



Patented
Medicine Prices
Review Board

Conseil d'examen
du prix des médicaments
brevetés

Managing the “Expense” in Expensive Drugs for Rare Diseases



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Patented Medicine Prices Review Board,**

CADTH, April 2019

Canada

What we do



The PMPRB assesses new drugs for level of therapeutic benefit relative to existing therapies and assigns a ceiling price that is based on either:

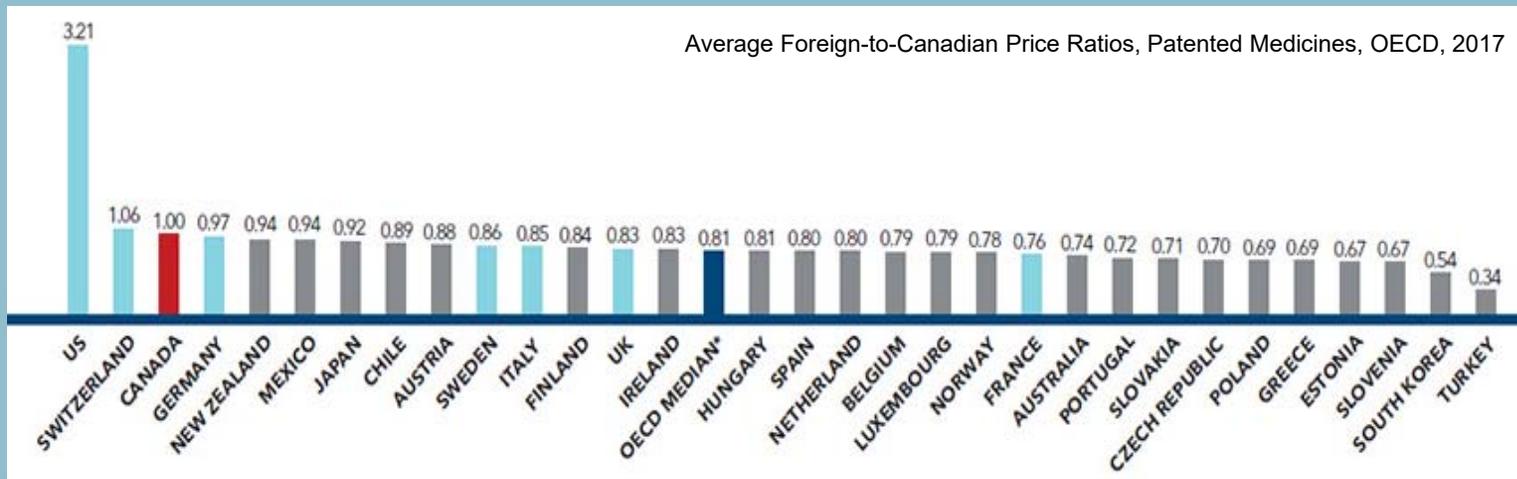
1. The median international price;
2. The highest price in the domestic therapeutic class, or;
3. Some combination of the two.

After entering the market, the price of a drug can increase in keeping with CPI but never to the point of becoming highest of the PMPRB7.

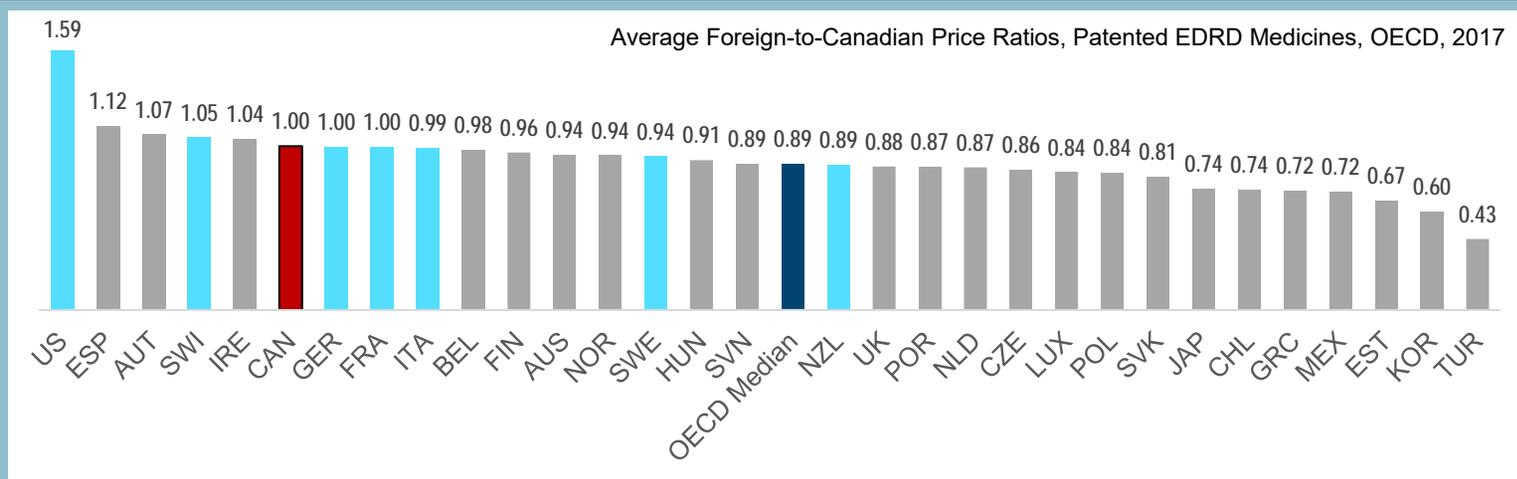
In the event of disagreement over the appropriate ceiling price, a hearing may be held before the PMPRB's Board.

If the Board decides a drug is excessively priced, it can issue a court order requiring the patentee to reduce its price and/or pay back excess revenues.

Canada's prices some of the highest in the OECD



Canadian patented medicine prices are **3rd** highest



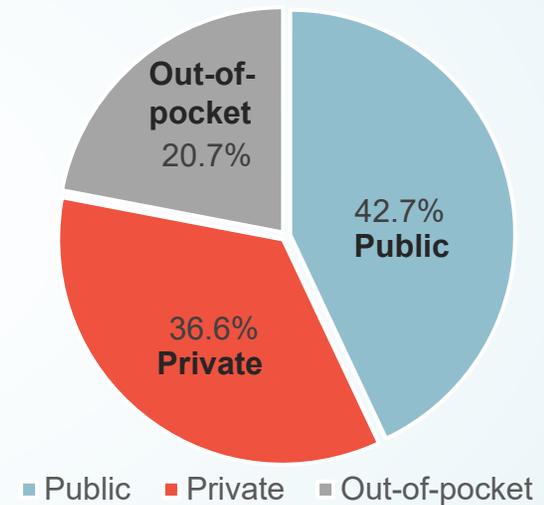
Canadian EDRD prices are **6th** highest

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

Challenges faced by payers

- pan-Canadian Pharmaceutical Alliance (pCPA) negotiates rebates off of the list price for public plans only.
- Large private insurers negotiate prices, but not as a buying group
- The uninsured pay the highest prices for drugs, the list prices.
- All payers, national or international, have little leverage in negotiating for drugs that have few or no therapeutic options.

Prescription drug spending, 2018*



*Data source: Canadian Institute for Health Information, Prescribed Drug Spending in Canada, 2018

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.
- It is based on publicly available list prices, which are increasingly divorced from the true price net of confidential rebates/discounts.
- For many high cost drugs, the only factor the PMPRB can consider in setting the ceiling price is its public list price in the PMPRB7
- All drugs are subject to the same level of regulatory scrutiny, regardless of price/cost and market dynamics.
- Our only absolute ceiling for existing drugs is highest international price.

Proposed reforms



Would give the PMPRB the modern tools and information it needs to protect Canadians from excessive drug prices:

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

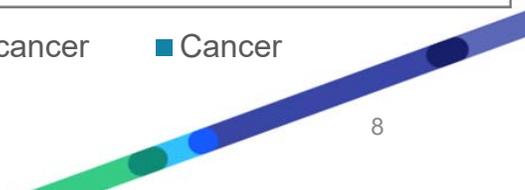
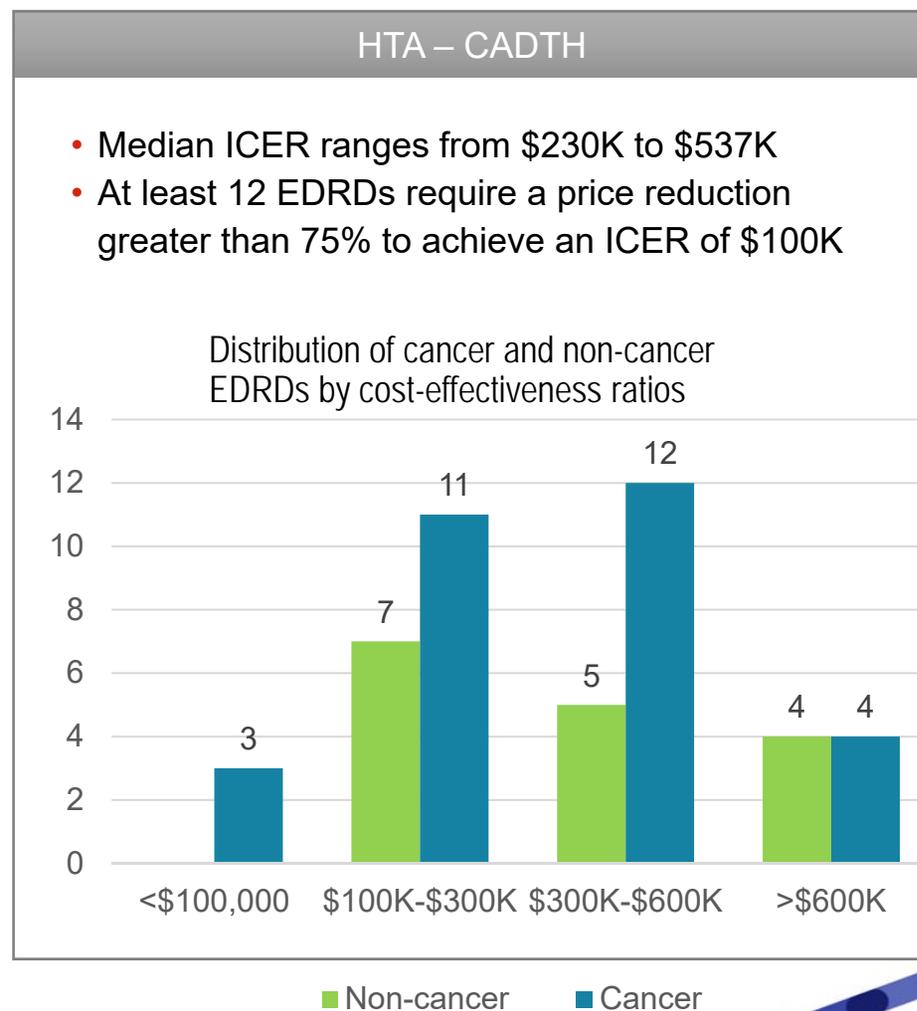
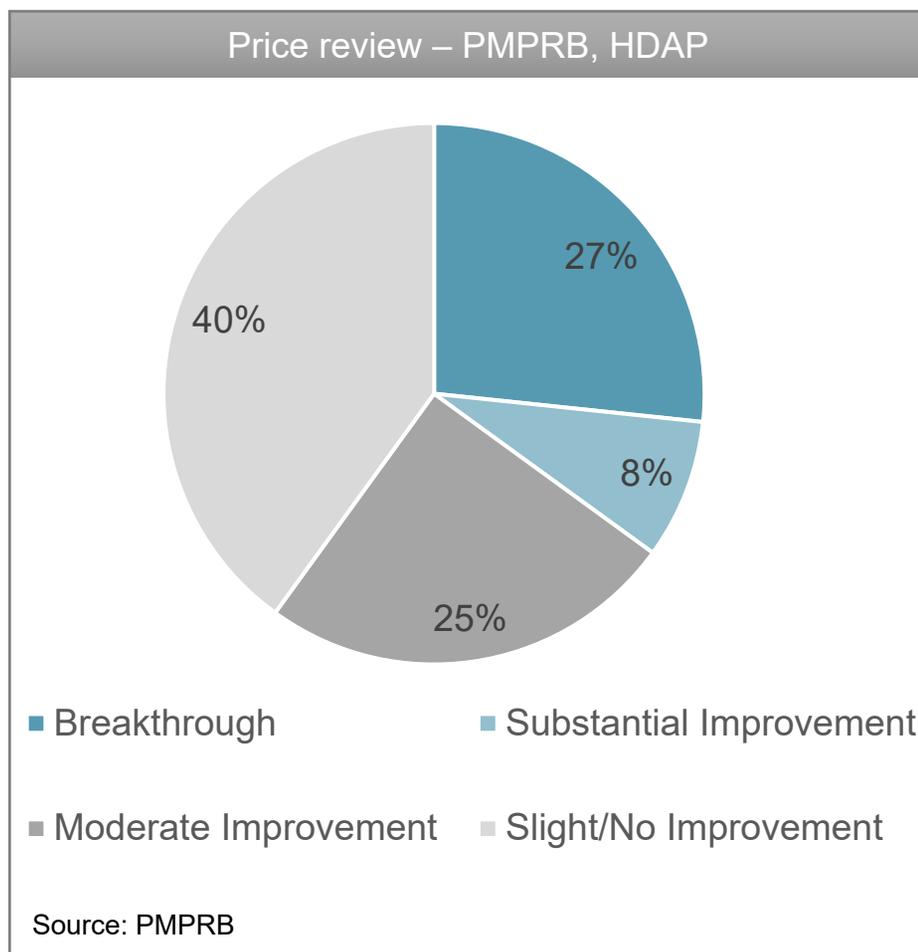
New price review factors



Most regulators consider additional factors beyond simply comparing prices paid in other countries.

Factor	Description	Comparator countries using the factor
Pharmacoeconomic Value	<p>What the drug costs relative to the health benefit it provides (i.e. its incremental cost per QALY – aka its “ICER”)</p> <ul style="list-style-type: none"> ▪ The price of a drug must come down if paying for it is likely to result in a net loss in total population health (because of the displacement of more cost effective technologies) 	
Size of the market	<p>What impact the drug is likely to have on overall drug expenditures because of the number of patients it is expected to treat</p> <ul style="list-style-type: none"> ▪ The price of a drug with a very large market must come down to avoid risk of rationing even if its price is considered cost effective, and the price of a drug with a with a very small market that is not considered cost effective can go up (within set parameters) to reduce the risk of non-entry 	
GDP and GDP per capita	<p>These factors allow the PMPRB to prioritize its regulatory resources and set market size threshold for drugs that are most likely to raise affordability issues for public and private payers or result in a net loss in population health</p>	

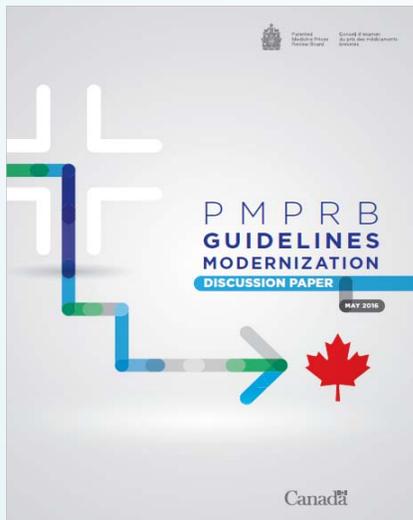
Most EDRDs are not cost-effective at their submitted prices



We've been consulting since June 2016



PMPRB Discussion paper on Guideline reform



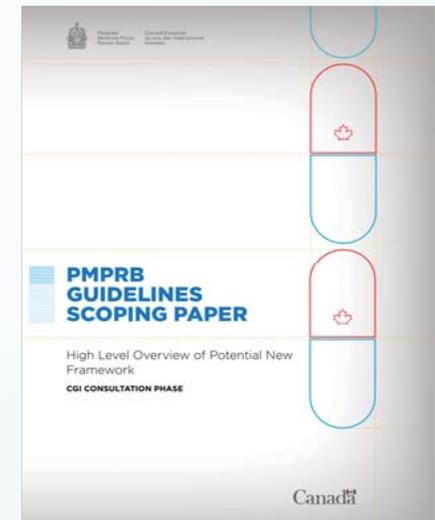
Health Canada pre-consultation on regulatory amendments



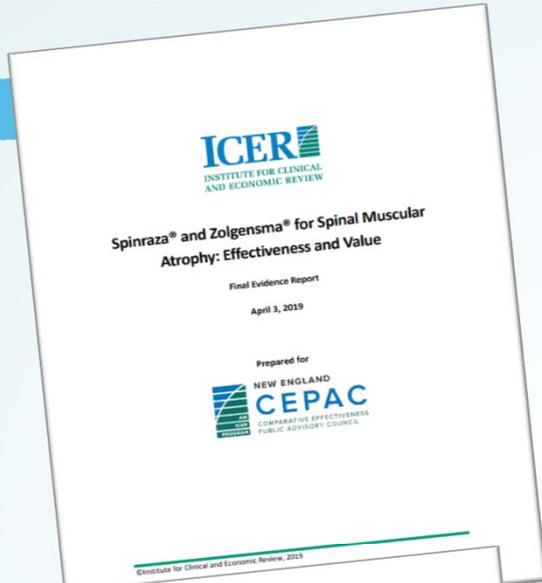
Health Canada Canada Gazette I



PMPRB Guidelines scoping paper



Why it matters



"Both Spinraza and Zolgensma dramatically improve the lives of children with SMA and that of their families," ... "However, the current price of Spinraza far exceeds common thresholds for cost-effectiveness. The price of Zolgensma is not yet known, but there has been public discussion of prices above commonly accepted cost-effectiveness thresholds as well. These treatments will be covered by US insurers regardless of the pricing, but the ripple effect of pricing decisions like these threatens the overall affordability and sustainability of the US health system."

"While our system can absorb one, two or maybe even dozens of high-cost drugs, it will collapse under the weight of hundreds, no matter how good they are. At the end of the day, the single most important determinant of access is affordability"



What's next?



Investing in the Middle Class
BUDGET 2019

Tabled in the House of Commons
by the Honourable
William Francis Morneau, P.C., M.P.
Minister of Finance
March 19, 2019

Government of Canada / Gouvernement du Canada

Home → [Budget 2017](#) → [Budget Plan](#)

Chapter 3 – A Strong Canada at Home and in the World

Prescription Medications and Health Innovation

To promote a more innovative health care system, Budget 2017 proposes measures that include:

- Improving access to prescription medications, lowering drug prices and supporting appropriate prescribing through an investment of \$140.3 million over five years, starting in 2017–18, with \$18.2 million per year ongoing, for Health Canada, the Patented Medicine Prices Review Board and the Canadian Agency for Drugs and Technologies in Health.

#YOURBUDGET2019

Canada

- The **Canadian Drug Agency**, a new national drug agency that would build on existing provincial and territorial successes, and take a coordinated approach to assessing effectiveness and negotiating prescription drug prices on behalf of Canadians. Negotiating better prices could help lower the cost of prescription drugs for Canadians by up to \$3 billion per year in the long term.
- A **national formulary**—a comprehensive, evidence-based list of prescribed drugs, to be developed as part of the Canadian Drug Agency. This would provide the basis for a consistent approach to formulary listing and patient access across the country.
- A **national strategy for high-cost drugs for rare diseases** to help Canadians get better access to the effective treatments they need. This is an important first step in expanding drug coverage through federal support.