines

Overview of key changes

Public Webinar

July 8, 2020

Outline

A. About the PMPRB and its path to reform

B. Overview of key Guideline changes

C. Case study

D. Frequently Asked Questions

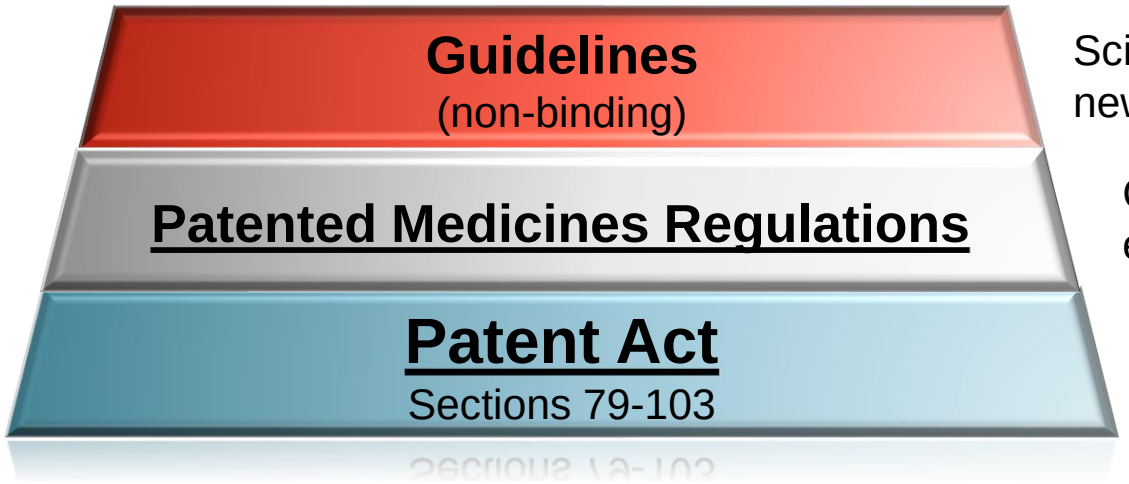
E. Questions and Answers

2

A. About the PMPRB and its path to reform

About the PMPRB

- An independent, quasi-judicial body established by Parliament in 1987 under the Patent Act
- A consumer protection agency with a dual regulatory and reporting mandate
- Through its regulatory mandate, it ensures that the prices of patented medicines sold in Canada are not excessive
- The PMPRB regulatory framework reposes on three legal instruments:



Scientific and price review process, price tests for new and existing drugs

Comparator countries and reporting requirements: e.g. prices of medicines, R&D investment

Excessivity factors, mandate, jurisdiction, structure and powers of the Board

How the PMPRB sets ceiling prices today

New patented medicines are assessed for level of therapeutic benefit relative to existing therapies and are assigned a ceiling price that is based on one, or a combination of the following:

1. The median international price based on the PMPRB7;
2. The highest price in the domestic therapeutic class;

After entering the market, the price of a medicine can increase in keeping with the Consumer Price Index (CPI) but never to the point of becoming highest of the PMPRB7.

Where PMPRB staff and a patentee disagree on whether a medicine is excessively priced, a hearing may be held before PMPRB Board Members.

If the Board decides a medicine is excessively priced, the patentee is ordered to reduce its price and/or pay back excess revenues.

Given the significant changes in the pharmaceutical environment in recent years, it has been increasingly challenging for the PMPRB to fulfill its consumer protection mandate.

New tools and information available to the PMPRB to set ceiling prices in the future

Amendments to the Patented Medicine Regulations are coming into force on January 1, 2021

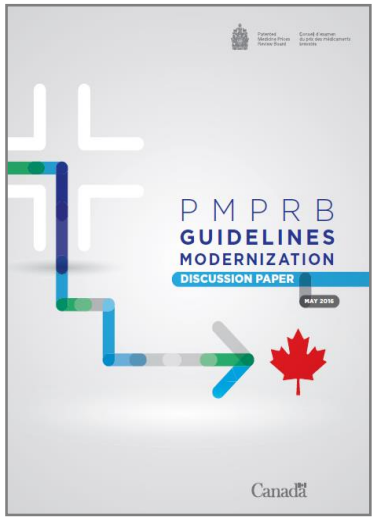
1. **An updated set of countries for benchmarking patented medicine prices**
   Countries more aligned economically and from a consumer price protection standpoint.
2. **Considering the value and the market size of a medicine**
   when setting the maximum price.
3. **Regulating at the level of the actual prices being paid in Canada**
   and not just the non-transparent manufacturer list prices.

Although Canada is the only country with a regulator that caps patented medicine prices, it is adopting best practices in most other developed countries by considering value and affordability.

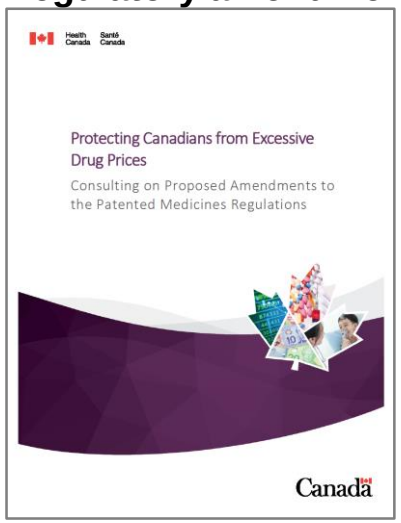
Canada is an outlier in the sense that it is the only developed country with a universal public healthcare system that does not include universal coverage of prescription drugs.

The path to PMPRB reform so far ….

PMPRB Discussion paper on Guideline reform

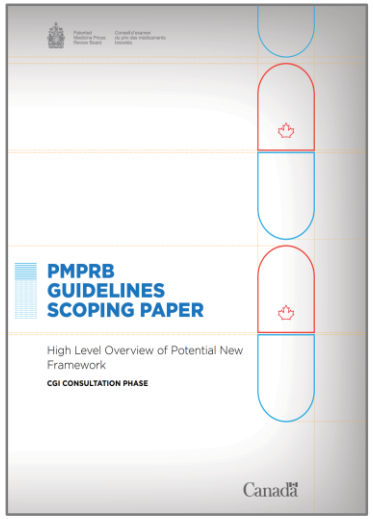


Health Canada pre-consultation on regulatory amendments

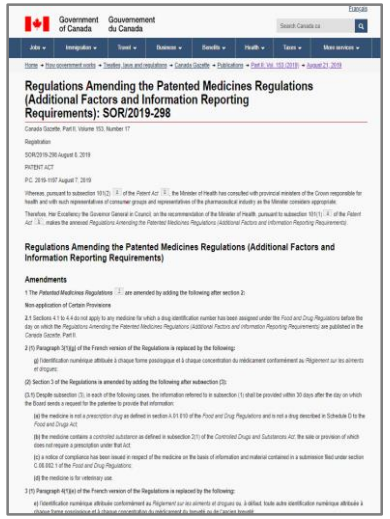


Health Canada Canada Gazette I

PMPRB Guidelines scoping paper



Health Canada Canada Gazette II



PMPRB Draft Guidelines

PMPRB consulted on a 1st set of draft Guideline

November 21st to February 14th

The PMPRB staff made significant efforts to identify and reach out to as many stakeholders as possible: over 1000 contacts representing more than 700 organizations were contacted directly by the PMPRB.

- Health Partners Working Group on Nov 15th (10 participants) and Jan 23rd (19 participants): one-day outreach session with health partner representatives including CADTH, INESSS, pCPA, Drug plans, Health Canada, and Cancer Agencies.
- Industry forum on December 9 (20 participants): one-day outreach session with representatives of IMC and BIOTECanada (Alt Hotel, Ottawa)
- Civil Society Forum on December 10 (48 participants): one-day outreach session that brought together patient groups and other non-institutional stakeholders with diverse voices
- Industry Webinar on January 17 (187 participants)
- Cross country bilateral meetings with a wide variety of stakeholders across the county (60+ meetings with 260+ participants): public and private payers, patient and patient groups, clinicians, industry and associations, pharmacists and distributors, health care organizations, etc.
- Bilateral meetings with pharmaceutical companies, and consultants (40+ meetings)

The information on dates, locations and stakeholder groups, as well as electronic versions of the presentations are available on the PMPRB website.

Written Submissions

Category	Submissions (#)	Submissions (%)
Consumer/patient advocacy total	**41**	**33%**
Patentee	34	28%
Patentee association	4	3%
Generics/biosimilars	2	2%
Patentee/patentee association total	**40**	**33%**
Distributor/consultant/pharmacist	11	9%
Industry associations (e.g. life sciences)	6	5%
Consultant	2	2%
Other total	**19**	**15%**
Union	7	6%
Clinician	4	3%
Academic	3	2%
Think tank	1	1%
International	1	1%
Civil academic/clinician/think tank total	**16**	**13%**
Public (e.g. agency, health authority, government)	5	4%
Private insurance	2	2%
Public entity or private insurance total	**7**	**6%**
Grand Total	**123**	**100%**

- The consultation received a total of 123 submissions. A similar exercise in 2016 resulted in 67 submission and a consultation in 2008 resulted in 43.
- One-third (33%) of the submissions received were from consumer and patient advocacy groups, and another third (33%) came from patentees and their industry associations.
- PMPRB also received almost 900 letters from individuals or patients, the majority of which were Cystic Fibrosis patients and their caregivers as part of an advocacy initiative spearheaded by Cystic Fibrosis Canada.

Next steps in the PMPRB Guideline consultation

June 19 to August 4

NEW
Deadline extension

Release of the revised Guidelines
30-day consultation period commences,
extended by 2 weeks for the submission of written feedback

Engagement sessions

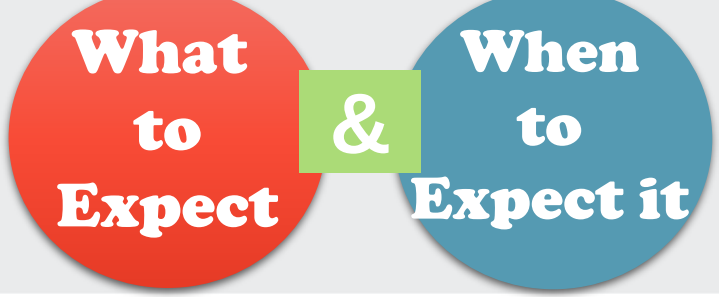
- Industry Webinar
- Public Webinar
- Health Partners Webinar
- Private Plans Webinar

Research Series target topics

1) EDRD's and Market Size
2) R&D, Clinical Trials and Drug Availability
3) Drug Shortages

B. Overview of key Guideline changes

Key Guideline Changes



- List prices of patented medicines
- Rebated price ceilings for high-cost **new** medicines
- Rebated price ceilings for high-sales **new** medicines
- The treatment of biosimilar, generics and tendered medicines
- Covid-19

List prices of patented medicines

What to Expect

Existing medicines

- List prices cannot be higher than the highest price of the new PMPRB basket of countries*, provided that prices are not increased above current levels
- Expect list prices to decline for nearly one-third of patented medicines, accounting for one-fifth of sales

Pros: Less impactful for patentees in terms of revenue loss

Cons: Canada will continue to be one of the highest paying countries for existing medicines

New medicines

List prices cannot be higher than the median price of the new PMPRB basket of countries*, where unavailable, they cannot be higher than the highest price of comparator medicines

Pros: Over time, as new drugs come on the market, Canada will increasingly align with international norms

PMPRB11 comparator countries include France, Germany, Italy, United Kingdom, Sweden, Australia, Belgium, Japan, Netherlands, Norway and Spain.

Source: PMPRB 2018, MIDAS IQVIA

Rebated price ceilings for high-cost/high-sales new medicines

What to Expect

New medicines that are high-cost and/or high-sales will be considered Category I and will be subject to a rebated price ceiling

All patentees are to report price and revenue information that is net of all adjustments including discounts, rebates and free goods and services.

Screening criteria:

- High-cost: above 150% of GDP/capita
- High-sales: above $50M (annual)

Based on recent trends, expect approximately one-quarter of new medicines to be categorized as Category I, accounting for two-thirds of total patented medicine sales

PMPRB11 comparator countries include France, Germany, Italy, United Kingdom, Sweden, Australia, Belgium, Japan, Netherlands, Norway and Spain.

Rebated price ceilings for high-cost new medicines

Pharmacoeconomic (PE) Value and Market Size factors

What to Expect

- **Rebated price ceilings are only applicable to annual sales above $12M – Only list price ceilings will be set for high-cost medicines with lower sales (e.g. drugs for rare diseases or disorders)**
- **For annual sales above $12M, the medicines need to meet more generous Quality Adjusted Life Year (QALY) thresholds depending on therapeutic criteria with built-in floors:**
  - Highest therapeutic benefit (Level I): $200K/ QALY and 20% maximum reduction
  - Levels II, IIII and IV: $150K/ QALY and maximum reductions of 30%, 40% and 50%, respectively
  - In the absence of a cost-utility analysis, a 50% price reduction applies
- **For annual sales above $50M, incremental market size adjustments apply, as follows**
  - 25% reduction for sales below $100M, and
  - 35% reduction for sales above $100M
- **Proposed approach no longer requires special treatment to medicines for rare and non-rare conditions.**

High-cost new medicines: 12-month treatment cost is greater than 150% of GDP per capita.

Pharmacoeconomic Value Thresholds used internationally

HTA is a common and effective tool used by national and regional pricing and reimbursement to inform drug prices

- NICE in the UK has an explicit cost effectiveness threshold of €30,000/QALY. However, in certain cases NICE will allow a higher threshold of £50,000/QALY for end of life treatments and €100,000 to €300,000 for "Highly Specialized Technologies" (HSTs) depending the QALY gain provided by the medicine.
- In other countries such as the Netherlands and Norway, the thresholds depend on the severity of the disease, among other factors.
- In the Netherlands, an informal willingness to pay threshold ranges from €20 000 (low burden) to €80 000 (high burden) per QALY depending on the burden of disease.
- Japan was the first country to adopt a tiered cost-effectiveness assessment scheme that requires a downward price adjustment, the amount of which depends on the drug's cost-effectiveness.

International jurisdictions use additional levers to improve affordability

- **Payback agreements** – turnover tax (France, Belgium, Spain); limits on spending growth (France, UK); pharmaceutical budget limits (Belgium, Italy)
- **Price cuts** – statutory price cuts (Australia, Belgium, Norway), price review (France, Netherlands)
- **Product costs** – (Australia, Belgium, Japan, Spain)

Canada is an outlier in how it deals with high cost medicines

By having the PMPRB consider value and affordability, this 'made in Canada' approach brings us in line with international best practices.

PMPRB Draft Guidelines 2020

Price adjustment		
Therapeutic Criteria Level	PVT	Reduction Floor off MLP
Level I	$200K/ QALY	20%
Level II	$150K/ QALY	30%
Level III	$150K/ QALY	40%
Level IV	$150K/ QALY	50%

Rebated price ceilings for high-sales new medicines

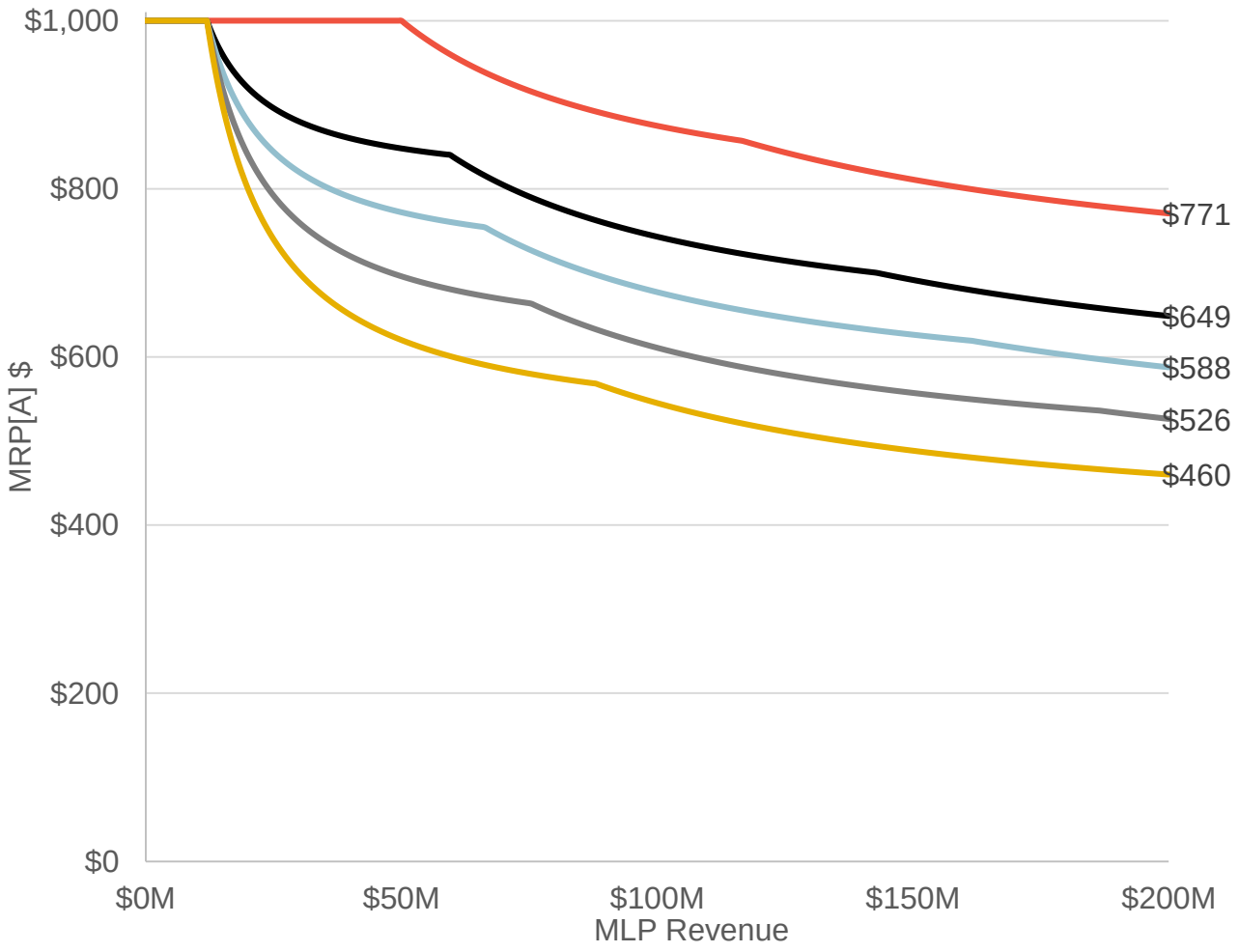
Market Size factor

What to Expect

- **For lower-cost medicines (treatment cost below 150% GDP/capita), rebated price ceilings are only applicable to annual sales above $50M**
- **For annual sales above $50M, the following incremental market size adjustments apply, provided that the medicine is priced in line with the median price levels of it therapeutic comparators.**
  - 25% reduction for sales below $100M, and
  - 35% reduction for sales above $100M

The rebated price ceiling for a medicine that costs $1,000 per unit

Example



Revenue		Up to $12M	$50M	$100M	$200M	$500M
Low-cost medicine		$1,000	$1,000	$875	$771	$698
High-cost medicine	Cost effective (0%)					
	Level I (20%)	$1,000	$848	$743	$649	$571
	Level II (30%)	$1,000	$772	$677	$588	$508
	Level III (40%)	$1,000	$696	$611	$526	$445
	Level IV (50%)	$1,000	$620	$545	$460	$381

The example assumes that neither the domestic therapeutic class comparison, nor a higher pharmacoeconomic price other than the pharmacoeconomic threshold apply.

Flexibility built into enforcement

When to Expect

Existing medicines

- Expect list prices to reduced to the highest price of the new PMPRB basket of countries* by January 2022

New medicines

- Expect list prices to be aligned with the median price of the new PMPRB basket of countries* at introduction
- For high-cost medicines, expect payers to pay lower rebated prices within a year from when sales reach threshold levels

PMPRB11 comparator countries include France, Germany, Italy, United Kingdom, Sweden, Australia, Belgium, Japan, Netherlands, Norway and Spain.

The treatment of biosimilar, generics and tendered medicines

- **Biosimilars and generics without an Abbreviated New Drug Submission (ANDS)**
  - New patented Biosimilars and New patented Generic medicines will be considered Category II and investigated only if there is a complaint

- **Tendered medicines (vaccines, blood products)**
  - In the case of an investigation, “Staff may consider whether the actual market size is materially lower than the estimated market size, or whether the patented medicine is a vaccine, blood product or other product subject to a tendering process”

Covid-19

Investigation of Covid-19 Patented Medicines

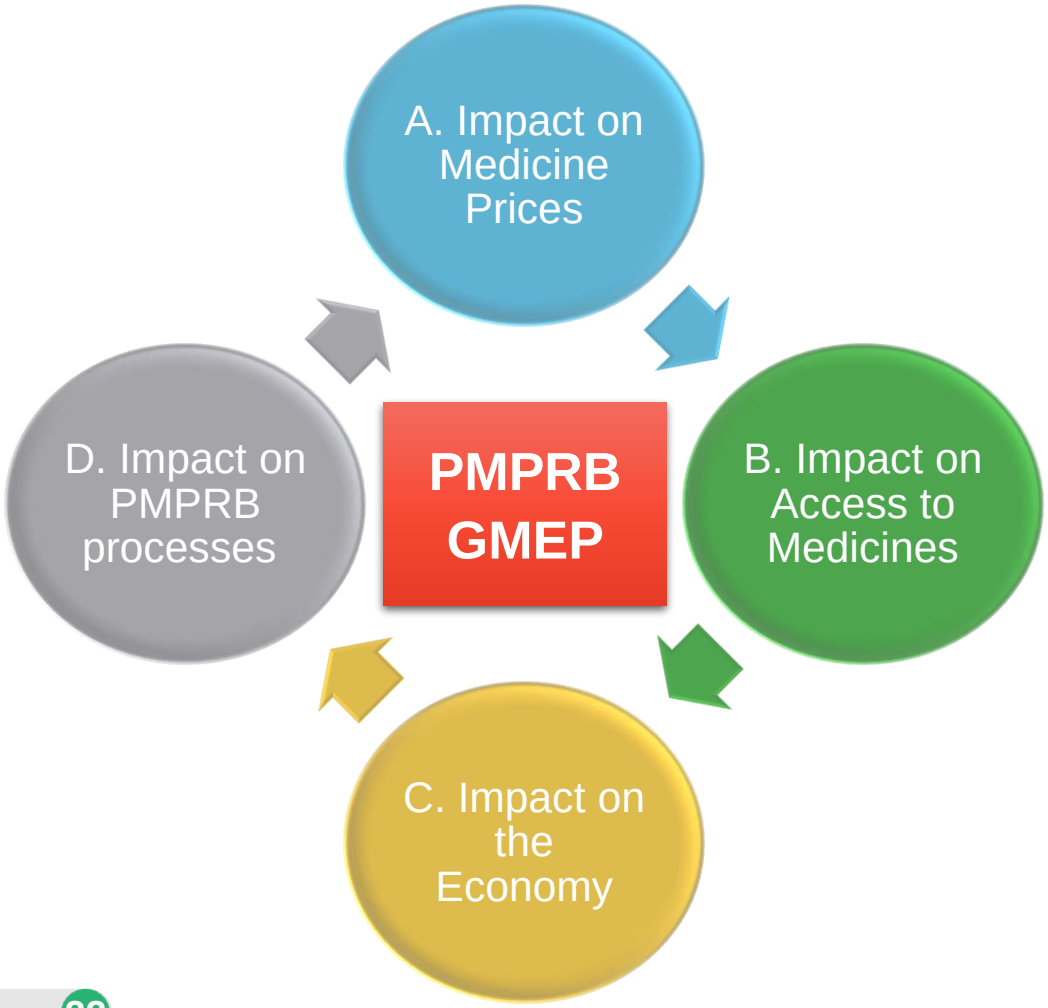
- patented medicine which appears on the *List of Drugs for Exceptional Importation and Sale* set out in accordance with s. 3 of the March 30, 2020 *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19* will not be subject to an investigation unless a complaint is received from either the federal Minister of Health or any of her provincial or territorial counterparts

Ability to Increase Price

Patentees have raised concern about entering into contracts or offering drugs at cost at introduction and not being able to increase their price afterwards due to the PMPRB.

- Rebates and discounts will not set list price ceilings
- Patentees will be able to increase their list price if Canadian prices become out of step with international levels over time
- Reassessment a key feature of new guidelines based on new indication, change in market size or update to HTA. A new indication may alter the patented medicine's market size, therapeutic class comparators, and cost-effectiveness. As a result, there may be an increase or decrease in the MRP

Guideline Monitoring and Evaluation Plan (GMEP)



- The PMPRB is committed to the development and execution of an extensive GMEP to assess their impact and inform any future enhancements.
- The new GMEP is the most comprehensive to date, aiming for an in-depth assessment of four key impact areas (shown in the graphic).
- Discussions with interested stakeholders, expected to shape the GMEP development.
- Both qualitative and quantitative indicators will be employed, and various administrative, commercial, international, domestic and internal data sources will be consulted.
- Trends prior and post framework implementation will be compared and reported regularly (i.e. baseline results versus post implementation).
- Some impacts are expected to be immediate, while others may take longer to materialize. Also, some impacts may be directly attributable to the PMPRB, while other may also be impacted by factors outside the PMPRB purview.

C. Case Study:

Hypothetical high-cost medicine

Hypothetical high-cost medicine

Case Study
High-cost medicine

- **The medicine could be treating a rare disease, oncology, etc.**
- **Two indications:**
  - Indication A with a prevalence of 2,000 Canadian patients, maximum annual treatment cost of $365,000
  - Indication B with a prevalence of 1,000 Canadian patients, maximum annual treatment cost of $250,000
- **Both indications meet the first criterion for Category I;**
- **Indication A is the relevant indication as it has the highest prevalence**
- **Market size gradually increases to reach its full potential of 1,000 patients at Year 6 (one-third of total Canadian potential population)**
- **Multiple scenarios are explored:**
  - Scenario 1: A cost-utility analysis is available from a publicly funded HTA agency
  - Scenario 2: A cost-minimization analysis is available from a publicly funded HTA agency
  - Scenario 3: No cost-utility analysis is available from a publicly funded HTA-agency

Scenario 1: Cost-utility analysis available

Case Study
High-cost medicine

- **Cost-utility analysis available from a publicly funded HTA agency for the relevant indication A**
  - The HTA agency re-analysis -> ICUR of $600,000 per QALY
  - The PMPRB's scientific review identified the medicine as Level II.
  - The pharmacoeconomic value threshold (PVT) for Level II is $150,000 per QALY gained
  - The PEP calculated based on the allowable Level II PVT would require a reduction of 75%
  - The reduction floor for Level II of 30% off the MLP applies

Price adjustment		
Therapeutic Criteria Level	PVT	Reduction Floor off MLP
Level I	$200K/ QALY	20%
Level II	$150K/ QALY	30%
Level III	$150K/ QALY	40%
Level IV	$150K/ QALY	50%
Pharmacoeconomic analysis is a cost minimization	Median of dTCC subject to 50% floor	
No pharmacoeconomic assessment	50% off MLP	

Scenario 1: Cost-utility analysis available

Case Study
High-cost medicine

Category I

- Annual Treatment cost: $365,000 > 150% GDP per capita
- Highest market size reached in year 6: 1,000 patients

Cost utility available, and PMPRB Level II (30% floor off MLP)

MLP: $1,000
MIP=$1,000
The MLP is set at the MIP

MRP[A]: $528
- Pharmacoeconomic Price
- Market size adjustment

Annual Revenues (units*price)	Incremental MLP adjustment factor	MRP	Scenario 1	
		Description	High Cost + CUA	
<$12M	0%	MLP	MLP	$1,000
$12M-$50M		Greater of PEP and Floor	Floor	$700
$50M-$100M	-25%		0.75 * Floor	$525
>$100M	-35%		0.65 * Floor	$455

	Intro Year	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Revenue at MLP	$2M	$6M	$12M	$30M	$50M	$100M	$365M
MRP/MRP[A]	**$1,000**			**$820**	**$772**	**$677**	**$528**
Revenues at MRP/ MRP[A]	$2M	$6M	$12M	$25M	$39M	$68M	$193M
	First $12M sold at MLP of $1,000			PEP / Floor applies after $12M (30% reduction, $700)		PEP/Floor and Market Size adjustment applies after $50M	

Scenario 2: Cost-minimization analysis

Case Study
High-cost medicine

- Upon review of the manufacturer submission for the relevant indication A, the HTA found no improvement over comparators (cost-minimization analysis).
- The PMPRB's scientific review completed the dTCC, and found that a 40% price reduction off the MLP is required to the meet the requirement for the median cost of treatment across the comparator medicines. The 50% floor is not reached.
- The dTCC price is subject to further market size adjustments

Price adjustment		
Therapeutic Criteria Level	PVT	Reduction Floor off MLP
Level I	$200K/ QALY	20%
Level II	$150K/ QALY	30%
Level III	$150K/ QALY	40%
Level IV	$150K/ QALY	50%
Pharmacoeconomic analysis is a cost minimization	Median of dTCC subject to 50% floor	
No pharmacoeconomic assessment	50% of MLP	

Scenario 2: Cost-minimization analysis available

Case Study
High-cost medicine

Category I

Annual Treatment cost: $365,000 > 150% GDP per capita
Highest market size reached in year 6 : 1,000 patients
Cost minimization (Median of dTCC subject to 50% floor)

MLP: $1,000
MIP=$1,000
MLP is set at the MIP

MRP[A]: $465
- Pharmacoeconomic Price
- Market size adjustment

dTCC (median): $600

Annual Revenues (units*price)	Incremental MLP adjustment factor	MRP		
		Description	Scenario High Cost + CMA	
<$12M	0%	MLP	MLP	$1,000
$12M-$50M		Median of dTCC subject to 50% floor	dTCC (median)	$600
$50M-$100M	-25%		0.75 * dTCC median	$450
>$100M	-35%		0.65 * dTCC median	$390

	Intro Year	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Revenue MLP	$2M	$6M	$12M	$30M	$50M	$100M	$365M
MRP/MRP[A]	**$1,000**			**$760**	**$696**	**$611**	**$465**
Revenues at MRP/MRP[A]	$2M	$6M	$12M	$23M	$35M	$61M	$170M
	First $12M sold at MLP of $1,000			dTCC / Floor applies after $12M (40% reduction, $600)		PEP/Floor and Market Size adjustment applies after $50M	

Scenario 3: No cost-utility analysis available

Case Study
High-cost medicine

- No cost utility analysis available from any of the publicly funded organizations for the relevant indication A
- The price reduction is 50% off the MLP, subject to further market size adjustment

Price adjustment		
Therapeutic Criteria Level	PVT	Reduction Floor off MLP
Level I	$200K/ QALY	20%
Level II	$150K/ QALY	30%
Level III	$150K/ QALY	40%
Level IV	$150K/ QALY	50%
Pharmacoeconomic analysis is a cost minimization	Median of dTCC subject to 50% floor	
No pharmacoeconomic assessment	50% of MLP	

Scenario 3: No cost-utility analysis available

Case Study
High-cost medicine

Category I

Annual treatment cost: $365,000 > 150% GDP per capita
Highest market size reached in year 6: 1000 patients
No pharmacoeconomic assessment (50% off MLP)

MLP: $1,000
MIP=$1,000
MLP is set at the MIP

MRP[A]: $402
- Pharmacoeconomic Price
- Market size adjustment

Annual Revenues (units*price)	Incremental MLP adjustment factor	MRP	Scenario 1	
		Description	High Cost + CMA	
<$12M	0%	MLP	MLP	$1,000
$12-50M		50% of MLP	0.5 * MLP	$500
$50M-$100M	-25%		0.375 * MLP	$375
>$100M	-35%		0.325 * MLP	$325

	Intro Year	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Revenue at List price (MLP)	$2M	$6M	$12M	$30M	$50M	$100M	$365M
MRP/MRP[A]	**$1000**			**$700**	**$620**	**$545**	**$402**
Revenues at MRP/MRP[A]	$2M	$6M	$12M	$21M	$31M	$54.5M	$147M
	First $12M sold at MLP of $1,000			50% reduction applies after $12M		50% reduction and Market Size adjustment applies after $100M	


Frequently
Asked
Questions

Frequently Asked Questions

Will most drugs have a rebated price ceiling?

Why are the prices of patented drugs a concern?

Why are drugs treating small populations a concern?

Why are stricter price controls needed when payers already negotiate lower prices?

Will lower prices result in fewer **drug launches** in Canada?

Will lower prices result in lower **R&D investments** in Canada?

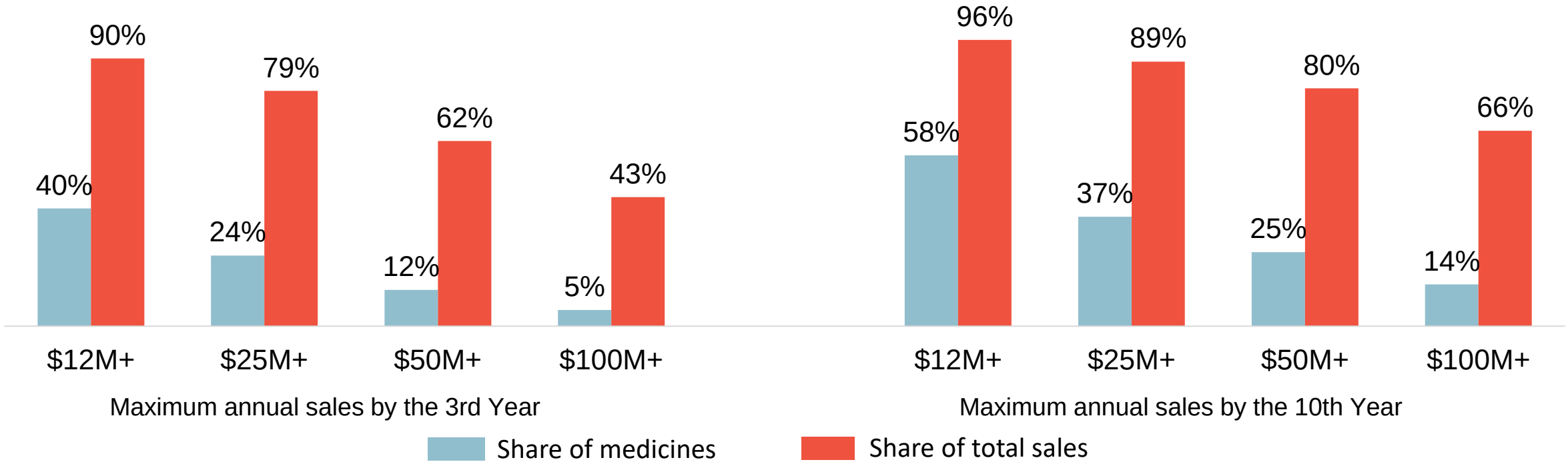
Will lower prices result in fewer **clinical trials** in Canada?

Will PMPRB reforms prevent patients from accessing Cystic Fibrosis (CF) drugs?

Will most drugs have a rebated price ceiling?

¼ of new drugs are expected to have a rebated price ceiling

Patented medicines in Canada, share of medicines and share of sales, by annual sales thresholds, by the 3rd and 10th year after introduction*



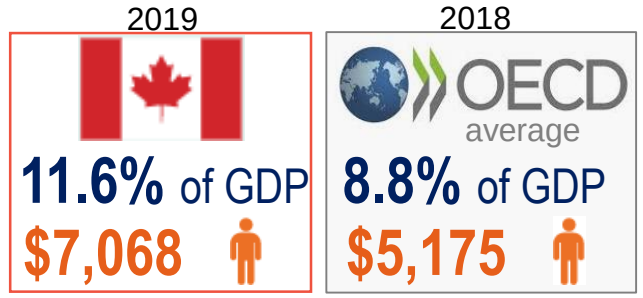
*Included patented medicines launched after 1998 in Canada; Sample Size: N=639 by the 3rd year: ; N=338 by the 10th year

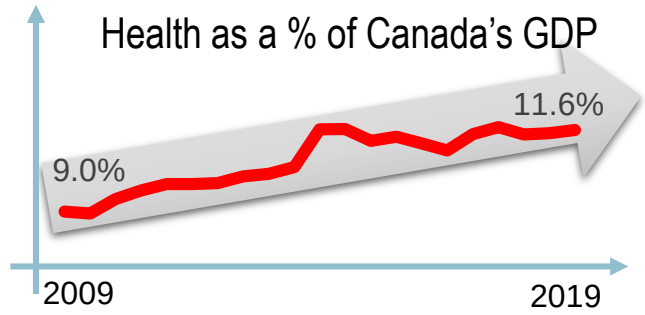
Data source: PMPRB, 2018; CPI applied to bring historical sales into 2018 value

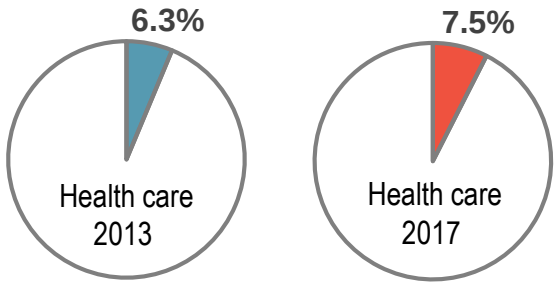
Why are prices of patented drugs a concern when they only represent a small portion of healthcare spending?

Patented drugs are capturing an increasing share of health care spending,
which in turn is capturing a greater share of the GDP and reaching levels above OECD norms

- **Canada is among the highest spenders on health care in the Organisation for Economic Co-operation and Development (OECD), estimated at $7,068 per person in 2019, or 11.6% of GDP, well above OECD norms.***
- **Total health expenditure captures an increasing share of Canada's GDP, from about 9% 20 years ago to 12% in 2019**
  - CIHI reports shifting shares of health spending over time, with spending on drugs increasing over the last 20 years, and are now accounting for the second-largest share of health spending, or 15.3% after Hospitals
- **Canada is the 2nd highest spender on patented drugs in the OECD, only after the US**
  - Patented drugs account for an increasing share of health care spending: 7.5% in 2017, up from 6.3% in 2013



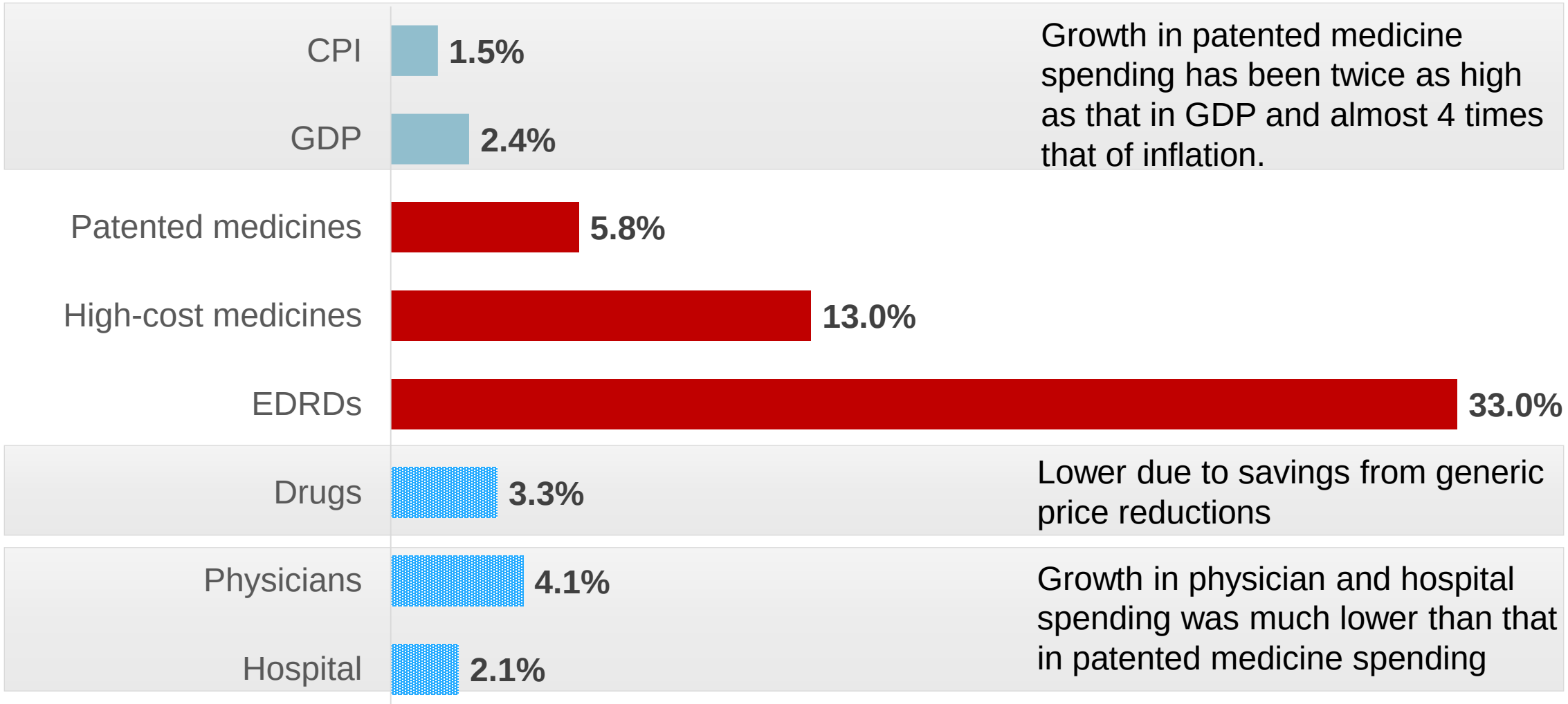




Sources: CIHI, National Health Expenditure Trends, 1975 to 2019, PMPRB; Statistics Canada; OECD

Why are prices of patented drugs a concern when they only represent a small portion of healthcare spending?

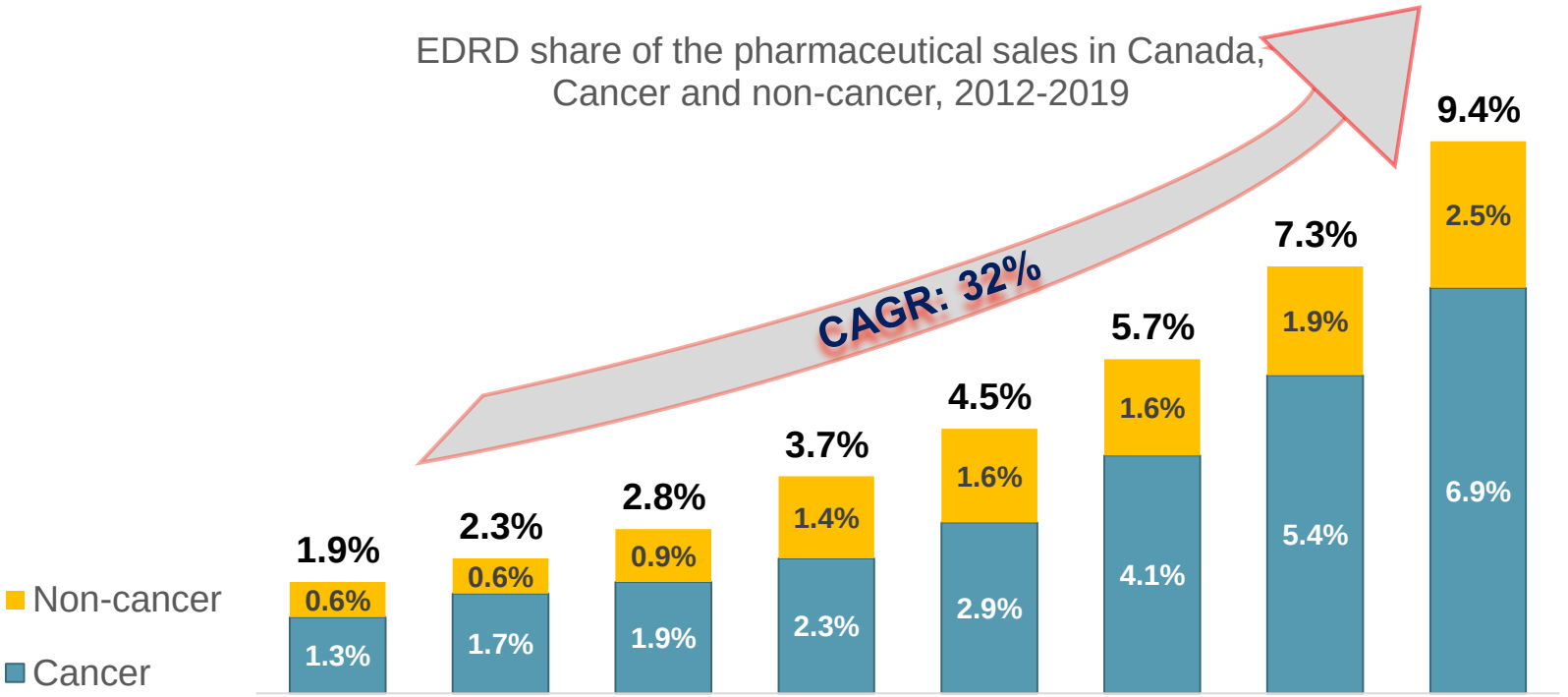
Spending on patented drugs is outpacing other healthcare categories and economic growth, 2013-2017



Why are drugs treating small populations a concern?

Expensive drugs for rare diseases now account for a sizable and growing share of drug sales

EDRD share of the pharmaceutical sales in Canada, Cancer and non-cancer, 2012-2019

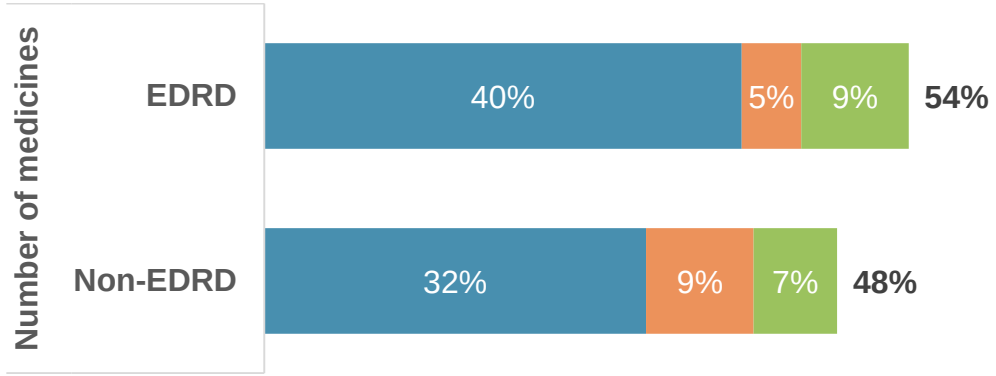


	2012	2013	2014	2015	2016	2017	2018	2019
Cumulative number of EDRDs approved	26	31	37	48	62	71	82	**93**
Sales per capita	$11	$13	$16	$23	$29	$38	$50	**$68**

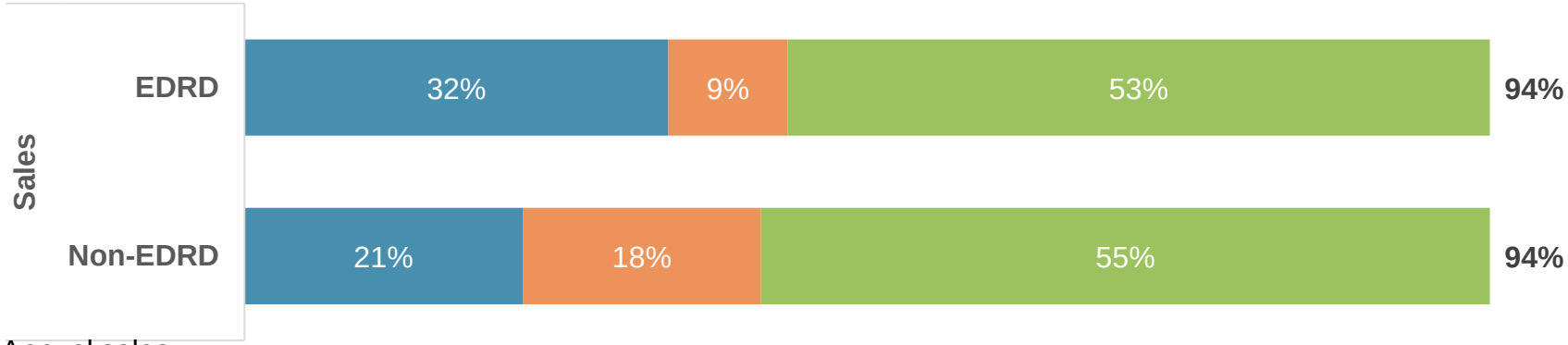
Notes: ** For this analysis, EDRDs are medicines with >=1 orphan designation (FDA or EMA), and est. treatment costs > $100K/yr (non-oncology) and $7,500 per 28 days (oncology). Data source(s): PMPRB, IQVIA MIDAS® Database, 2012 to 2019 (all rights reserved), IQVIA Private Pay Direct Drug Plan Databases.

EDRDs may generate higher sales than lower-cost, high-volume drugs

EDRD and non-EDRD distribution of medicines and of sales,
by the highest annual sales in the first three years after launch in Canada



	EDRD	Non-EDRD
Average Sales	$28M	$34M
Median Sales	$10.1M	$9.7M



Annual sales:
$10M-$50M $50M-$100M $100M+

Medicines for orphan diseases, despite smaller patient populations, have the commercial potential to generate revenue for the originator companies at least as great as for non-orphan medicines

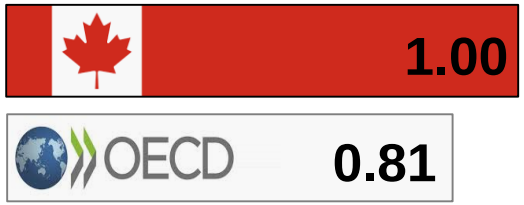
Note: Includes medicines launched in Canada since 2005; EDRDs had at least 2 years of sales.
Sample size: EDRDs; *N* = 43; Non-EDRDs; *N* = 255.
Data source: IQVIA MIDAS® Database (all rights reserved); PMPRB, US Food and Drug Administration, European Medicines Agency, and Health Canada databases.

Why are stricter price controls needed when payers already negotiate lower prices?

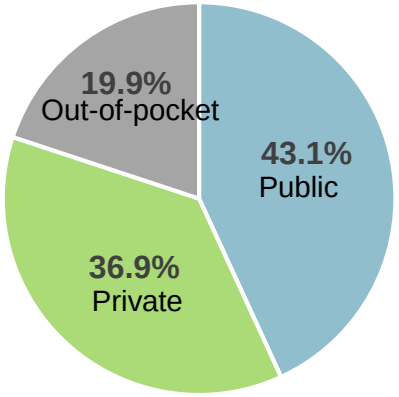
A sizable share of the Canadian market does not negotiate prices, and payers that do find them unfair, excessive and not cost-effective

- **Canadians pay the third highest patented drug prices among the OECD countries, about 20% more than the OECD median**
- **Confidential rebates are offered to Canadian public payers who jointly negotiate the reimbursed prices through the pan-Canadian Pharmaceutical Alliance. However, this has now been an international practice for many years and other countries are also paying lower negotiated prices**
- **Given that list prices are now the starting point for price negotiations, Canada is at a disadvantage, as its starting point is nearly 20% higher than the OECD norm.**
- **Canada is the only developed country with a universal public healthcare system that does not include universal coverage of prescription drugs.**
  - This means that pCPA negotiated prices which are available to public payers would cover less than half (43%) of the Canadian spending on drugs, with the majority of the spending being covered by private and out-of-pocket payers.
  - These payers either do not negotiating to the same extent, or not negotiating at all.
- **As a result, greater regulatory scrutiny is required to ensure that consumers and payers do not pay excessive prices**

Average patented medicine prices



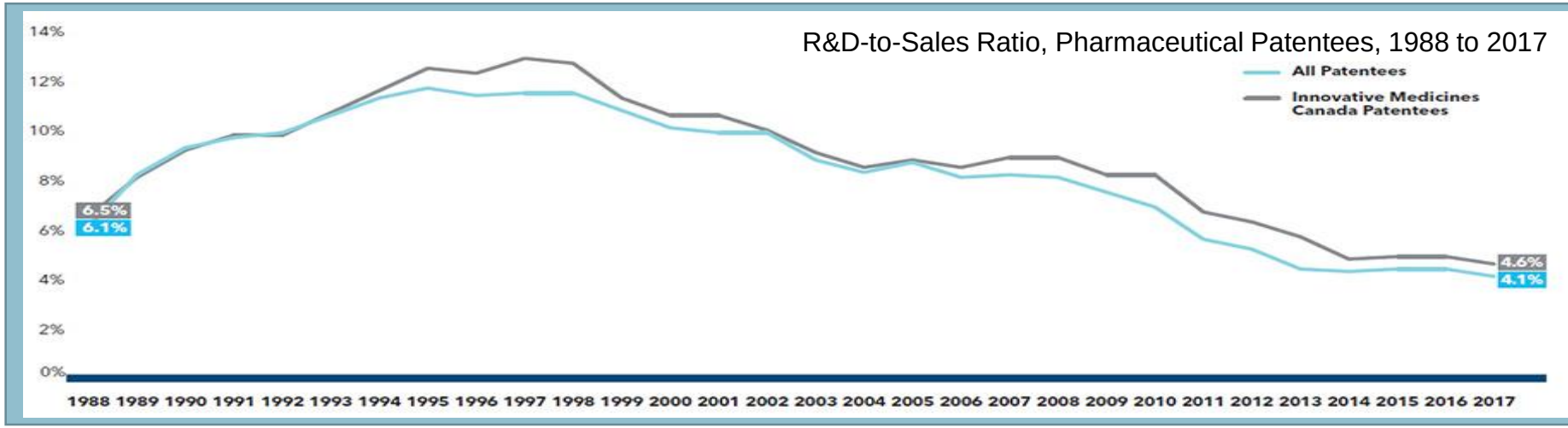
pCPA *"remains very concerned that prices achieved through negotiation remain largely unfair, excessive and not cost-effective."*



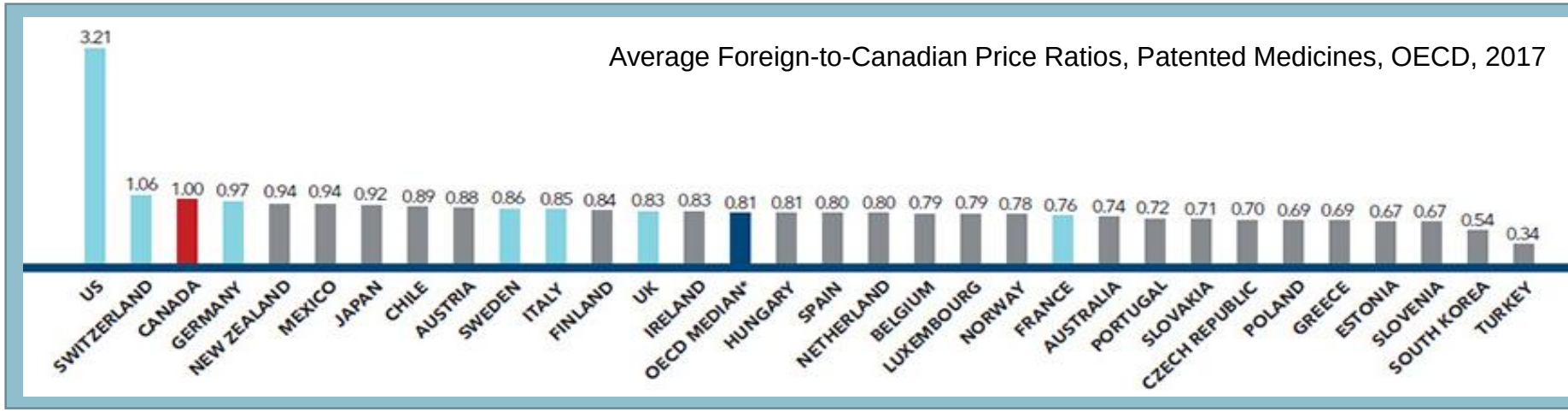
Source: CIHI, Prescribed Drug Spending in Canada, 2019, House of Commons' Standing Committee on Health

Will lower prices result in lower R&D investments in Canada?

R&D spending has declined in Canada, despite Canadian paying some of the highest prices in the OECD



R&D are at a 30-year low: **4.1%**



Canadian prices are **3rd** highest

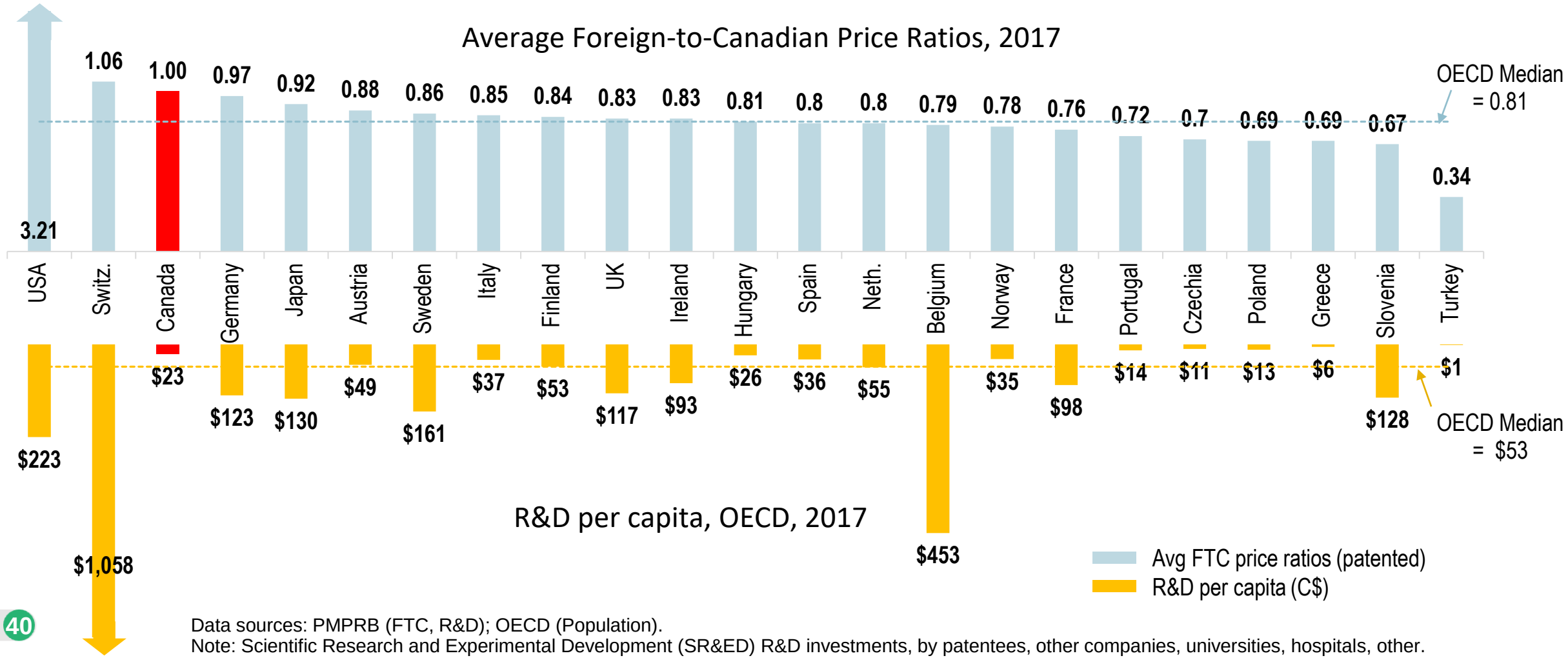
Figure source: PMPRB Annual Report, 2017

Data source: PMPRB, MIDAS™ database, 2017, IQVIA. All rights reserved.

Note: Scientific Research and Experimental Development (SR&ED) R&D investments.

Will lower prices result in lower R&D investments in Canada?

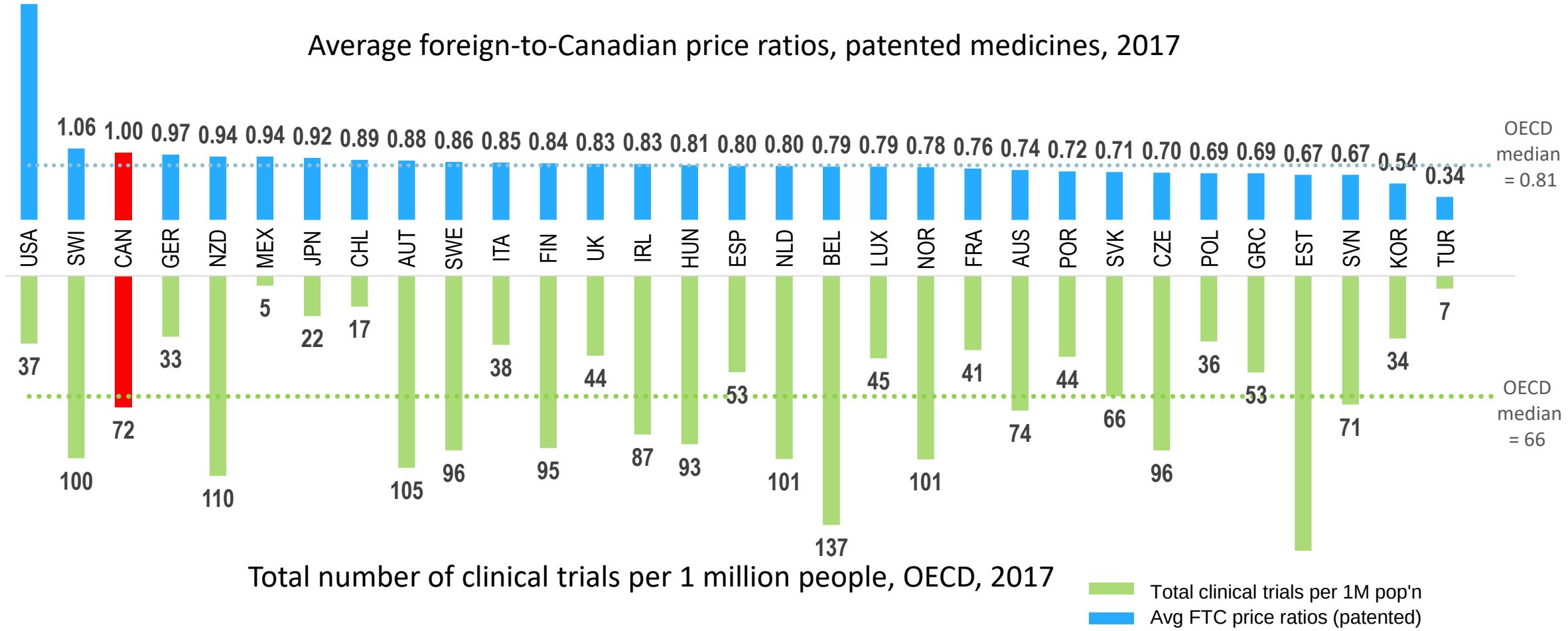
Many countries with lower patented drug prices than Canada have higher per capita R&D investments



Data sources: PMPRB (FTC, R&D); OECD (Population).
Note: Scientific Research and Experimental Development (SR&ED) R&D investments, by patentees, other companies, universities, hospitals, other.

Will lower prices result in fewer clinical trials in Canada?

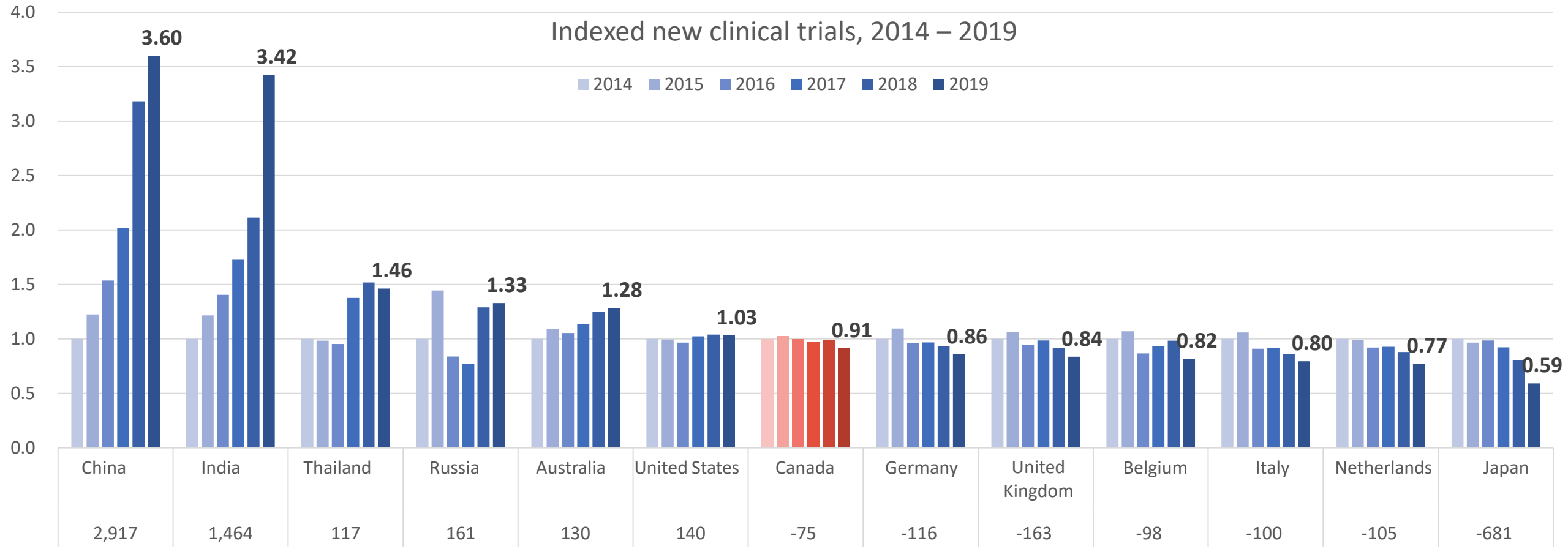
Many countries with lower patented drug prices than Canada have more clinical trials per 1 million people



Data sources: PMPRB Annual Report, 2017; GlobalData®; OECD (population).

The globalization of clinical trials

The number of new clinical trials are on decline in Canada and other developed markets as emerging markets experience substantial growth



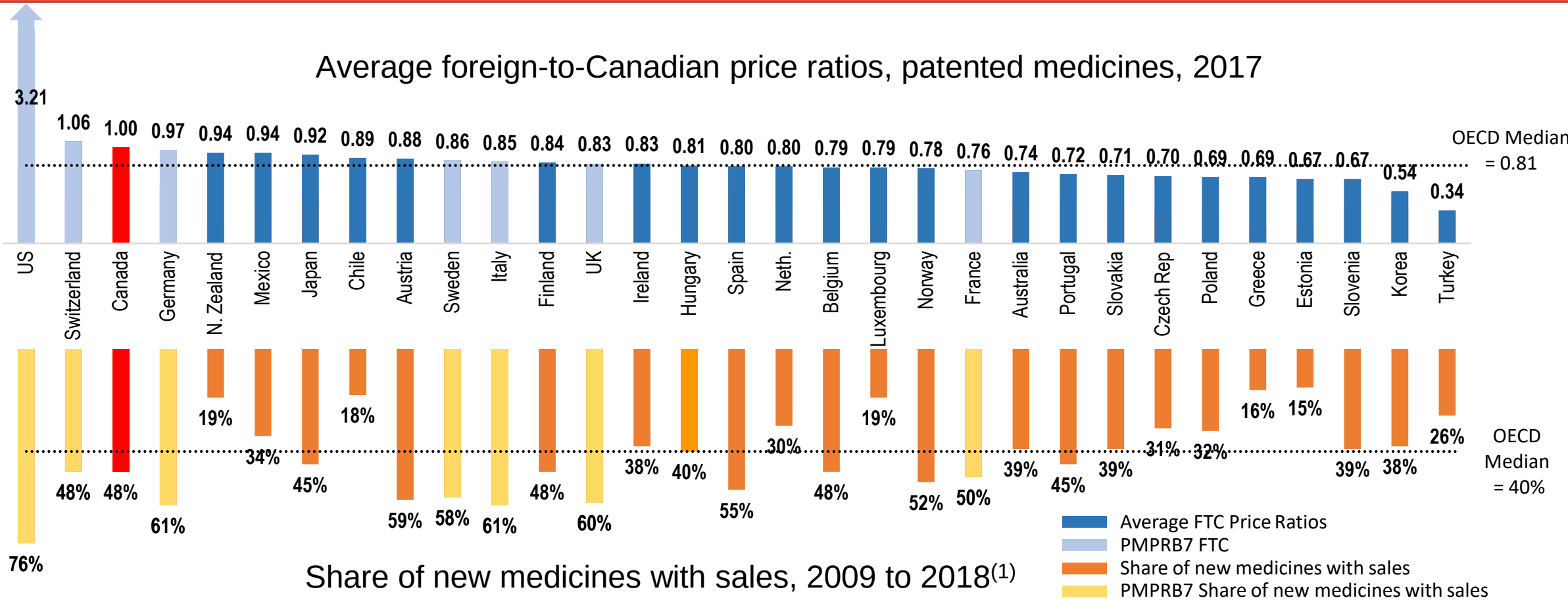
6 countries with the largest increases in new clinical trials

6 countries with the largest decreases in new clinical trials

Data sources: GlobalData®, country ranks determined by the difference between 2019 and the 2014 – 2018 median.

Will lower prices result in fewer drug launches in Canada?

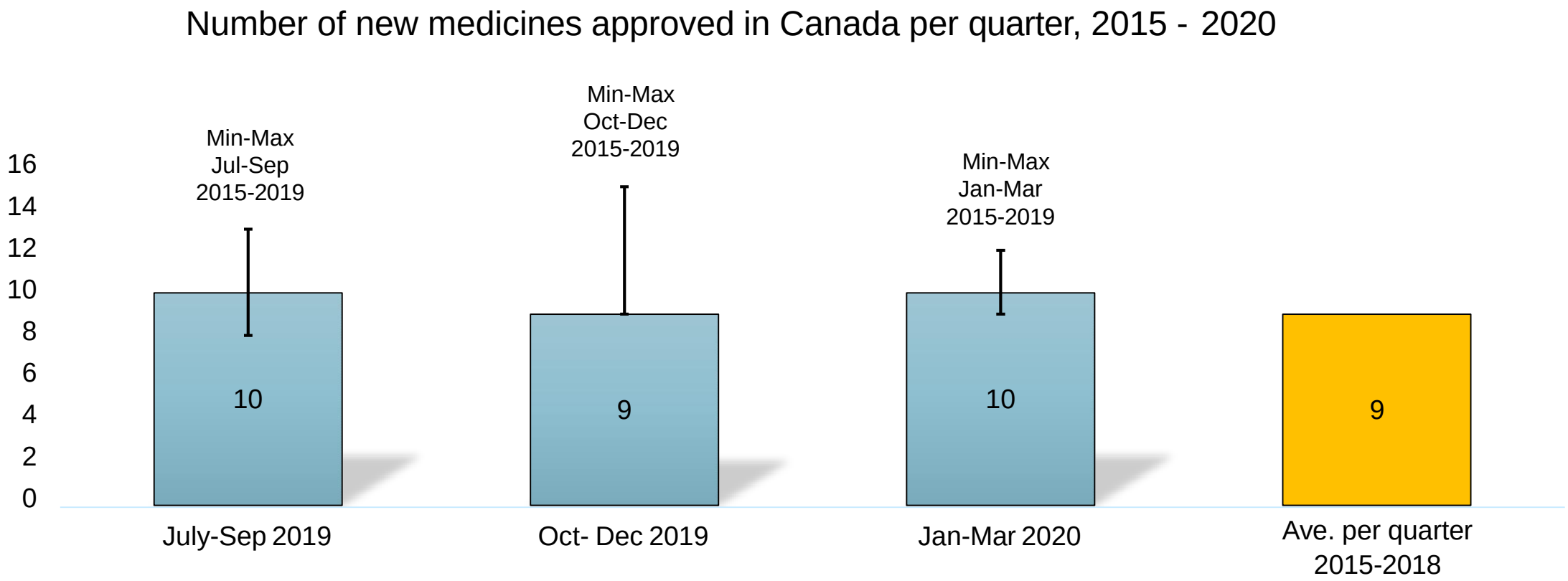
Countries with lower patented drug prices than Canada may have greater availability of new medicines



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.

Will lower prices result in fewer drug launches in Canada?

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

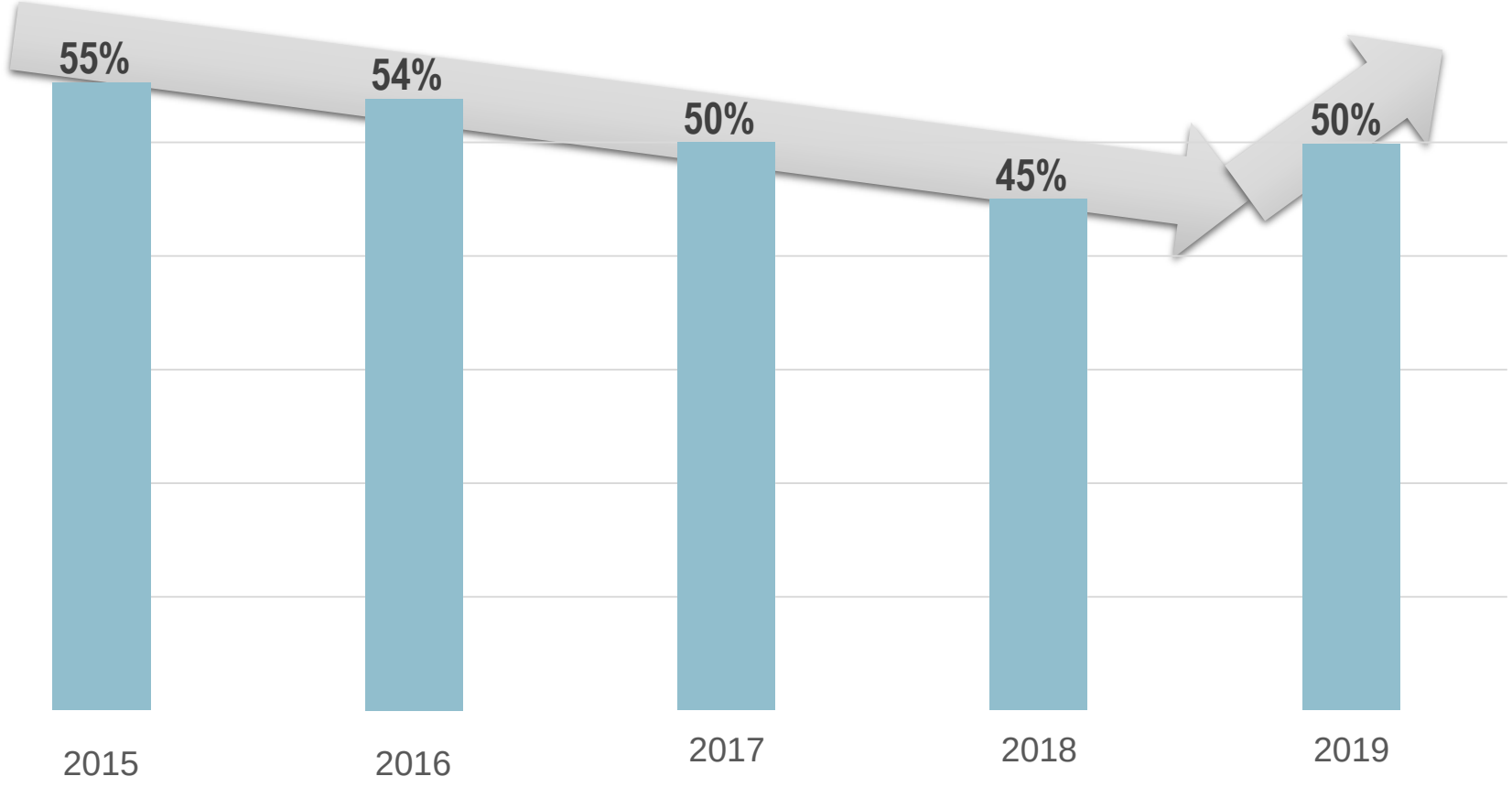


Data source: Health Canada Drug Product Database

Will lower prices result in fewer drug launches in Canada?

The share of new drugs approved in Canada within one year of the US was higher in 2019 than in 2018

Share of new medicines approved by Health Canada within one year of FDA approval



Data sources: FDA and Health Canada Drug Product Database

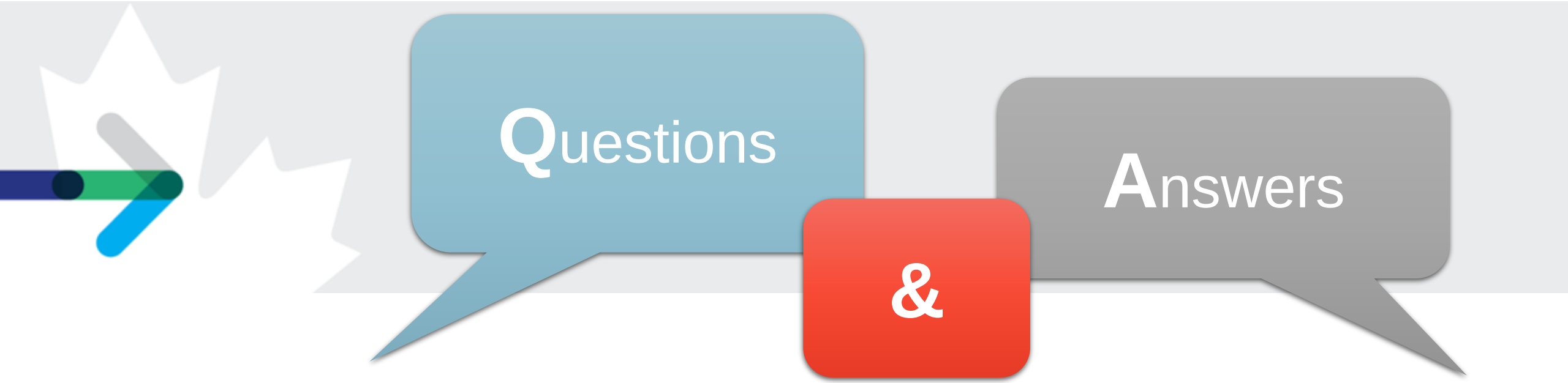
Will PMPRB reforms prevent patients from accessing Cystic Fibrosis (CF) drugs?

- **Patients had limited access to the three CF drugs available in Canada even prior to the PMPRB reforms, under the more relaxed PMPRB regime, as these medicines received limited or no funding in private and public plans given the affordability concerns**
  - Canada pays 3rd highest prices in OECD for Orkambi, while for Kalydeco, the Canadian prices are in line with OECD median
- **CF advocates oppose the PMPRB reforms, which, in their view, deter the launch in Canada of the latest CF drug, Trikafta.**
- **The CF medicines cost more than $250K per patient per year, and with more than 4,300 Canadians suffering from CF, these drugs have the potential to achieve sales comparable to blockbuster medicines despite treating a fraction of the population**
- **Under the PMPRB proposed Guidelines, Trikafta could still become a top selling drug in Canada.**

	Treatment population	Treatment cost	Potential sales	Share of patented sales
Kalydeko	1,758	$307K*	$539M	3.2%
Orkambi	3,724	$249K*	$927M	5.5%
Symdeko	3,028	$270K**	$819M**	4.9%
Trikafta	3,028	$337K***	$1,020M***	6.1%

Top selling drugs between 2006 and 2019	
	Max Sales (IQVIA MIDAS)
Lipitor	$1.19B
Remicade	$1.12B
Humira	$0.85B
Crestor	$0.71B
Epclusa	$0.65B
Harvoni	$0.62B
Eylea	$0.55B

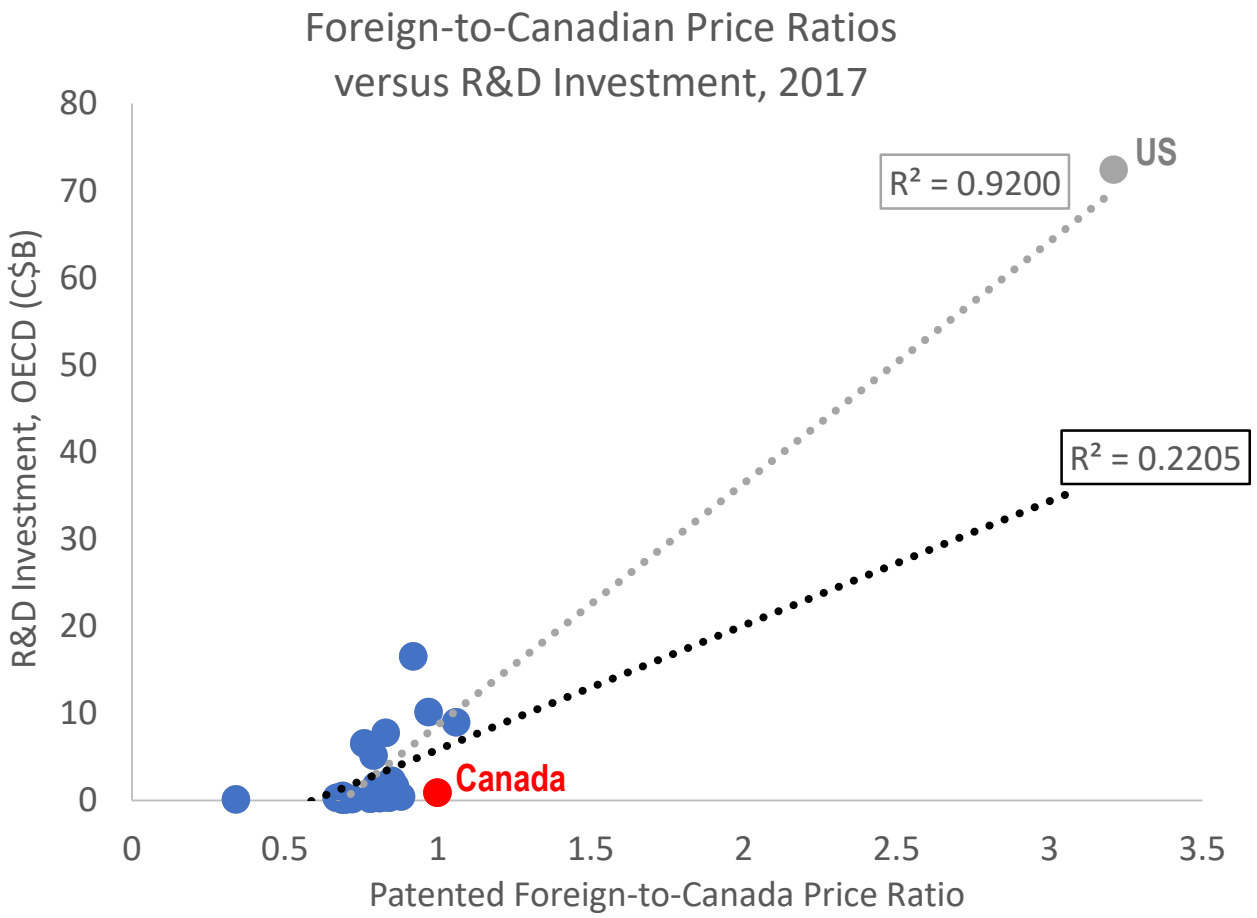
* CADTH **HIP PMPRB11 ***Canadian price based on the US price (Data source: IQVIA MIDAS)

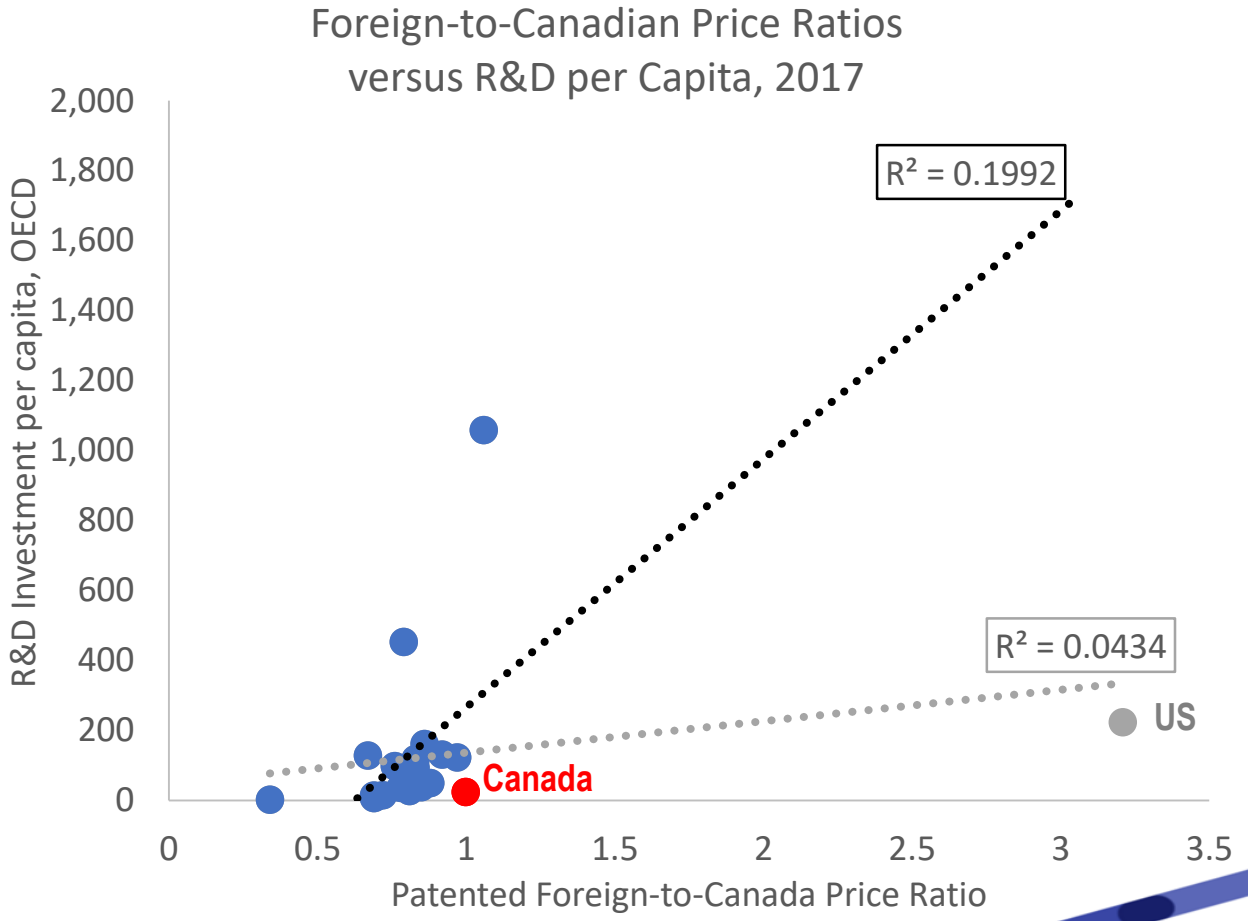

Questions
&
Answers

THANK YOU

Annex

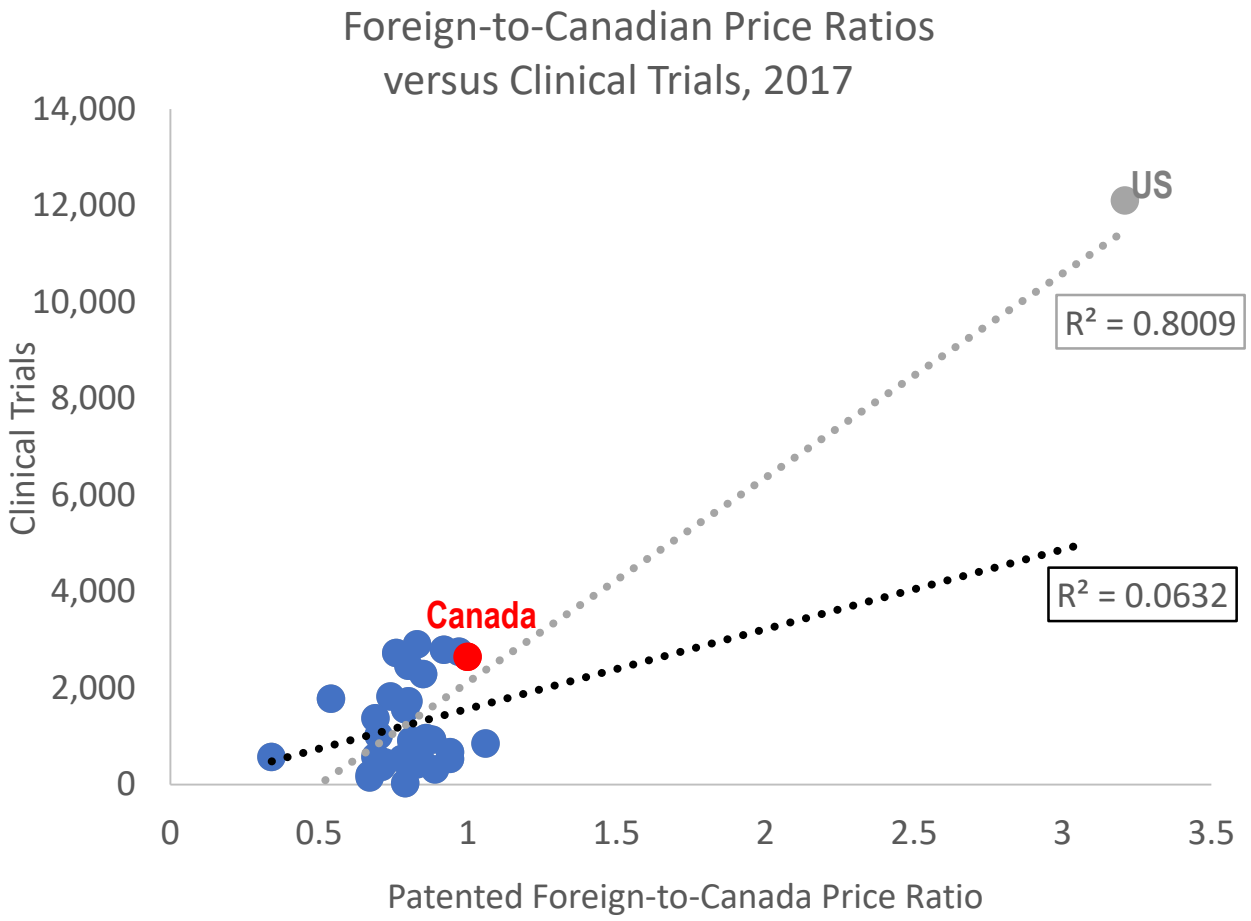
2 Higher prices do not result in greater R&D investments

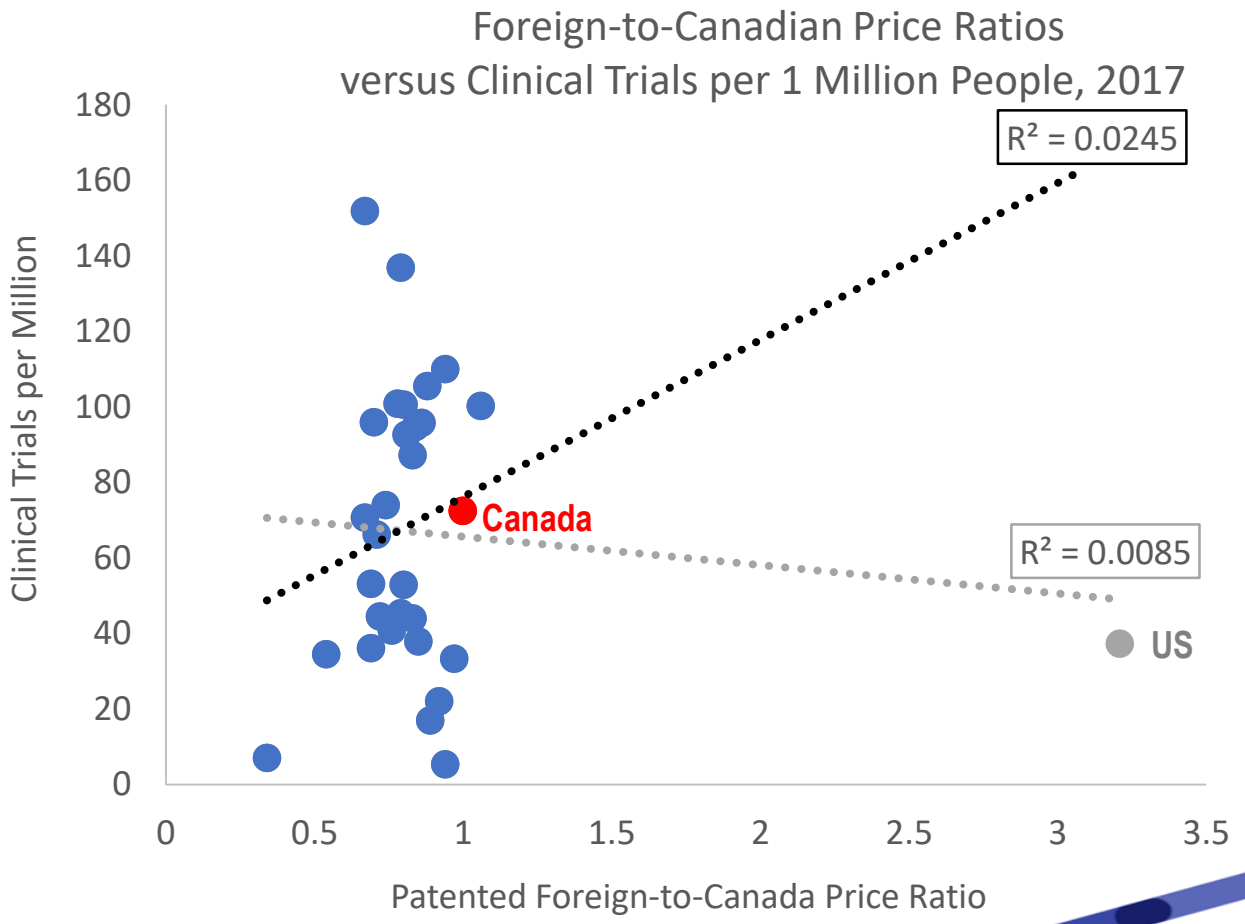




Data sources: PMPRB Annual Report, 2017 (FTC, R&D); OECD (population).
Notes: Scientific Research and Experimental Development (SR&ED) R&D investments. R^2 is the percentage of the response variable variation that is explained by a linear model. As a significant outlier the United States has a disproportionate effect on the R^2

3 Higher prices do not result in more clinical trials





Data sources: PMPRB Annual Report, 2017; GlobalData®; OECD (population).
Notes: R^2 is the percentage of the response variable variation that is explained by a linear model. As a significant outlier the United States has a disproportionate effect on the R^2

6 List of new medicines approved by Health Canada per quarter 2019-2020

Jul-Sep 19		
	Trade Name	NOC date
1	Netspot	03-Jul-19
2	Esperoct	04-Jul-19
3	Vitrakvi	10-Jul-19
4	Dacogen	11-Jul-19
5	Nerlynx	16-Jul-19
6	Lokelma	25-Jul-19
7	Emgality	30-Jul-19
8	Ultomiris	28-Aug-19
9	Calquence	23-Aug-19
10	Talzenna	06-Sep-19

Oct-Dec 19		
	Trade Name	NOC date
1	Trulance	10-Oct-19
2	Balversa	25-Oct-19
3	Intrarosa	01-Nov-19
4	Galli Eo	13-Nov-19
5	Aklief	25-Nov-19
6	Mylotarg	28-Nov-19
7	Xospata	23-Dec-19
8	Rinvoq	23-Dec-19
9	Vascepa	30-Dec-19

Jan-Mar 20		
	Trade Name	NOC date
1	Vyndaqel	20-Jan-20
2	Rozlytrek	10-Feb-20
3	Cablivi	28-Feb-20
4	Nubeqa	20-Feb-20
5	Xofluza	19-Feb-20
6	Mayzent	20-Feb-20
7	Beovu	12-Mar-20
8	Piqray	11-Mar-20
9	Cabenuva	18-Mar-20
10	Vocabria	18-Mar-20

Note: List contains all trade names approved by Health Canada in 2019- 2020 (1st quarter) under the submission of a NAS (New Active Substance) and Priority- NAS.
Data sources: Health Canada Drug Product Database

6 List of new medicines approved by Health Canada in 2019

Trade Name (medicinal ingredient)	NOC Date	FDA Approval Date	Lag in years
Lutathera (lutetium (177lu) oxodotreotide)	2019-01-09	2018-01-26	1.0
Onstryv (safinamide)	2019-01-10	2017-03-21	1.8
Symdeko (ivacaftor, tezacaftor)	2019-06-27	2018-02-12	1.4
Vonvendi (von willebrand factor (recombinant), vonicog alfa)	2019-01-10	2015-12-08	3.1
Rinvoq (upadacitinib)	2019-12-23	2019-08-16	0.4
Mylotarg (gemtuzumab ozogamicin)	2019-11-28	2017-09-01	2.2
Aklief (trifarotene)	2019-11-25	2019-10-04	0.1
Gallieo (gallium (68ga) chloride)	2019-11-13	2019-08-21	0.2
Intrarosa (prasterone)	2019-11-06	2016-11-16	3.0
Balversa (erdafitinib)	2019-10-25	2019-04-12	0.5
Trulance (plecanatide)	2019-10-10	2017-01-19	2.7
Talzenna (talazoparib)	2019-09-06	2018-10-16	0.9
Ultomiris (ravulizumab)	2019-08-28	2018-12-21	0.7
Calquence (acalabrutinib)	2019-08-23	2017-10-31	1.8
Emgality (galcanezumab)	2019-07-30	2018-09-27	0.8
Lokelma (sodium zirconium cyclosilicate)	2019-07-25	2018-05-18	1.2
Nerlynx (neratinib maleate)	2019-07-16	2017-07-17	2.0
Dacogen (decitabine)	2019-07-11	2006-05-02	13.2

Trade Name (medicinal ingredient)	NOC Date	FDA Approval Date	Lag in years
Vitrakvi (larotrectinib)	2019-07-10	2018-11-26	0.6
Esperoct (antihemophilic factor viii [recombinant, b-domain truncated], pegylated)	2019-07-04	2019-02-19	0.4
Netspot (oxodotreotide)	2019-07-03	2016-06-01	3.1
Zejula (niraparib)	2019-06-27	2017-03-27	2.3
Evenity (romosozumab)	2019-06-17	2019-04-09	0.2
Tibella (tibolone)	2019-05-10	Not approved	
Skyrizi (risankizumab)	2019-04-17	2019-04-23	0.0
Libtayo (cemiplimab)	2019-04-10	2018-09-28	0.5
Verzenio (abemaciclib)	2019-04-05	2017-09-28	1.5
Vizimpro (dacomitinib)	2019-02-26	2018-09-27	0.4
Lorbrena (lorlatinib)	2019-02-22	2018-11-02	0.3
Demylocan (decitabine)	2019-01-21	2006-05-02	12.7
Vascepa (icosapent ethyl)	2019-12-30	2012-07-26	7.4
Xospata (gilteritinib fumarate)	2019-12-23	2018-11-28	1.1
Onpattro (patisiran sodium)	2019-06-07	2018-08-10	0.8
Yescarta (axicabtagene ciloleucel)	2019-02-13	2017-10-18	1.3
Oxervate (cenegermin)	2019-02-08	2018-08-22	0.5
Idhifa (enasidenib mesylate)	2019-02-06	2017-08-01	1.5

Approved by Health Canada within one year of FDA approval

Note: List contains all trade names approved by Health Canada in 2019 under the submission of a NAS (New Active Substance).
Data sources: FDA and Health Canada Drug Product Database