



Patented
Medicine Prices
Review Board

Conseil d'examen
du prix des médicaments
brevetés

PMPRB Framework Modernization

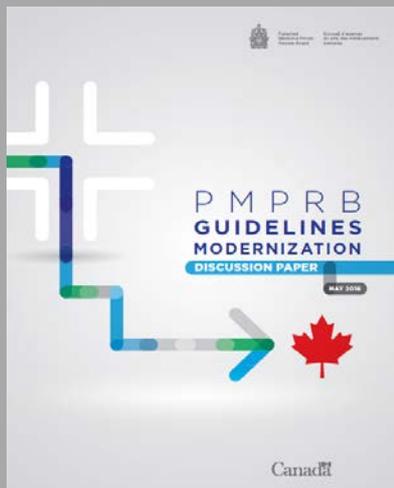
*Presentation to Working Group
July 26, 2018*

Outline

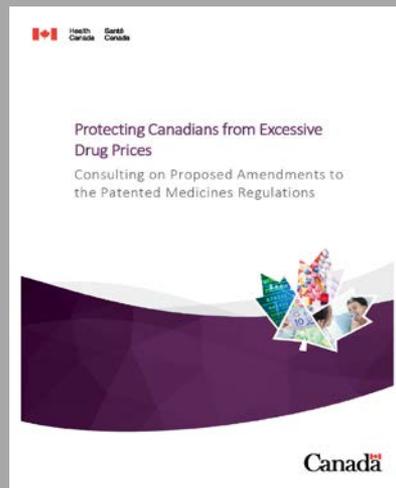
- Summary of proposed regulatory amendments
- Overview of proposed New Guidelines framework
- Steering Committee Mandate

We've been consulting since June 2016

PMPRB
Discussion paper on
Guideline reform



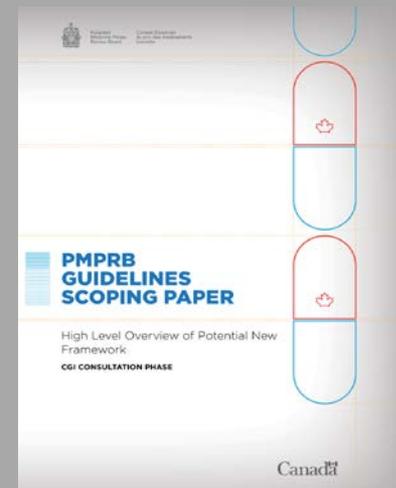
Health Canada
pre-consultation
on regulatory
amendments



Health Canada
Gazette 1



PMPRB
Guidelines
scoping paper



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.

Framework modernization

The three key changes being proposed will allow PMPRB to:

1. Compare prices to basket of countries that align more closely with Canadian context and priorities;
2. See what actual prices are being charged in Canada, so that whole regime isn't based on false values from the outset;
3. Consider the value of a drug and its potential impact on pharmaceutical spending in the price review process.

Changing the basket of countries

Currently, the PMPRB checks the prices of patented drugs in 7 comparator countries to set the ceiling price of a new drug in Canada

The Government is proposing to include additional comparator countries and to drop the 2 outliers:

- United States whose drug prices are three times higher than other countries
- Switzerland whose GDP per capita is almost double that of Canada

PMPRB-7 (existing basket)		
Country (¹ retained in new basket)		CDN Price Ratio
 France ¹		0.78
 Germany ¹		1.00
 Italy ¹		0.83
 Switzerland		1.06
 Sweden ¹		0.89
 United Kingdom ¹		0.84
 United States		2.91

PMPRB-12 (new basket)			
Country (² added to new basket)	CDN Price Ratio	Country (² added to new basket)	CDN Price Ratio
 Australia ²	0.78	 Norway ²	0.75
 Belgium ²	0.80	 South Korea ²	0.54
 France	0.78	 Spain ²	0.80
 Germany	1.00	 Sweden	0.89
 Italy	0.83	 United Kingdom	0.84
 Japan ²	0.92		
 Netherlands ²	0.79		

Regulating true prices

- When the PMPRB was created, actual prices paid in the market matched the public list prices
- Now, as a result of significant discounts and rebates to third-party payers, actual prices paid in the market are significantly lower than list prices
- Without access to this information, the PMPRB is unable to set ceiling prices that are actually meaningful to payers.

Current



Proposed



New pricing factors

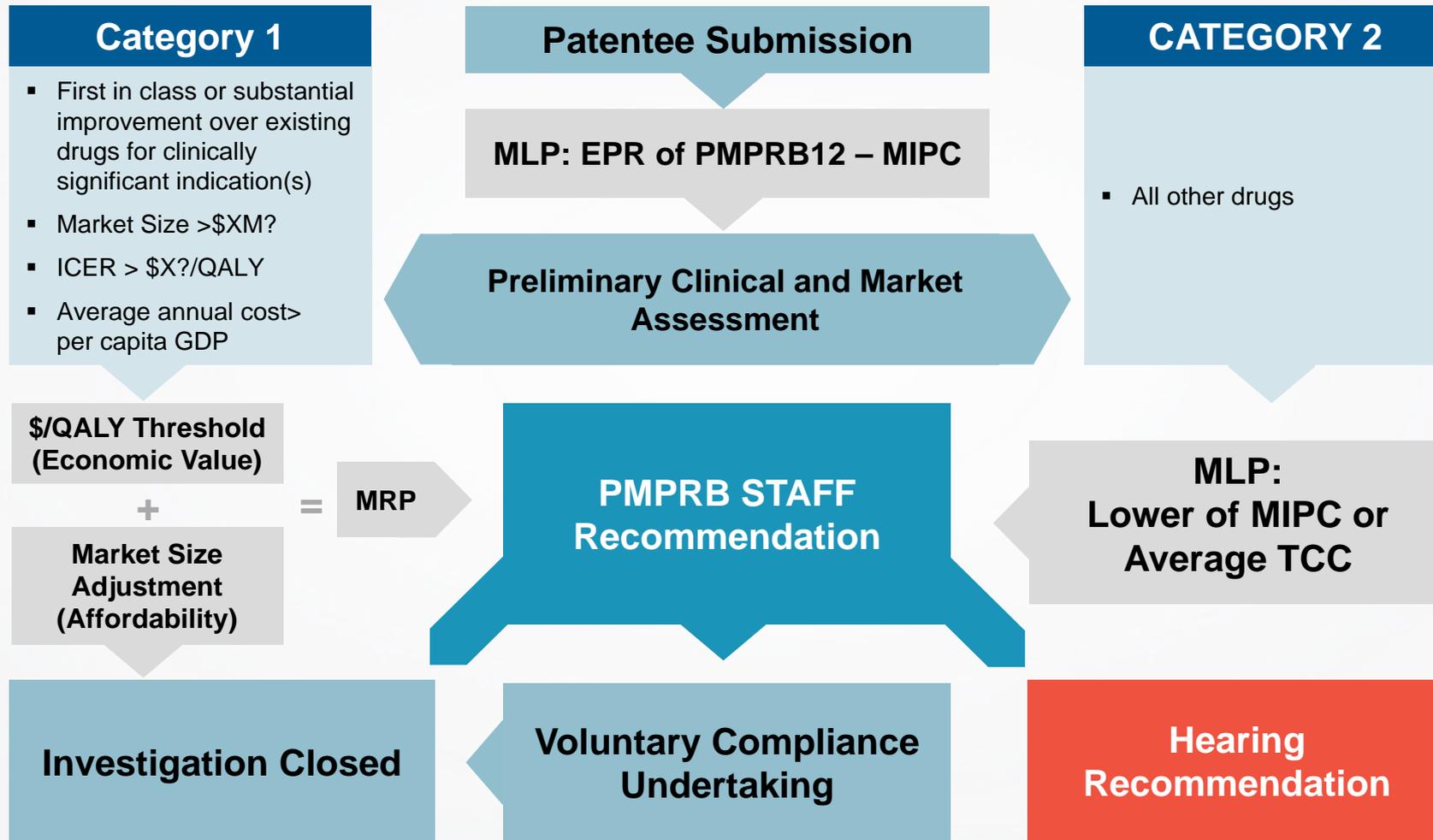
Most other regulators look at additional factors beyond simply comparing prices paid in other countries, such as value for money and the size of the market

Factor	Description	Comparator Countries Using the Factor
Value for Money	<ul style="list-style-type: none"> Comparison of the costs and benefits of a drug to patients and the healthcare system If paying for the drug would result in a net loss in total population health because it costs substantially more than existing drugs which provide the same or greater amount of health benefit, the price must come down 	
Size of the market	<ul style="list-style-type: none"> Consideration of ability-to-pay in Canada and the flexibility to re-assess subsequent changes in market size So, if a drug serves a significant number of patients, its high cost could make it unaffordable and limit access to a subset of the patient population 	
Canadian GDP and GDP per capita	<ul style="list-style-type: none"> Growth in GDP can be used as an indicator of the country's ability to pay while per capita GDP is a proxy for buying power at the level of the individual So, if the price exceeds the ability of Canada (measured by GDP) or Canadians (measured by GDP per capita) to pay for the drug, it may suggest that the drug price is excessive 	

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



Old vs new regime...

Rule	How The Current Regime Works	How The Updated Regime Would Work
How international prices affect maximum prices in Canada	A new and improved drug cannot be priced higher than the median price of that same drug in the PMPRB7	All new drugs cannot be priced higher than the median price of that same drug in the PMPRB12
How domestic prices affect maximum prices in Canada	A new drug that isn't an improvement over existing drugs cannot be priced higher than the highest priced existing comparator drug in Canada	A new drug that isn't an improvement over existing drugs cannot be priced higher than the lower of the average price of existing comparator drugs in Canada and the median of the PMPRB12
How inflation affects maximum prices in Canada	The price of a drug can increase every year with inflation. However, if a drug's price decreases in one year, its ceiling price the next year will be constrained by that decrease in price.	The ceiling price of a new drug is fixed at introduction. Prices can vary freely below this level in subsequent years. .
Changes to the maximum ceiling price after a new drug enters Canada	Once a new drug is given its ceiling price, it can only change through inflation or if the drug company voluntary lowers it.	The maximum price may be rebench after a few years based on specific changes in market conditions.

Old vs new regime (continued)

Rule	How The Current Regime Works	How The Updated Regime Would Work
Pharmacoeconomics	How much a drug costs for the amount of benefit it provides (e.g., \$100 a pill for a year of healthy life) is not considered by the PMPRB in setting a maximum price	The cost-effectiveness of Category 1 drugs in terms of cost per quality-adjusted life year (QALY) is assessed against an evidence based threshold
Market size and GDP*	The total amount of money available to be spent on new drugs every year is not considered by the PMPRB in setting a maximum price	The market size of a new drug is a function of how much it costs and how many patients will need it. Drugs that are expected to have a significant market size and impact on the healthcare system will have a lower ceiling price to deter rationing.

*Each year, the amount of money available to be spent on new drugs depends on total spending on drugs the year before and how much the economy is growing. For example, if Canada spent \$1000 on drugs in 2018 and its economy grew by 2%, it would have \$20 more to spend on the new drugs that come to market in 2019 (for a total of \$1020)

Part 1: Median international price test (MIPC)



- All new drugs are assigned a Maximum List Price (MLP) based on the median of the PMPRB 12 (MIPC).
- IMS will be used to verify international list prices.
- Category 1 drugs will be given both an MLP based on the MIPC and a Maximum Rebated Price (MRP)
- All other drugs will be deemed Category 2 and have an MLP based on the lower of the MIPC and the average of the domestic therapeutic class (ATCC).
- No Category 2 drug will be given an MLP that is lower than the lowest price country in the PMPRB12 (LIPC floor).

Part II: Screening



- Drugs will be screened into Category 1 if they are:
 1. First in class or substantial improvement over existing therapy
 2. Expected to have sales in excess of a \$X million/year market size threshold
 3. Above a \$X/QALY threshold for clinically significant indications
 4. Have an average annual treatment cost above per capita GDP.

Part III: MRP for Category 1 drugs



- Step 1: application of pharmacoeconomic factor
 - Empirical work undertaken by Karl Claxton at the University of York suggests a \$30K/QALY opportunity cost threshold for Canada.
 - Question whether and to what extent that estimate should be taken into account in at the screening phase to determine whether a drug should go in Category 1 or Category 2.
 - Category 1 drugs will then be subject to a baseline maximum value-based price ceiling of \$X/QALY, for reasons of practicality and efficiency.
 - Drugs that meet certain clinical characteristics (e.g., high burden of disease or significant absolute gain in QALY) may be subject to a higher \$/QALY ceiling.

Part III: MRP for Category 1 drugs (continued)

- Step 2: application of market size and GDP factors
 - A Category 1 drug that meets the applicable \$/QALY ceiling may still face an adjustment in price if the application of the market size and GDP factors raise affordability concerns.
 - Using new drug contribution to GDP and GDP growth over the last five years, the PMPRB is estimating a threshold of \$XM per new drug.
 - New Category 1 drugs with an estimated market size that exceeds this threshold within any of its first five years of sale will require further price adjustments.
 - The adjustment would see the MRP reduced by a certain percentage discount which would increase as the expected market size increases (see next slide).
 - The market size threshold would also increase annually based on GDP growth and/or CPI.

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)

Part IV: MLP for Category 2 drugs



- As mentioned, Category 2 drugs have an MLP based on the lower of the MIPC and the average of the domestic therapeutic class (ATCC).
- However, no Category 2 drug will be given an MLP that is lower than the lowest price country in the PMPRB12 (LIPC floor).

Part V: Re-benching



- All new drugs will be given an interim MLP of 3 years or until the drug is sold in 7 countries, whichever comes first.
- MLP is then frozen, as is MRP, unless re-benching is triggered by one of the following criteria:
 - Approval of a new indication
 - Sales in excess of expected market size
 - New evidence on cost-effectiveness (e.g. CADTH therapeutic class review or lifting of HC conditions on NOC)
 - Significant changes in international prices (eg. MIPC < MIPC at intro by more than 25%)
- Patentees may apply for a re-benching with evidence of increased cost-effectiveness, smaller market, or a significant increase in CPI

How compliance with new price ceilings will be assessed

- Price reviews will be conducted for the following customer classes:
 - National Retail – list price assessed against MLP
 - National Private Payer – average transaction price (ATP) assessed against MRP
 - Provincial Public Payer – ATP assessed against MRP in each market
- ATPs are calculated net of all discounts to determine compliance with confidential MRP.
- Category 2 drugs will be assessed against MLP.

How pricing complaints will be managed



Complaints received by the PMPRB will trigger an investigation, during which the PMPRB will assess whether:

1. a drug is in compliance with the Guidelines; and
2. whether circumstances in the market have changed to warrant a rebenching/reclassification.

Application of new Guidelines to existing drugs



- Existing drugs will be given an interim price ceiling based on the MIPC of the PMPRB12.
- An existing drug will only be classified as Category 1 if it fails a \$X/QALY screen for any indication (would be higher than screen used for new drugs, for administrative and operational reasons).
- Existing drugs that are screened into Category 1 will be prioritized for re-benching.
- Category 2 drugs will be re-benched later unless a complaint is received.
- All drugs within a therapeutic class will be assessed at the same time for the purposes of the ATCC test.
- Patentees will be advised in advance of re-benching and given two reporting periods to come into compliance.

PMPRB Guidelines Modernization Steering Committee

- The Steering Committee is being asked to provide targeted stakeholder feedback on key features of a new Guidelines framework which will serve 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.
- In deliberating on the above, the Steering Committee should seek to strike a balance between the following guiding principles:
 - Sustainability
 - Predictability
 - Consistency
 - Functionality
 - Fairness
- The Steering Committee will be informed by the technical Working Group (the “**Working Group**”).

Suggested questions for Steering Committee

- Is the proposed division and treatment of Category 1 and Category 2 drugs a reasonable risk-based regulatory approach?
- Is an MLP based on the median of the PMPRB12 (MIPC) for all drugs reasonable?
- Should exceptions be made to the MLP-MIPC test and, if so, when and why?
- Should there be a price floor for Category 2 drugs based on LIPC?
- Should further drug categories exist with different treatment modalities from those proposed?
- Should more or less criteria be considered in screening a drug as higher risk and, where should the line be drawn with respect to the criteria?
- Should the pharmacoeconomic, market size and GDP factors apply both as screens and thresholds?
- Should Category 2 drugs be scrutinized more or less than proposed?
- Should the cost effectiveness threshold for Category 1 drugs vary?
- Should a Category 1 drug ever have more than one MRP?
- Are there economic considerations that would support a higher MRP for some Category 1 drugs than would result from the proposed application of the new factors?
- How often and in what circumstances should a drug be rebenchmarked?
- Should confidential third party pricing information only be used for compliance purposes?
- Is there a better way to deal with existing drugs under the new framework?
- Are there opportunities to further reduce regulatory burden while respecting the dual objectives?