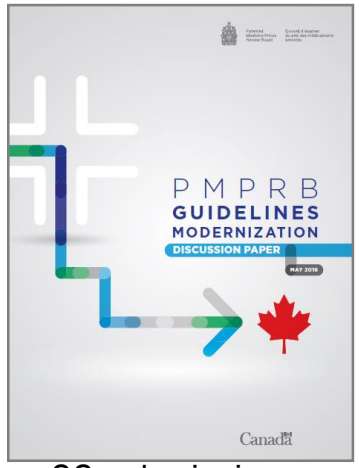
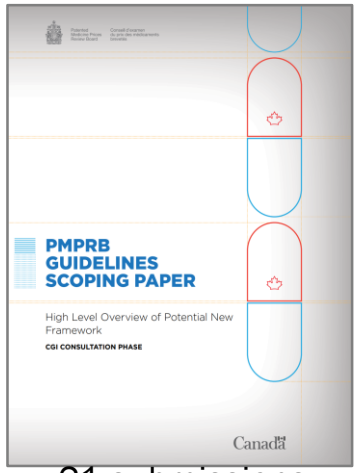
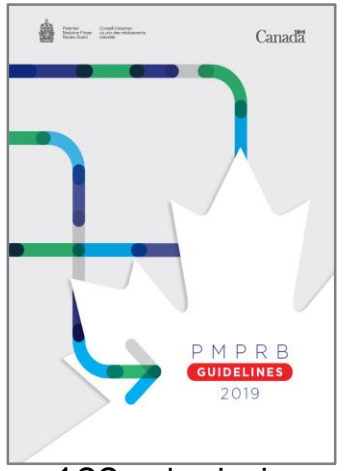
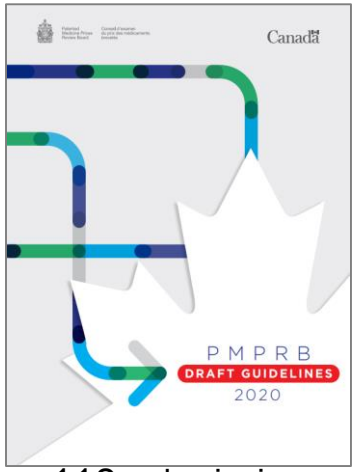
Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

Canada

New PMPRB Guidelines

Modernizing Canada's drug pricing framework

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.

A year-long PMPRB consultation on its new Guidelines

The November 2019 Draft Guidelines

- Subject to the most intensive and far reaching public consultation in our more than three decades long history.
- PMPRB hosted multiple policy forums, webinars and bilateral meetings in Ottawa with key stakeholders
- PMPRB attended over 60 meetings across Canada, with more than 260 members of its stakeholder community, including bio-pharmaceutical companies, their trade associations, public agencies, federal and provincial health authorities, other government bodies, patients, patient advocacy groups, unions, academics, pharmaceutical distributors, pharmacists, consultants, academics, private insurers, clinicians and other health professionals.
- Over 120 written submissions were received at the close of an 85-day process.

The June 2020 Draft Guidelines

- Reflected the feedback we received on the first draft.
- Subject to a 47-day written consultation period which ended August 4, 2020
- Elicited 112 written submissions.

Modernizing Canada's pricing framework

- On October 23, 2020, the PMPRB published its new Guidelines
- The Guidelines give effect to the amended Patented Medicines Regulations which come into force on January 1, 2021.
- Together, these two instruments strengthen and modernize Canada's pricing framework for patented medicines so that the PMPRB can continue to fulfill its statutory mandate to protect Canadian consumers from excessive prices in an era where high-cost medicines account for a rapidly growing share of public and private spending on pharmaceuticals.
- The Guidelines explain the steps that will typically be taken by Staff at the PMPRB in assessing whether a patented medicine appears to be priced excessively in Canada. The Guidelines also explain what information patent-holding pharmaceutical companies must provide to the PMPRB to enable that assessment.

Modernizing Canada’s pricing framework

Key Guideline features

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)

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

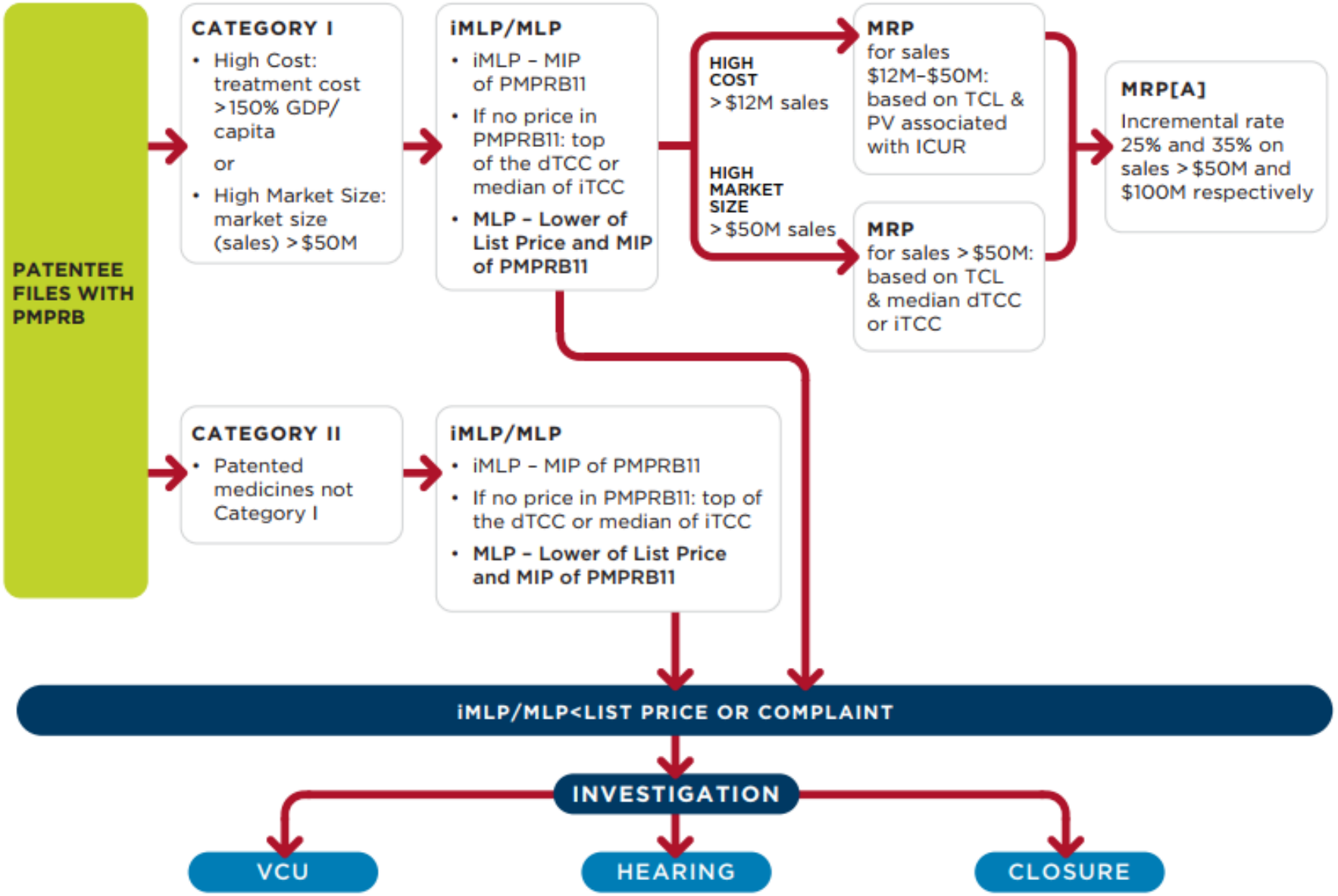
Category II medicines (lower risk)

- 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.

Price Review Process for New Medicines

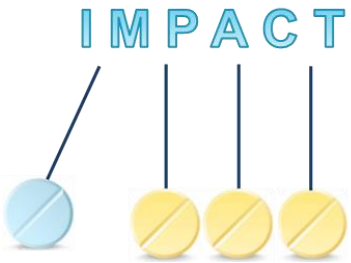
START

END



Impact on existing patented medicines

List prices for Grandfathered medicines cannot be higher than the highest price of the new basket of PMPRB11 countries



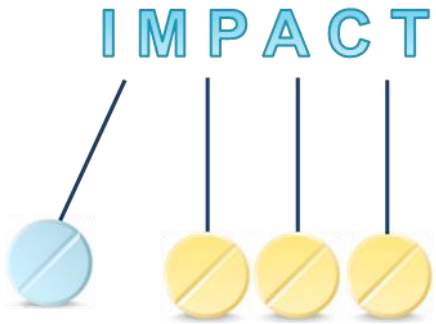
- List price reduction will have an immediate benefit for Canadians
- Expect list prices of existing medicines to decline on average by **5%**, with **34%** requiring a price reduction
- Existing medicines (Grandfathered and Gap) will account for **81%** all patented drug sales over the next decade and **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) 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

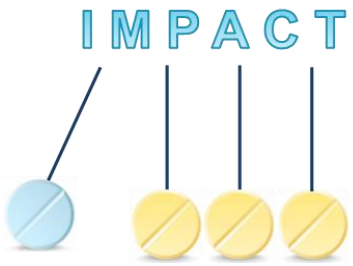
*The estimate assumes 100% voluntary compliance. A 7% present value discount rate was assumed, as per the Treasury Board of Canada Secretariat guidance.

Impact on Category II new medicines

List prices of new patented medicines considered to be at lower risk of excessive pricing cannot exceed the median price (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.

Modernizing Canada’s pricing framework

Overview of final Guideline changes

Overview of changes between the June 2020 draft and the final Guidelines

1. The reassessment for Grandfathered and Line Extension medicines limited to HIP
2. Vaccines to be subject to similar complaints-based investigation criteria as patented biosimilars and generics
3. Maximum Rebated Price (MRP) not a trigger to investigation
4. Allowing for increases in the Maximum Rebated Price for Category I new medicines to the Maximum List Price level
5. Reduction in the Pharmacoeconomic Value Threshold (PVT) for Therapeutic Criteria Level IV

1. The reassessment for Grandfathered and Line Extension medicines limited to HIP

- The list price ceiling for Grandfathered and Line Extension medicines is set at the lower of (i) the highest international price ("HIP") for the PMPRB11 countries for which the patentee has provided information; or (ii) the patented medicine's ceiling under the Guidelines applicable prior to the issuance of these Guidelines.
- The final Guidelines also provide for the reassessment of these medicines in the cases in which the prevailing HIP is lower than the list price ceiling for two consecutive reporting periods. In such cases, the list price ceiling will be reset by the prevailing HIP.
- In response to the feedback received on the June 2020 draft Guidelines, the Board decided to remove the extra reassessment provision that would have required these medicines to further reduce their prices to the median international price ("MIP") if in two consecutive subsequent periods, the prevailing MIP was lower than the list price ceiling by more than 10%.

2. Vaccines to be subject to similar complaints-based investigation criteria as patented biosimilars and generics

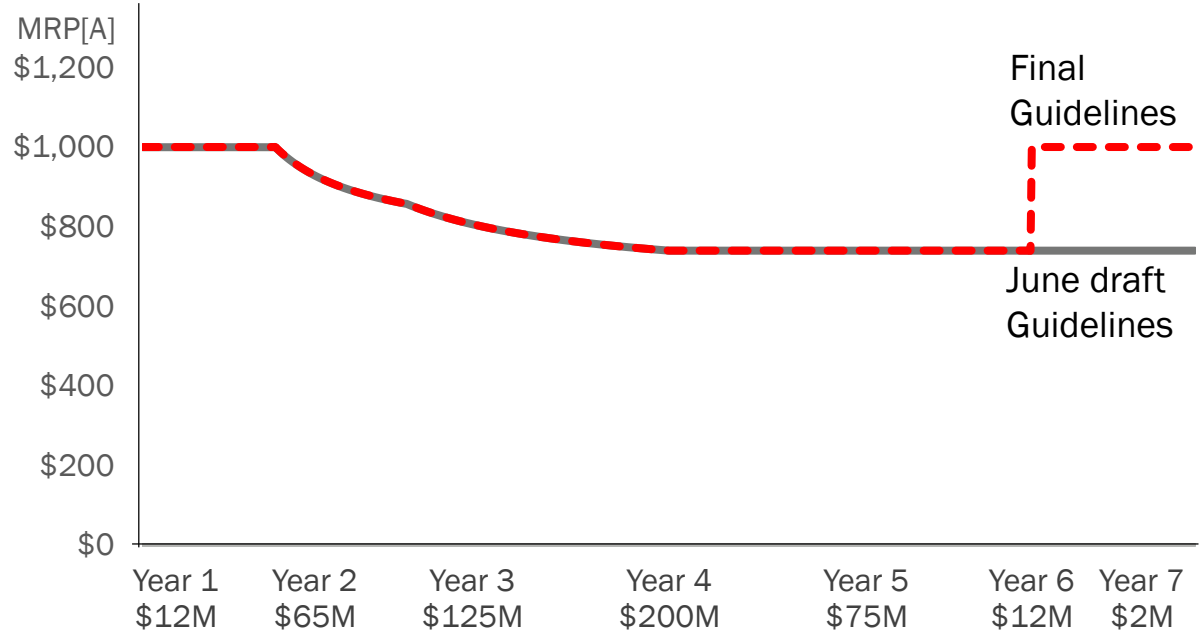
- In response to feedback from vaccine manufacturers and their trade association regarding the unique market dynamics surrounding vaccine provision in Canada, the final Guidelines provide that vaccines shall be subject to the same investigation criteria as patented biosimilars and patented generics.
- Accordingly, new patented vaccines will only be subject to a price review and investigation if a complaint is received by the PMPRB.
- In such an instance, a vaccine that meets the Category I criteria will be assessed accordingly (in contrast to biosimilars and generics which will always be Category II medicines).
- Generics approved through non-ANDS pathways, patented biosimilars and vaccines remain subject to the reporting requirements set forth in the *Patent Act* and the *Patented Medicines Regulations*.

3. Maximum Rebated Price (MRP) not a trigger to investigation

- Pending the Federal Court of Appeal's ruling on IMC's appeal of the decision of Justice Manson, absent a complaint being filed, the PMPRB will only commence an investigation into the price of a Category I medicine where it appears that the patentee has failed to comply with the Maximum List Price (MLP).
- Whether the patentee appears to be in compliance with the MRP will not be a relevant consideration in that regard.
- However, the MRP may become a relevant consideration in an actual investigation or in the context of a hearing before the Board.
- MRP will not be used for GAP medicines price review or reassessment.
- All relevant tests will be considered in the context of an investigation.

4. Allowing for increases in the Maximum Rebated Price for Category I new medicines to the Maximum List Price level

- Both the November 2019 and June 2020 draft Guidelines only provided for downward adjustment to the MRP based on increases in a medicine's market size.
- However, the final Guidelines allow the MRP to be adjusted both downwards and upwards, as revenues expand or contract.
- Accordingly, under the Guidelines, it is possible for the MRP to increase back to the MLP if revenues fall to $12 million or less for High Cost medicines, or to $50 million or less for High Market size medicines.



The Guidelines define High Cost medicines as exceeding the treatment cost threshold of 150% of GDP per capita, and High Market size medicines as those with sales exceeding the $50M threshold

5. Reduction in the Pharmacoeconomic Value Threshold (PVT) for Therapeutic Criteria Level IV

- In order to align better with domestic and international norms and the sliding scale approach taken in many other countries, the PVT for Therapeutic Criteria Level (TCL) IV is $100K / QALY, as opposed to the $150K /QALY proposed in the June 2020 draft Guidelines.
- As a result, the PVT thresholds are as follows: $200K /QALY for TCL I; $150K / QALY for TCL II and III, and $100K / QALY for TCL IV.
- While these thresholds may appear high to some, they apply to a select group of medicines that are very high-cost and are felt to be consistent with the PMPRB's role as a regulator of ceiling prices, not a price setting body

Price adjustment based on Therapeutic Criteria Level for MRP calculation

Therapeutic Criteria Level (See Appendix E – The Scientific Review Process)	**PVT**	**Reduction Cap off MLP**
Level I	$200K/QALY	20%
Level II	$150K/QALY	30%
Level III	$150K/QALY	40%
Level IV	$100K/QALY	50%
Pharmacoeconomic analysis does not report an ICUR	Median of dTCC subject to 50% reduction cap	
No pharmacoeconomic analysis filed	50% of MLP	

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

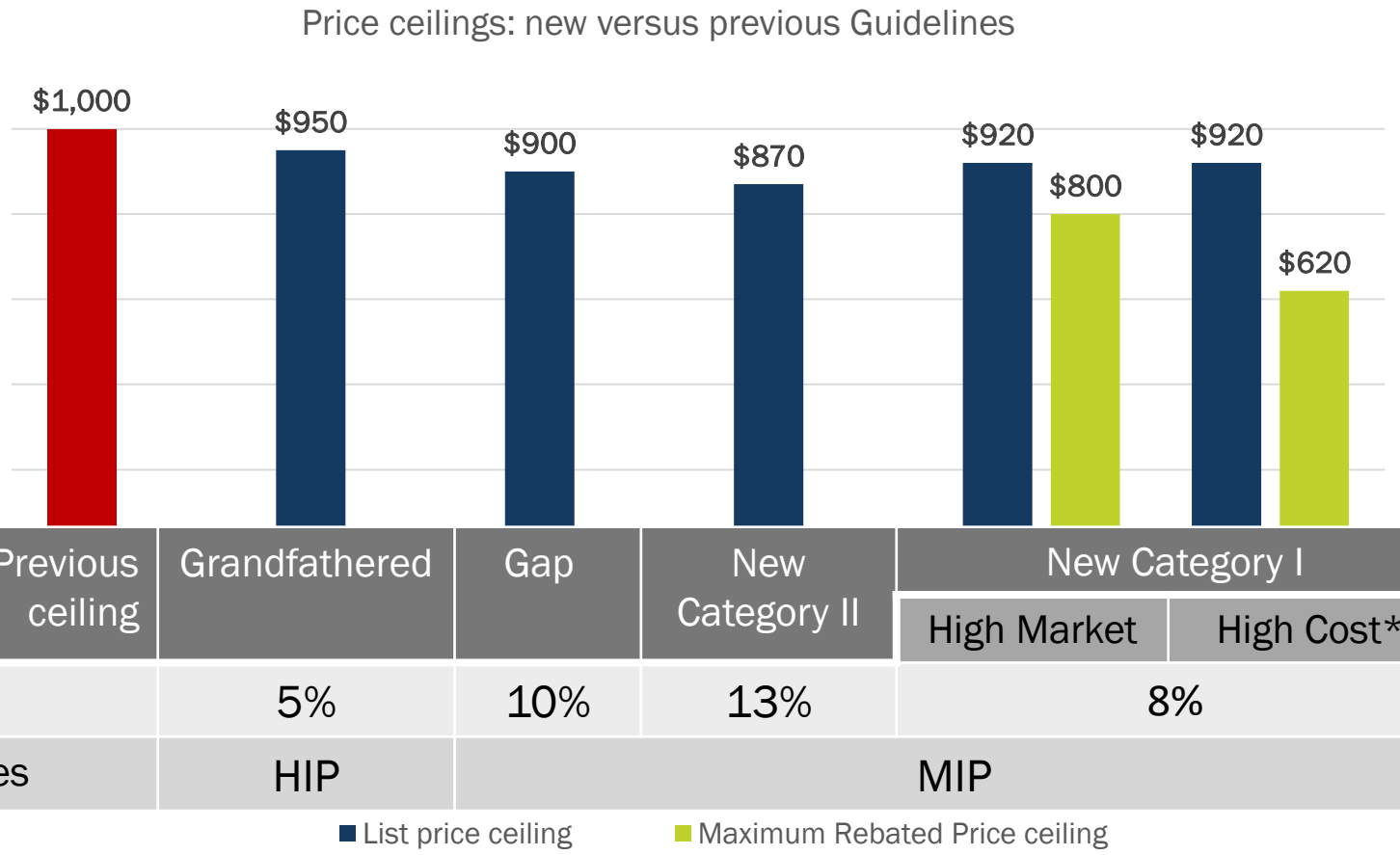
- Any medicines on Health Canada's List of Drugs for Exceptional Importation and Sale, set out in accordance with section 3 of the March 30, 2020 Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19, or on the list(s) published by Health Canada 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 public international and domestic commercial list prices, and not on introductory non-commercial pandemic prices in Canada and the non-commercial pandemic prices in PMPRB11. Price reviews will not take into account sales made while the medicine was on the applicable list, for the purpose of determining the market size.
- 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.

Changes to Guidelines in Response to Stakeholder Feedback

Proposed	Final
Grandfathered drugs subject to median international price	Grandfathered drugs subject to highest international price
Drugs screened in as Category I if treatment cost > 50% GDP per capita or annual sales above $25 million	Drugs screened in as Category I if treatment cost > 150% GDP per capita or annual sales above $50 million
All sales of high cost Category I drugs subject to MRP	Only sales above $12 million annually subject to MRP reduction for high cost Category I drugs
MRP only adjusted downward as sales go up	MRP adjusted downward or upward based on whether sales go up or down below the market size thresholds
No cap on MRP required price reduction	MRP required reduction capped at between 20% and 50% depending on therapeutic criteria level
Pharmacoeconomic threshold set at $60K/QALY (1.5x$60K/QALY for rare disease drugs)	Pharmacoeconomic threshold varies from $100K to $200K/QALY
Maximum market size based MRP reduction = 50%	Maximum market size based MRP reduction = 35%
Non-compliance with MLP or MRP, and complaints are triggers for investigation	Only non-compliance with MLP and complaints are triggers for investigation, while MRP may be a relevant consideration in an investigation or hearing
Biosimilars, certain generics and vaccines subject to automatic review, including MRP, like any other patented prescription drug (excluding generic, OTC and vet drugs)	MRP not applicable to biosimilars and generics. These medicines and vaccines subject to price review only if complaint received.
No special treatment for COVID-19 treatments or vaccines	COVID-19 treatments and vaccines subject to price review only if a complaint received

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

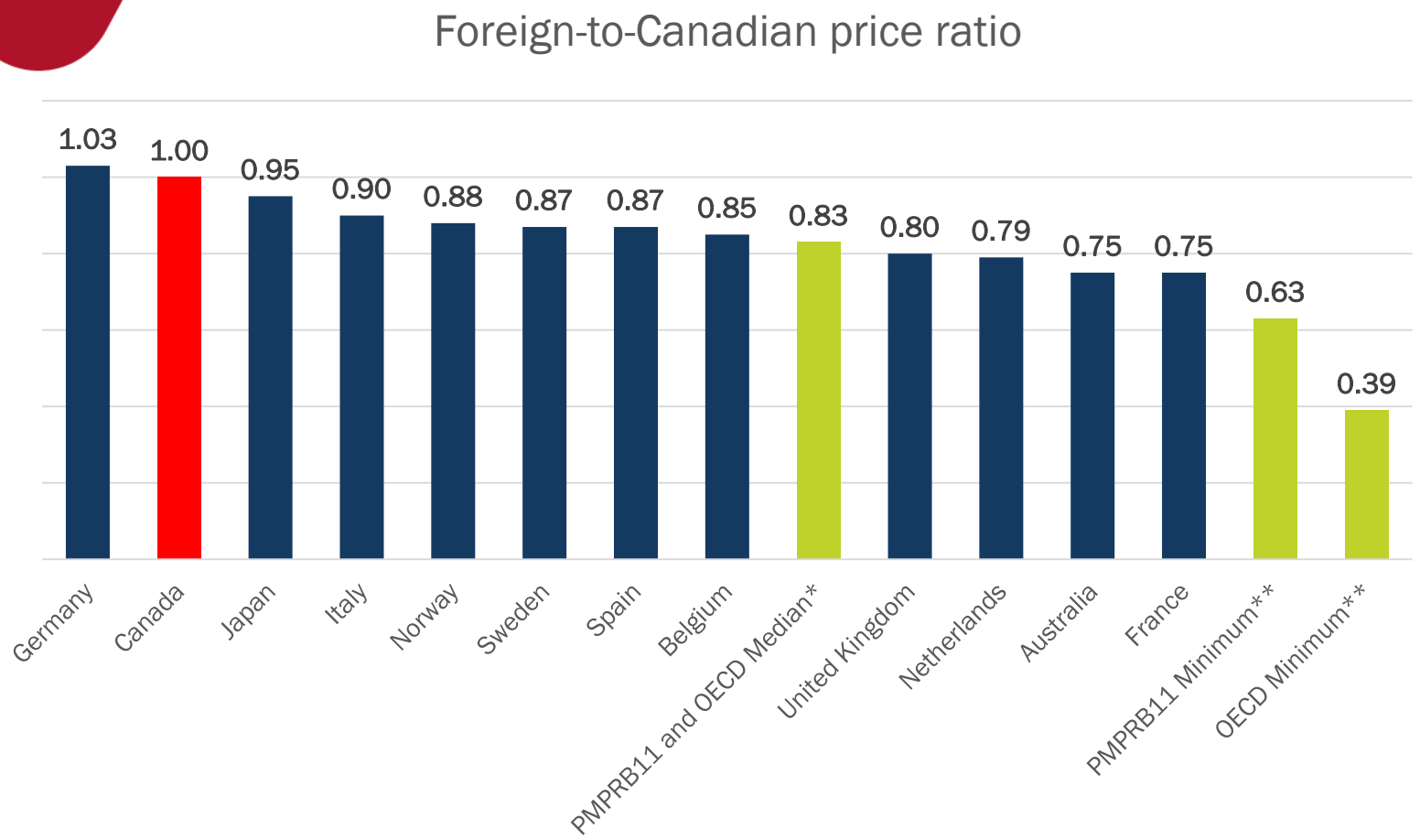


	Previous ceiling	Grandfathered	Gap	New Category II	New Category I	
					High Market	High Cost*
Average list price reduction under new Guidelines		5%	10%	13%	8%	
Type of reduction based on the PMPRB11 countries		HIP	MIP			

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

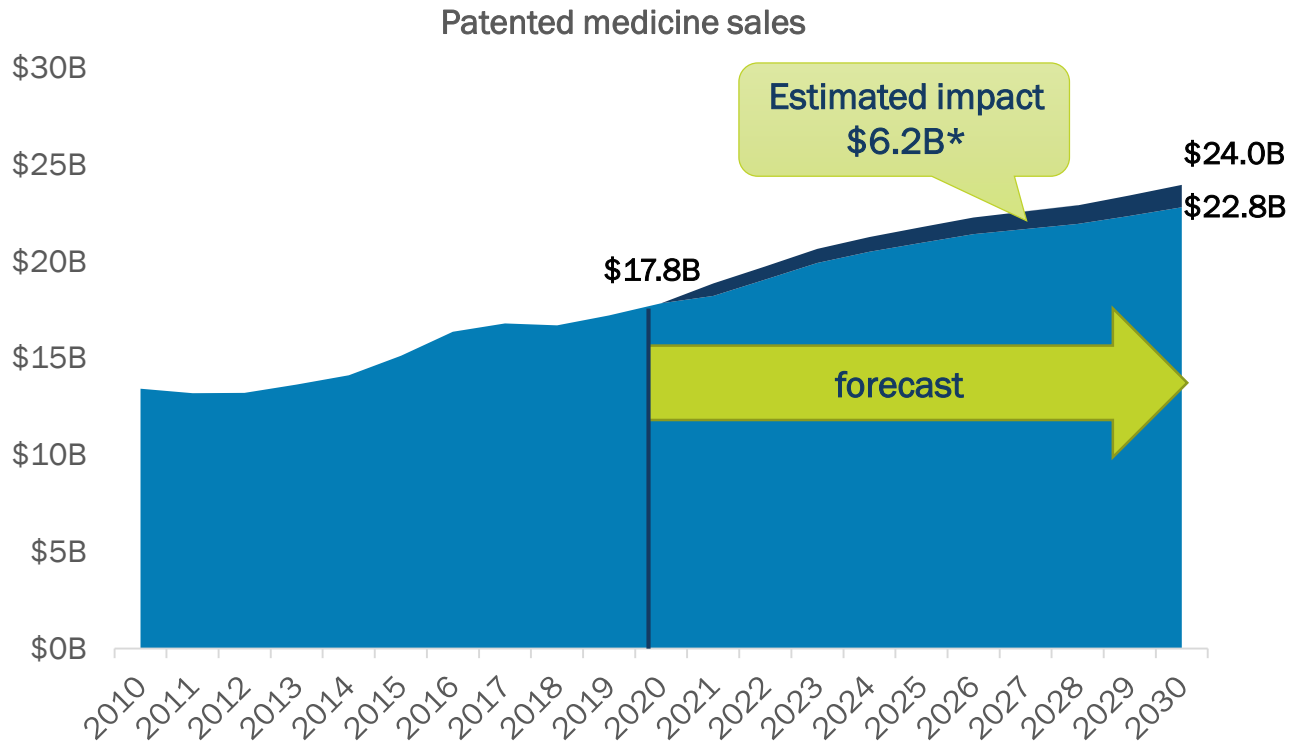


- PMPRB11 median list prices are 17% lower than in Canada, and the lowest PMPRB11 prices are 37% lower
- Canadian prices will remain at the higher end of the PMPRB11 over the next decade because existing medicines (i.e. Grandfathered and Gap) will dominate sales for some time.

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

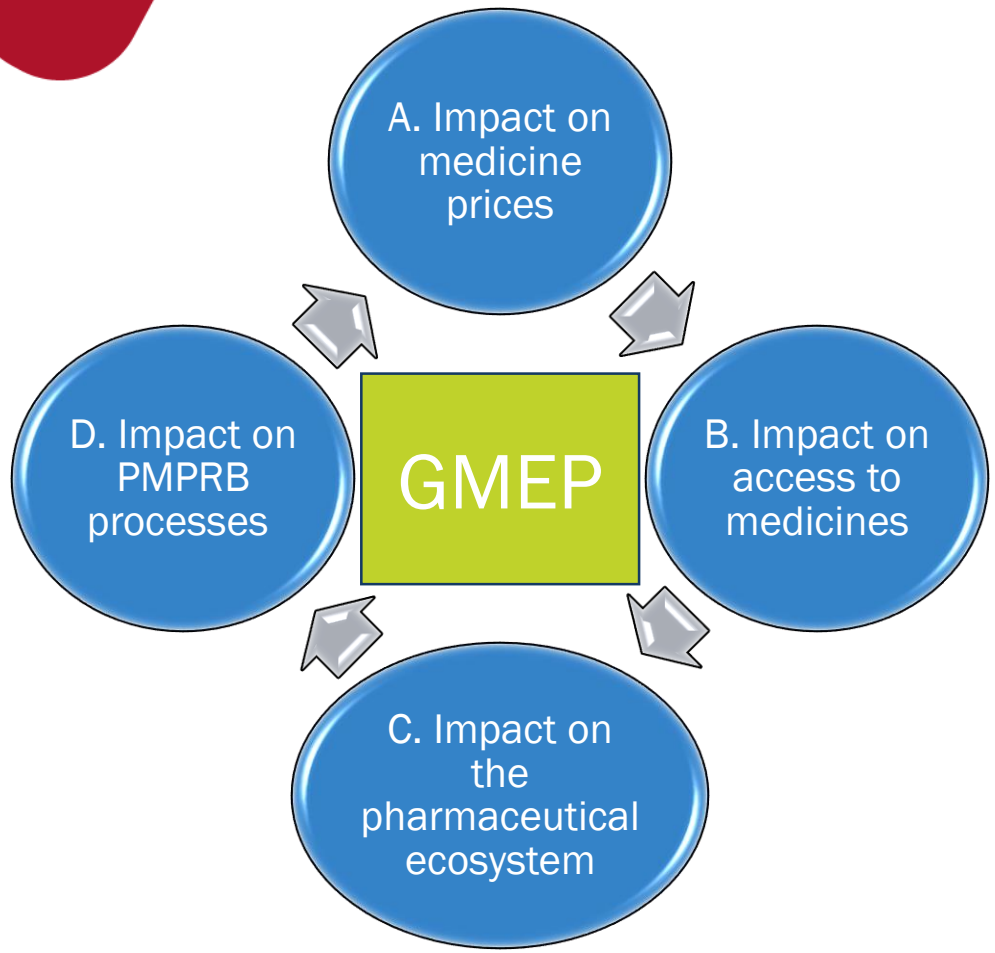
- Sales of patented medicines are expected to continue to rise, even as prices come down, from an estimated $17.8B in 2020 to $22.8B in 2030.
- Under the new framework, the sales of patented medicines over the next 10 years are expected to be 3.9% lower than under the previous framework
- The impact 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.

Guidelines Monitoring and Evaluation Plan (GMEP)



- The PMRRB is developing and implementing a comprehensive Guidelines Monitoring and Evaluation Plan (GMEP) to assess the impact of the Guidelines and inform any future adjustments required to ensure that they are working as intended.
- The GMEP will consist of four key areas of focus, and each will be monitored and evaluated by comparing trends prior to and post implementation of the PMPRB's new regulatory framework.
- Baseline results (benchmarks) will be generated for the trends under the Guidelines as they were up to and including 2020.
- Starting in 2021, the trends under the new Guidelines will be monitored on an ongoing basis and compared against the established benchmarks.
- The PMPRB will be seeking input in due course from the stakeholder community on the scope and methods to be used in the GMEP.