Patented Medicine Prices Review Board

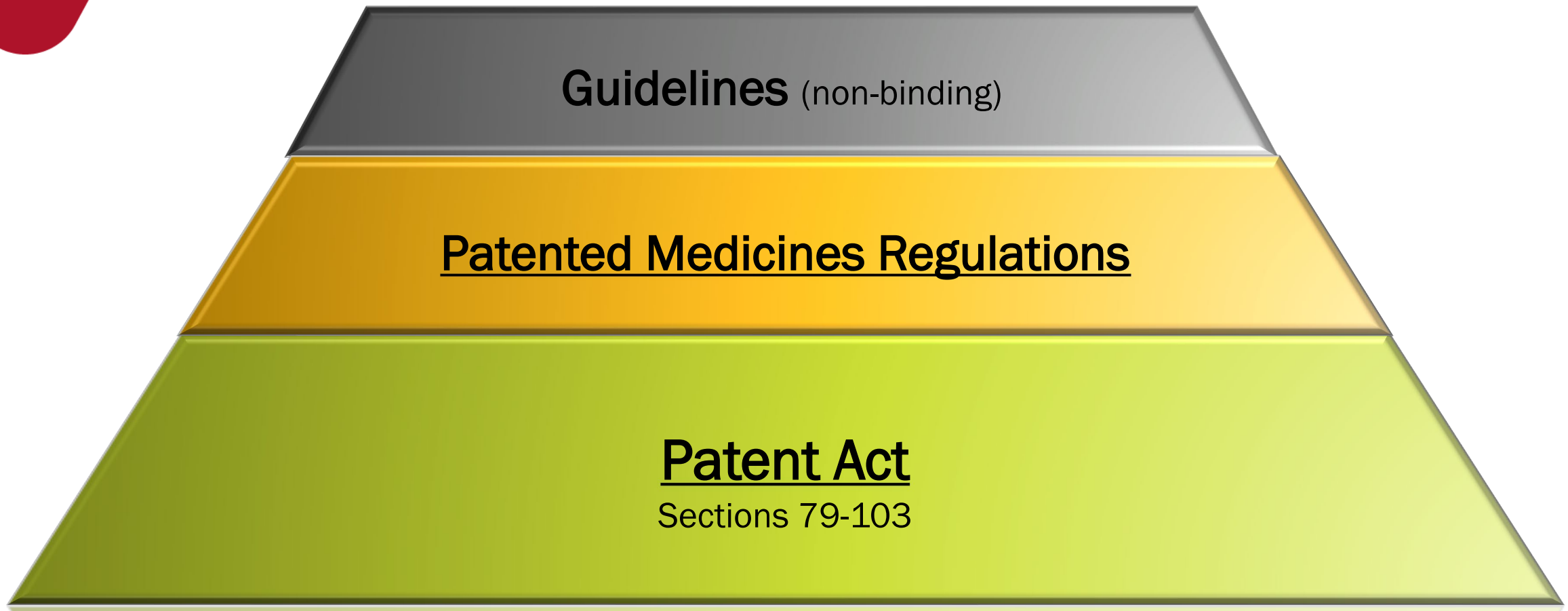
Conseil d'examen du prix des médicaments brevetés

Canada

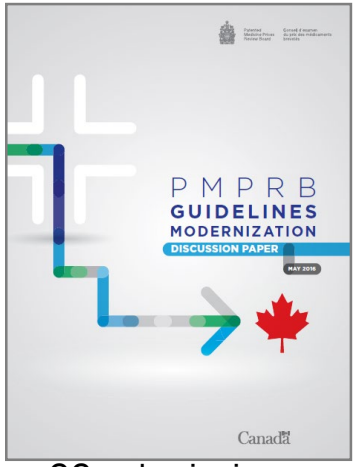
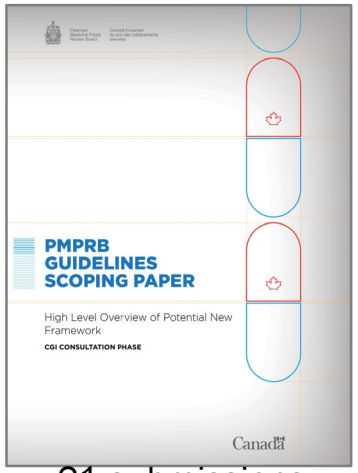
New PMPRB Guidelines

Modernizing Canada's drug pricing framework

About the PMPRB



New Guidelines are culmination of 5-year consultative process

2015	2016	2017	2019			2020
PMPRB Strategic Plan	**PMPRB Discussion Paper on Guideline Reform**	**PMPRB Guidelines Scoping Paper**	**PMPRB Steering Committee Report**	**Health Canada Canada Gazette II**	**PMPRB November Draft Guidelines**	**PMPRB June Draft Guidelines**
						
	66 submissions	21 submissions			123 submissions	112 submissions

Amendments to the *Patented Medicines Regulations*
Key changes

1. Updated schedule of comparator countries (the new "PMPRB11").

France – Germany – Italy – Sweden – Switzerland – United Kingdom – United States

Australia – Belgium – France – Germany – Italy – Japan – Netherlands – Norway – Spain – Sweden – United Kingdom

2. Additional section 85 price regulatory factors: pharmacoeconomic value; market size; and gross domestic product (GDP) and GDP per capita in Canada.

3. Changes in the reporting requirements – require patentees to report prices and net revenue information of all price adjustments.

The Federal Court recently found that the inclusion of some types of rebates in the calculation of net prices is outside the scope of the Patent Act and thus ultra vires the Governor-in-Council's regulation-making authority. That decision has been appealed to the Federal Court of Appeal.

Modernizing Canada’s pricing framework

Key Guideline changes

A risk-based approach for new medicines

New medicines that are at higher risk of excessive pricing will face greater scrutiny

Category I medicines (higher risk)

- High Cost medicines above $1.5 X GDP/capita,

or

- High Market Size: above $50 million (annual)

Category II medicines (lower risk)

- All other new medicines are classified as Category II
- Patented biosimilars and patented generics will be classified as Category II, even if they would otherwise meet the Category I criteria.

- A minority of the new medicines are expected be Category I but will account for over three-quarters of new patented medicine sales by 2030.
- This approach will ensure that the PMPRB exercises greater regulatory scrutiny over a minority of new medicines that account for the majority of sales.

Price Review Process for New Medicines

START

END

PATENTEE FILES WITH PMPRB

CATEGORY I

- High Cost: treatment cost >150% GDP/ capita

  or

- High Market Size: market size (sales) >$50M

iMLP/MLP

- iMLP – MIP of PMPRB11
- If no price in PMPRB11: top of the dTCC or median of iTCC
- **MLP – Lower of List Price and MIP of PMPRB11**

HIGH COST
>$12M sales

HIGH MARKET SIZE
>$50M sales

MRP
for sales $12M–$50M: based on TCL & PV associated with ICUR

MRP
for sales >$50M: based on TCL & median dTCC or iTCC

MRP[A]
Incremental rate 25% and 35% on sales >$50M and $100M respectively

CATEGORY II

- Patented medicines not Category I

iMLP/MLP

- iMLP – MIP of PMPRB11
- If no price in PMPRB11: top of the dTCC or median of iTCC
- **MLP – Lower of List Price and MIP of PMPRB11**

iMLP/MLP<LIST PRICE OR COMPLAINT

INVESTIGATION

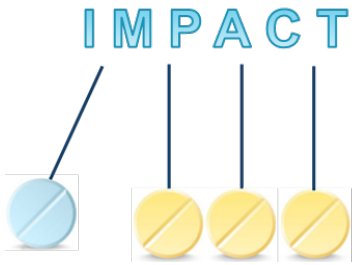
VCU

HEARING

CLOSURE

Impact on existing patented medicines

List prices for Grandfathered medicines cannot be higher than the highest price of the new basket of PMPRB11 countries ("HIP test")



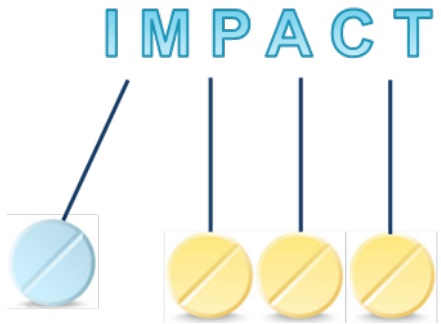
- List price reduction will have an immediate benefit for Canadians
- Expect list prices of existing medicines to decline on average by **5%**, with **34%** requiring a price reduction
- Existing medicines (Grandfathered and Gap) will account for **81%** all patented drug sales over the next decade and **59%** of total sales in 2030
- Potential savings are estimated at **$4.6B*** over the next decade

*The estimate assumes 100% voluntary compliance. A 7% present value discount rate was assumed, as per the Treasury Board of Canada Secretariat guidance.

Impact on Category I new medicines

List prices of new patented medicines considered high risk cannot exceed the median price ("MIP test") among the new basket of comparator countries.

The PMPRB will also calculate a Maximum Rebated Price ("MRP") based on new s.85 factors but only commence an investigation if patentee fails to comply with the MLP (given the Federal Court decision)



- Category I medicines are expected to have **8%** lower list prices than under the previous framework
- Savings from Category I medicines will be gradual as the uptake in these meds will reach **34%** of the sales in the patented market by 2030
- Lower prices for Category I medicines are expected to provide direct savings to Canadian consumers, estimated at **$1.1B*** over the next decade

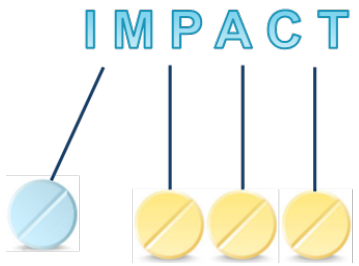
*The estimate assumes 100% voluntary compliance. A 7% present value discount rate was assumed, as per the Treasury Board of Canada Secretariat guidance.

Impact on Category II new medicines

List prices of new patented medicines considered to be at lower risk of excessive pricing cannot exceed the (MIP among the new basket of comparator countries ("PMPRB11").

No MRP will be calculated for Category II medicines.

All patented biosimilars and patented generics will be classified as Category II.

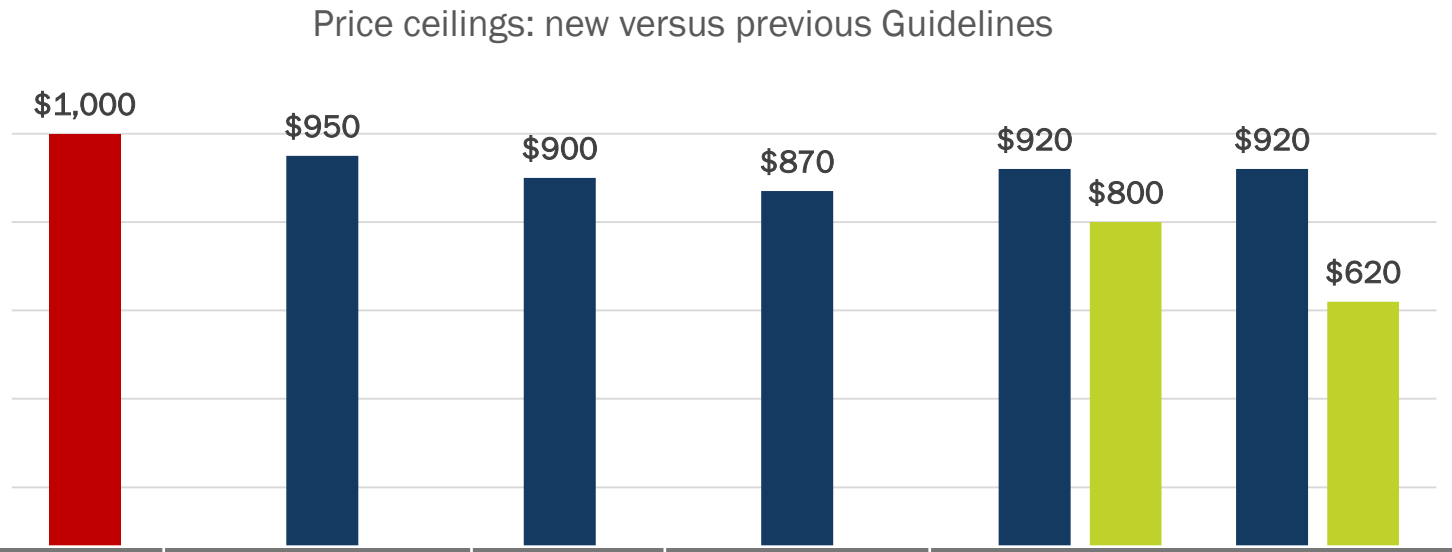


- Category II medicines will have **13%** lower list prices than under the previous framework
- However, this emerging market segment will account for only **7%** of the patented market by 2030
- Lower list prices for Category II medicines are expected to provide direct savings to Canadian consumers, estimated at **$0.5B*** over the next decade

*The estimate assumes 100% voluntary compliance. A 7% present value discount rate was assumed, as per the Treasury Board of Canada Secretariat guidance. A 10% assumption of existing rebates was applied to ensure consistency with the approach modeled in the Cost Benefit Analysis.

Example:
Medicine with price ceiling of $1000 under previous framework

- Expect an existing medicine to reduce its list price to between $950 and $900 or lower
- Expect a Category II medicine list price to be $870 or lower
- Expect a Category I medicine list price to be $920 or lower

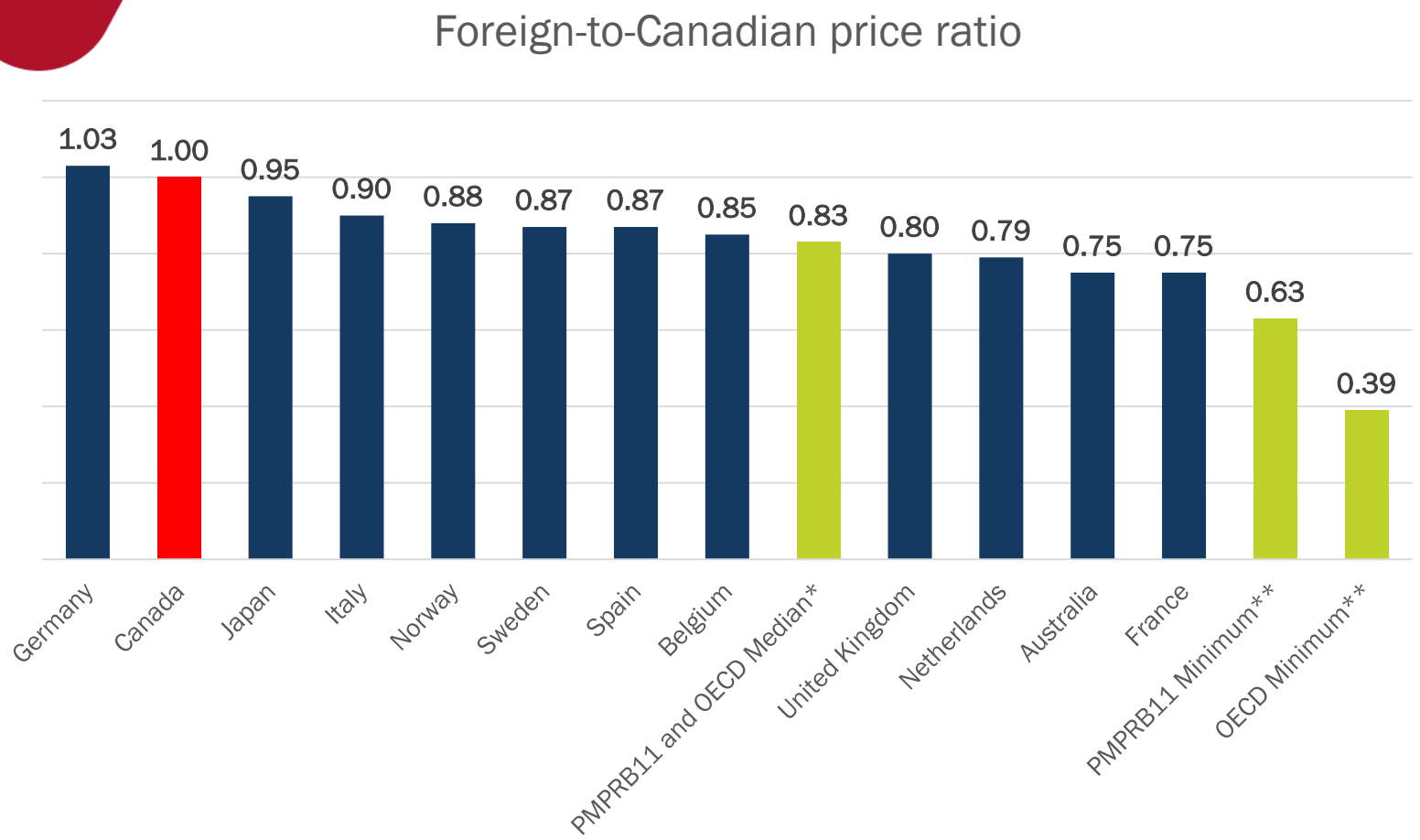


	Previous ceiling	Grandfathered	Gap	New Category II	New Category I	
					High Market	High Cost*
Average list price reduction under new Guidelines		5%	10%	13%	8%	
Type of reduction based on the PMPRB11 countries		HIP	MIP			

The new framework will gradually reduce list prices of patented medicines in Canada, on average by **6%** over the next 10 years

Notes: The MRP/MRP[A] was calculated for a medicine that realizes $100M in annual sales at the Maximum List Price (MLP)
* Assumption of ICUR available, PMPRB TCL II (30% floor off MLP)

Alignment of Canadian prices with international norms will not happen overnight

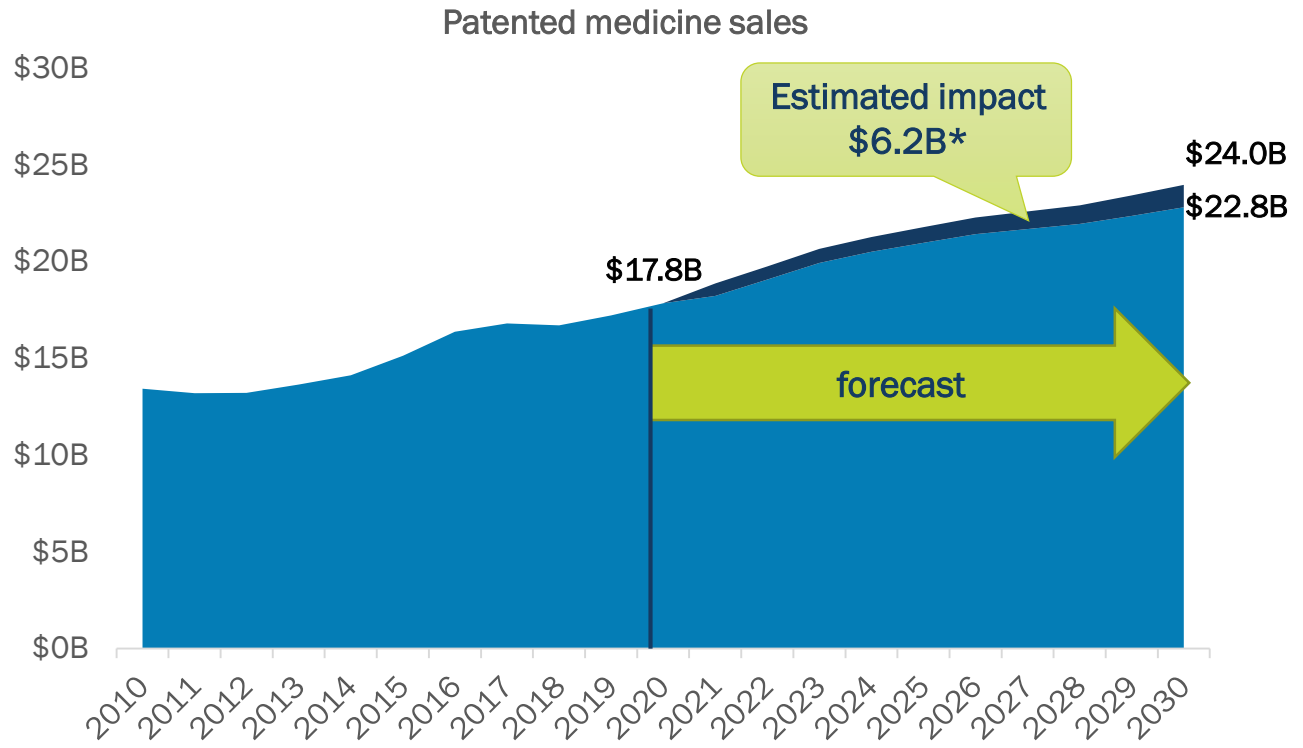


- PMPRB11 median list prices are 17% lower than in Canada, and the lowest PMPRB11 prices are 37% lower
- Canadian prices will remain at the higher end of the PMPRB11 over the next decade because existing medicines (i.e. Grandfathered and Gap) will dominate sales for some time.

Data source: MIDAS® database, 2018, IQVIA (all rights reserved)
* Calculated at the medicine level for medicines with prices available in at least three foreign markets.
** Calculated at the medicine level for medicines with prices available in at least two foreign markets.

Potential savings estimated at $6.2B* over the next 10 years, while patented medicines sales will continue to grow

- Sales of patented medicines are expected to continue to rise, even as prices come down, from an estimated $17.8B in 2020 to $22.8B in 2030.
- Under the new framework, the sales of patented medicines over the next 10 years are expected to be 3.9% lower than under the previous framework
- The impact is expected to be progressive, from a 3.4% reduction in sales in the first year, to a 4.8% reduction by year 10
- Lower prices are expected to result in increased utilization



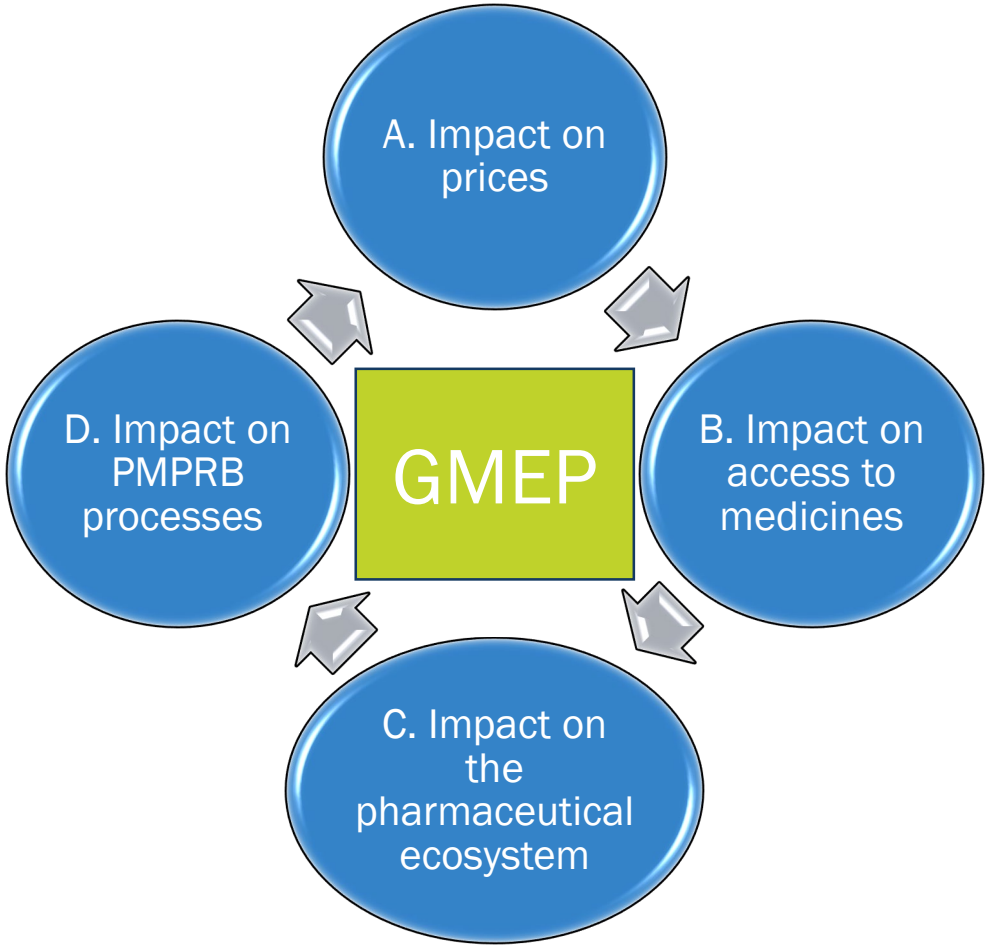
The estimated impact assumes 100% voluntary compliance. A 7% present value discount rate was assumed, as per the Treasury Board of Canada Secretariat guidance.

* Assumes 10% existing rebates for Category II medicines.

Drugs and vaccines for COVID-19 to be investigated on a complaints basis only

- Any medicines on Health Canada's List of Drugs for Exceptional Importation and Sale, set out in accordance with section 3 of the March 30, 2020 Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19, or on the list(s) published by Health Canada pursuant to the September 16, 2020 Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 will not be subject to review or an investigation unless a complaint is received from the federal Minister of Health or any of her provincial or territorial counterparts.
- This will be case for as long as the Interim Orders are in effect.
- Upon the expiry or repeal of the Interim Orders or the removal of a patented medicine from the applicable list, absent a pre-existing complaint, price reviews for these medicines will be based on prevailing international and domestic list prices, and not on introductory discounted prices in Canada.
- This policy has been adopted as part of a government wide effort to provisionally ease the regulatory pathway for drugs and medical devices urgently needed for COVID-19 diagnosis, treatment, mitigation or prevention.

Guidelines Modernization Evaluation Plan (GMEP)



Question period