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

PMPRB Framework Modernization

Canadian Association for Pharmacy Distribution
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Canada

Outline

- Summary of proposed regulatory amendments
- Overview of proposed New Guidelines framework
- Next Steps

Reform of federal drug price regime long overdue

- The PMPRB and its regulatory framework were designed at a time before the Internet or cell phones
- Built to respond to changing intellectual property standards of the mid-1980s, price protection for patentees was seen as a good trade-off for attracting R&D
- Price ceilings were based on pricing data that was public and compared against the highest R&D jurisdictions in the hopes of emulating them
- In the 30 years since, the anticipated benefits haven't materialized and the regulatory pricing model is broken

Assessing Canada's Patented Drug Pricing Regulations

Original design and intent vs. current realities

Designed to respond to realities of the mid-1980s

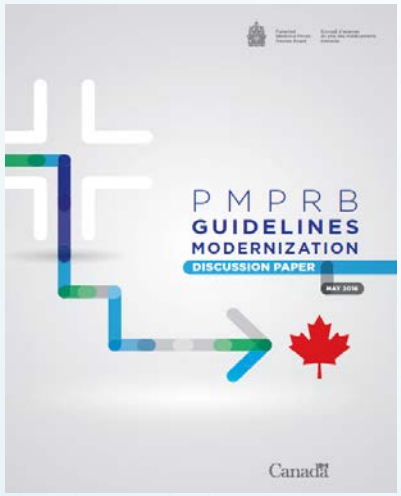
Like any technology intensive industry, pharma has evolved significantly

- Changes to IP and price regimes in exchange for increased domestic R&D investment
- Price ceilings based on public list prices that reflect market prices
- Market dominated by small molecule drugs indicated for more common ailments

- Higher prices and a decline in domestic R&D investment
- Confidential rebates and inflated list prices
- Specialized biologic and genetic therapies are fastest growing drug classes

We've been consulting since June 2016

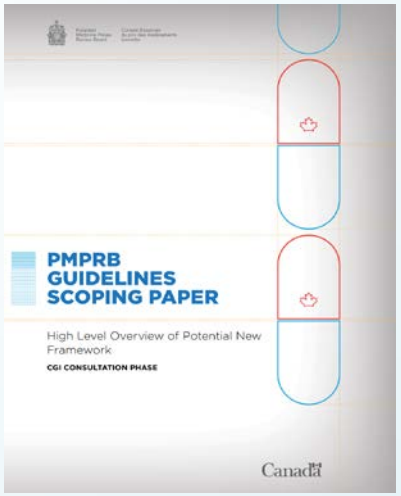
PMPRB Discussion paper on Guideline reform



Health Canada pre-consultation on regulatory amendments

Health Canada Gazette 1

PMPRB Guidelines scoping paper

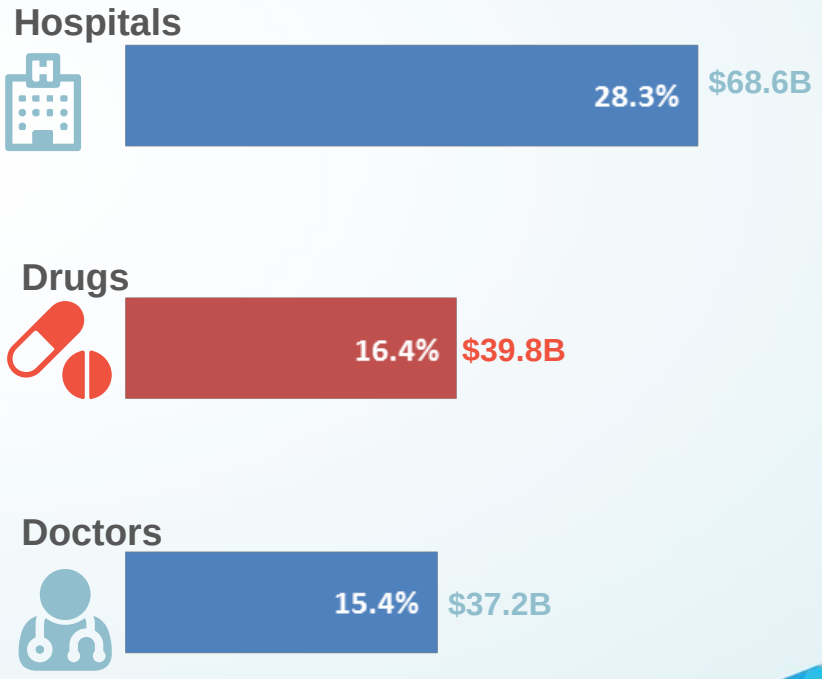


Pharmaceuticals are important to the health of Canadians and form a vital part of our health care system

- Drugs are helping to cure or manage previously debilitating or fatal diseases, allowing Canadians to live longer, healthier and more satisfying lives
- New classes of drugs, including biologics and genetic therapies, have begun offering innovative treatments for such diseases as hepatitis C, HIV and arthritis
- In 2017, Canadians spent nearly **$40 billion** on pharmaceuticals
- At **16.4%** of total health care spending, drugs now rank ahead of spending on doctors

2017 Canadian Health Care Spending by Use of Funds

% of total health care spending; total amount of spending $ billions



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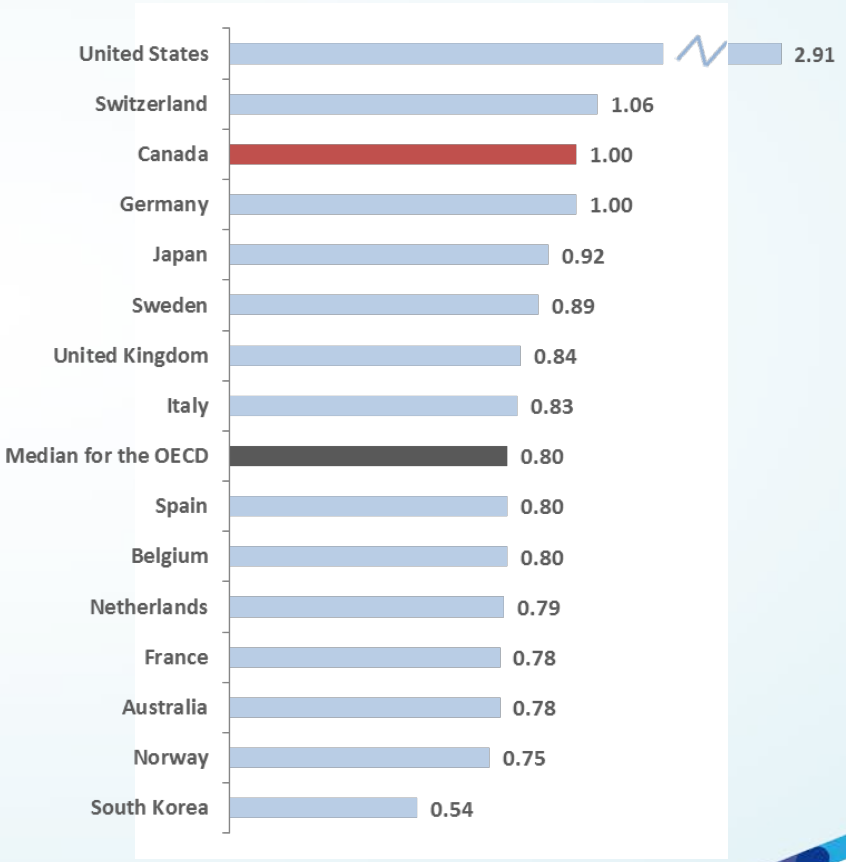
Unfortunately, Canadians are paying higher prices for prescription drugs than they should

- Patented drug prices in Canada are the third highest in the world behind only the US and Switzerland
- Moreover, Canadians are paying **25%** more, relative to the OECD average, for the same patented drugs
- This disparity is costing Canadians and their public and private drug plans billions of dollars each year

Example:

In Ontario, a top-selling arthritis drug costs almost $30,000/year. In France, that same drug costs about $22,000/year. Paying France's price for that drug would have saved $220 million last year on just that one drug.

Average Foreign-to-Canadian Price Ratios
Patented drugs, selected comparator countries, 2016



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For many Canadians, affording prescription drugs is a heavy burden or even completely out of reach

- About **1 in 5** Canadians report having no prescription drug coverage while many more are underinsured or face high deductibles or co-pays
- Almost **1 in 10** Canadians have had to forego filling a prescription drug in the past year for reasons related to cost
- Many Canadians who forego filling prescriptions seek additional health care services
- The cost of paying for prescription drugs means that many Canadians must forego paying for basic necessities like food and heat

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

Percentage of Canadians without prescription drug coverage

Percentage of Canadians who had to forego filling a prescription because of cost

374K

Canadians used additional health services as a result of foregoing a prescription drug in the past year

1.4M

Canadians had to forego other spending, including basic necessities, to pay for prescription drugs in the past year

The answer isn't to spend more; we need a solution that will bring fair prices and sustainable drug costs for Canada

- Canada already spends more money on drugs per capita than every other country in the world except the US and Switzerland, which are seen as outliers
- And yet we lag our peers in almost every measure of drug affordability and accessibility
- As the trend toward higher-cost, specialty drugs continues, we cannot simply continue to pay higher-than-average prices for drugs
- Canada needs a modernized approach to regulating drug prices that will provide long-term sustainability and protect Canadians from excessive prices

Per Capita Spending on Drugs

Total expenditures on drugs per capita, Canadian dollar purchasing power parity, selected comparator countries, 2015

The Current Regime

New patented drugs are assessed for level of therapeutic benefit relative to existing therapies and assigned 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.

Where PMPRB staff and a patentee disagree about whether a new or existing drug is excessively priced, a hearing may be held before PMPRB Board Members.

If Members decide a drug is excessively priced, they can order the patentee to reduce its price and/or pay back excess revenues.

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 Changes to the *Patented Medicines Regulations*

These changes will give the Patented Medicine Prices Review Board (PMPRB) the modern tools and information it needs to protect Canadians from excessive drug prices

1. We will **benchmark prices against countries that are more like Canada** economically and from a consumer price protection standpoint

2. We will enable the PMPRB to **see the actual prices being paid in Canada** and not just the list prices being published by pharmaceutical companies

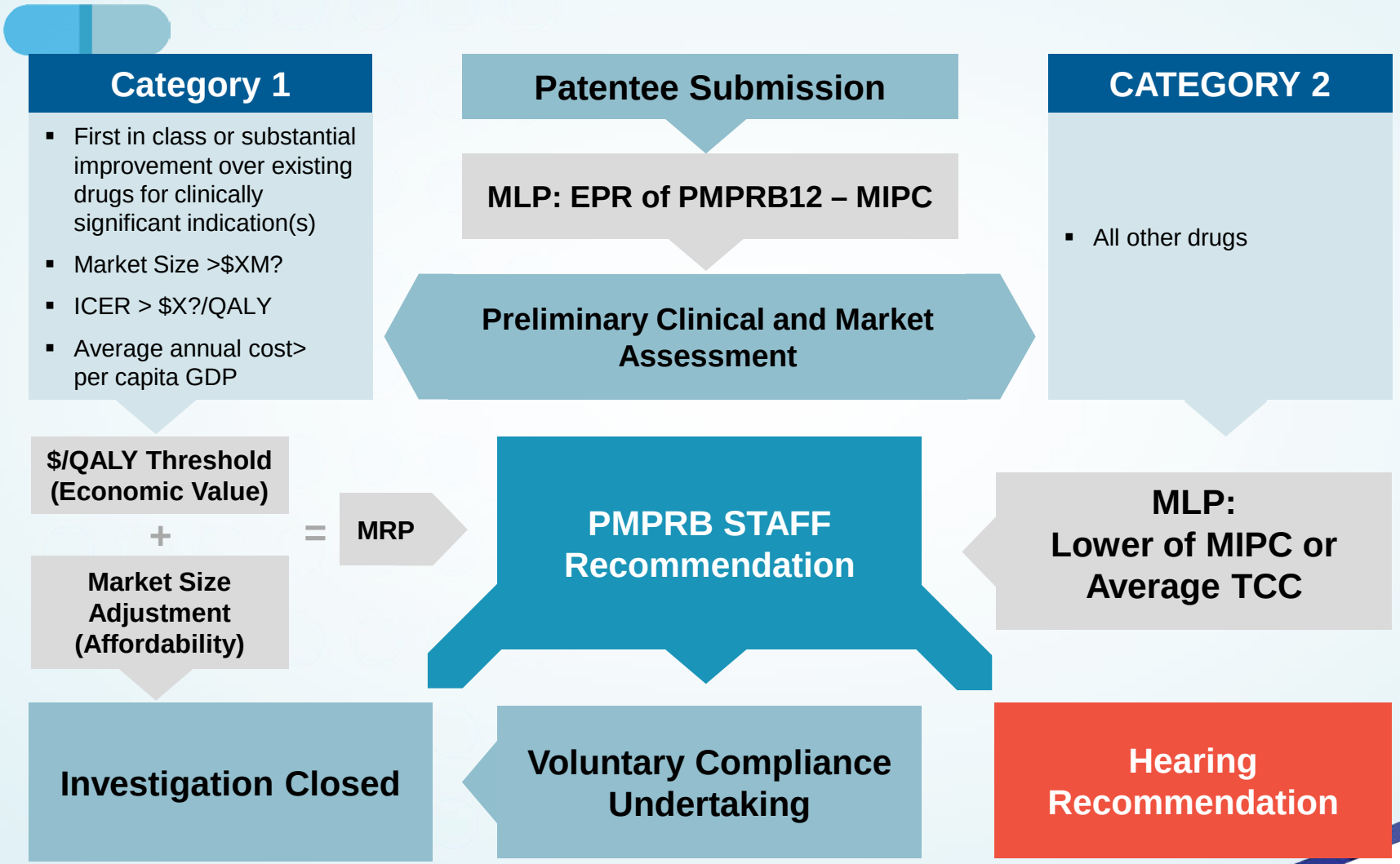
3. We will **take a drug's value and overall affordability into account** when setting the maximum price

These proposals will bring us in line with the policies and practices of most other developed countries

Overview of new Guidelines framework

- A risk-based approach to price regulation that considers value and affordability, in addition to list prices in other like-minded countries.
- Basic structure can be broken down into 5 parts:
  - Part I: ‘Maximum List Price’ (MLP) for all new drugs at introduction based on median of PMPRB12 (MIPC)
  - Part II: Screening of drugs into high priority (Category 1) or low priority (Category 2)
  - Part III: ‘Maximum Rebated Price’ (MRP) for Category 1 drugs based on new pharmacoeconomic, market size and GDP factors
  - Part IV: Lower of MIPC and average of Therapeutic Class (ATCC) for Category 2 drugs
  - Part V: Re-benching
- The MLP will be a transparent ceiling based on public list prices but the MRP, which applies to Category 1 drugs only, will be confidential.
- To comply with the MRP, patentees of Category 1 drugs will be required to submit information on undisclosed rebates to third parties.

Proposed PRICE Review Schematic



Application of new factors to Category 1 drugs – potential thresholds

Type of review	$/QALY target to set MRP	Market impact adjustment
Baseline New Drug (market size up to $20M)	$60K	N/A
"Premium" New Drug (e.g. high burden, EDRD, significant absolute QALY gain)	$90K to $150K	N/A
High Impact New Drug (market size over $20M)	$60K	10% reduction on MRP for each additional $10M market size (to 50% maximum)

Separating myths from facts

Myth: These changes will lead to a loss of R&D and manufacturing

Fact:

- Most of Canada's peer countries receive far greater levels of R&D investment despite having considerably lower drug pricing
- For example, Belgium receives 13 times more R&D investment dollars per resident than Canada despite the fact that Belgian prices are 20% lower than Canadian prices
- Canada has been and will continue to be one of the top nations in per capita drug spending and yet pharmaceutical R&D and manufacturing in Canada have been steadily decreasing – a trend that was well underway before any proposal to amend regulations

Comparison of R&D Spending Relative to Pricing

Selected comparator countries

Country	R&D Spending per Resident (relative to Canada)	Price Discount (relative to Canada)
Belgium	↑ 1215%	↓ 20%
Sweden	↑ 546%	↓ 11%
United Kingdom	↑ 408%	↓ 16%
France	↑ 292%	↓ 22%
Netherlands	↑ 115%	↓ 21%
Canada	--	--

Myth: New drugs won't come to market in Canada as quickly or at all

Fact:

- Canada's access to new patented drugs is in line with the average for comparator countries
- In fact, all these countries have lower drug prices, yet several have better access to new drugs
- The reality is that new medicines are launched in countries with higher and lower priced medicines in comparable timeframes
- Even with reduced prices, Canada will continue to be a significant consumer of medicines and an important market for new patented drugs

Comparison of New Drugs Launched Relative to Pricing

Selected comparator countries

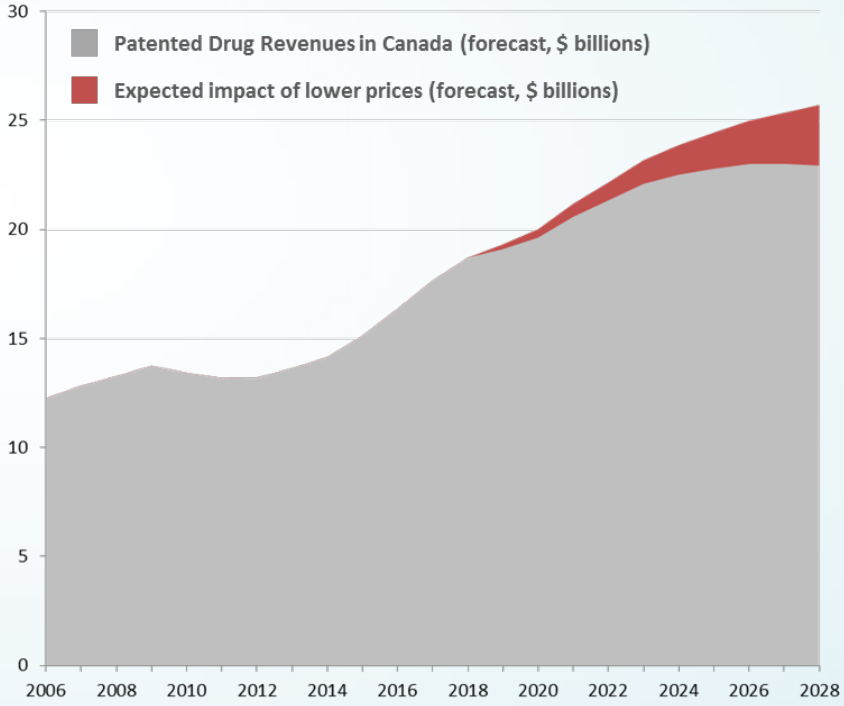
Country	New Drugs (relative to Canada)	Price Discount (relative to Canada)
United Kingdom	↑ 36%	↓ 16%
Sweden	↑ 22%	↓ 11%
Italy	↑ 18%	↓ 17%
Norway	↑ 12%	↓ 25%
France	↑ 2%	↓ 22%
Canada	--	--

Myth: Drug companies will see huge financial losses

Fact:

- In fact, overall spending on patented drugs is expected to continue to rise, even as prices drop
- The proposed reforms are expected to have only a modest impact on prices, gradually reducing average prices of patented drugs in Canada by about 11% over the next 10 years
- These reductions are expected to be further mitigated by the likelihood that lower prices should actually increase the use of drugs overall

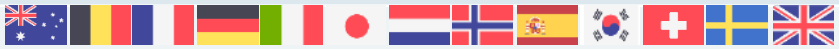
Patented drug spending will continue to rise



Myth: Canada's approach is out of step with approaches in the rest of the world

Fact:

- The reality is that Canada, as a nation, is actually falling behind
- Many of our international partners long ago updated their rules to constrain rising drug prices and to improve access and appropriate use
- The measures that we are proposing are, in fact, similar to or drawn directly from those already in place in other countries—including those with large pharmaceutical industries

Approach to Drug Pricing	Countries that don't	Countries that do
Use international price referencing		
Explicitly consider opportunity cost in pricing decisions		
Price regulator informed of actual market prices		

We're not out of step—we're playing catch-up

Next Steps

PMPRB Framework Modernization Steering Committee and Technical Working Group:

Provide feedback and advice on proposed framework which aims to achieve the following dual objectives:

1. Operationalize amendments to the Patented Medicines Regulations designed to lower patented drug prices; and,

2. Support a risk-based approach to regulating drug prices that simplifies and streamlines compliance for patentees.