PMPRB Draft Guidelines Consultation

Webinar – Friday, January 17, 2020

PMPRB GUIDELINES 2019

Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Outline

- Amendments to the Patented Medicine Regulations
- PMPRB draft Guidelines
- Next steps

Amendments to Patented Medicine Regulations

Published in Canada Gazette, Part II on August 21, 2019
Coming into force on July 1, 2020

PMPRB

New basket of countries

Applies to all patented medicines

Canada Gazette Part II (CGII)

6. The schedule to the Regulations is replaced by the schedule set out in the schedule to these Regulations.

SCHEDULE (Subparagraph 4(1)(f)(iii)

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

- Countries with similar consumer protection priorities, economic wealth and marketed medicines as Canada

Previous comparator countries: PMPRB7	Foreign-to-Canadian price ratio		New comparator countries: PMPRB11
France	0.75	0.75	France
Germany	1.12	1.12	Germany
Italy	0.95	0.95	Italy
United Kingdom	0.94	0.94	United Kingdom
Sweden	0.93	0.93	Sweden
Switzerland	1.12	0.74	Australia
		0.79	Belgium
		0.92	Japan
United States	3.36	0.80	Netherlands
		0.78	Norway
		0.80	Spain

New factors

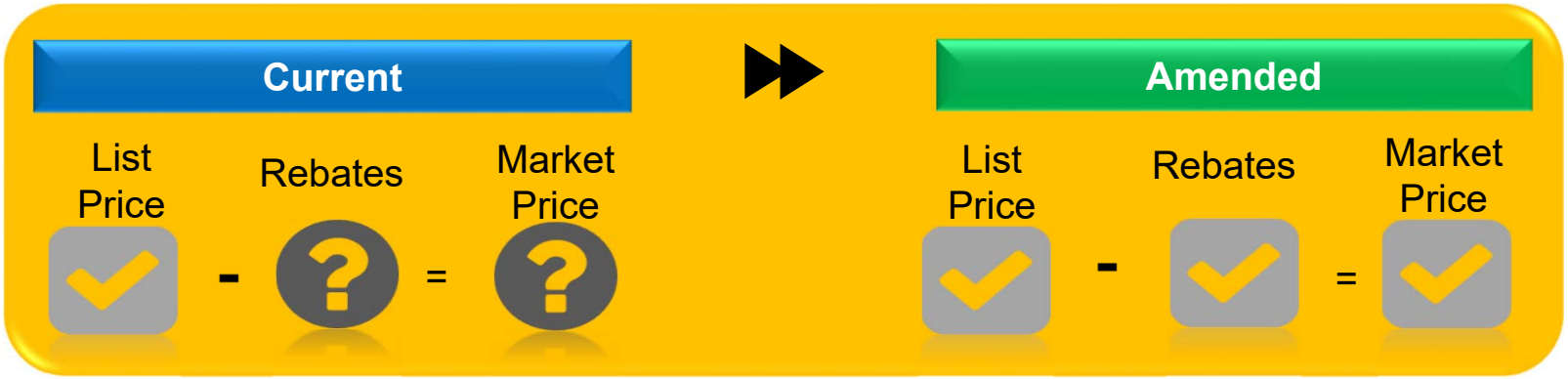
Apply to new patented medicines approved starting with August 21, 2019

Canada Gazette Part II (CGII): *4.4 […] the other factors that the Board shall take into consideration to determine whether a medicine that is sold in any market in Canada after June 30, 2020 is being or has been sold at an excessive price are the following:*
(a) the medicine's pharmacoeconomic value in Canada;
(b) the size of the market for the medicine in Canada; and
(c) the gross domestic product in Canada and the gross domestic product per capita in Canada.

Factor	Description	Comparator countries using the factor
Value for Money	The PMPRB will consider the opportunity cost of a medicine in the health system when evaluating whether its price is excessive.	
Size of the market	PMPRB will consider the economic impact of paying for the medicine for everyone who needs it when evaluating whether its price is excessive.	
GDP and GDP per capita	In looking at market size, the PMPRB will consider GDP and GDP per capita as indicators of what Canada and individual Canadians, respectively, can afford to pay for new patented medicines.	

Modernized reporting requirements for patentees:
Must provide information relating to both direct and indirect rebates

Canada Gazette Part II (CGII): *3(4) […]*
(a) in calculating the average price per package of a medicine, the actual price obtained by the patentee shall be used, taking into account any adjustments that are made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine and any reduction given to any party in the form of free goods, free services, gifts or any other benefit of a like nature; and
(b) in calculating the net revenue from sales … the actual revenue obtained by the patentee shall be used, taking into account any adjustments that are made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine and any reduction given to any party in the form of free goods, free services, gifts or any other benefit of a like nature.



Modernized reporting requirements for patentees:
Must provide information relating to the new factors

Canada Gazette Part II (CGII): *4.1 (1) […]* the patentee shall provide to the Board every cost-utility analysis prepared by a publicly funded Canadian organization, if published and communicated to the patentee, for which the outcomes are expressed as the cost per quality-adjusted life year for each indication that is the subject of the analysis.
4.1(5) An analysis shall be provided to the Board only if any cost for the medicine as identified in the analysis is or would be, when that cost is pro-rated to account for that medicine's use over a 12-month period, greater than or equal to 50 per cent of the gross domestic product per capita in Canada at the time of publication of the analysis.
4.2(1) […] the patentee shall provide to the Board the estimated maximum use of the medicine in Canada, as measured by the total quantity of the medicine in final dosage form expected to be sold.

Overview of the new PMPRB regulatory framework

Key differences between the old and new regulations

		Old regulations	New regulations
Existing factors (as per the Patent Act)	Internal price referencing	√	√
	External price referencing	PMPRB7: France, Germany, Italy, Sweden, Switzerland, United Kingdom, United States	PMPRB11: Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, Spain, Sweden, United Kingdom Applies to all patented medicines
	CPI changes	√	√
New factors (as per the amended regulations) Apply to new patented medicines	Pharmacoeconomic value (only for high-cost medicines)	X	Given the limitations of evaluating if a price is excessive on the basis of unit price, the PMPRB will consider the opportunity cost of a medicine in the health system when evaluation if a price is excessive.
	Market size	X	PMPRB will consider the economic impact from the sales for the medicine when evaluating if a price is excessive.
	GDP and GDP per capita	X	These measure are a proxy of what the entirety of the Canadian population, or the individual consumers can afford to pay for the new patented medicines
Reporting requirements	Net revenues	Excluding: rebates, discounts, refunds, free goods, free services, gifts or other benefit of a like nature	Excluding: reductions given to any party in the form of free goods, free services, gifts or any other benefit of a like nature (e.g. rebates and discounts provided to third party insurers)
	Patented OTC/ veterinary/ generics	√	Reduced reporting obligations for medicines at the lowest risk of excessive pricing
	Pharmaco-economic info*	X	Cost-utility analyses from a publicly funded Canadian organization.
	Market size information**	X	Estimated maximum use of the medicine in Canada, based on the prevalence of the approved therapeutic use of the medicine in Canada

Difference between the proposed and final amended regulations

1. **Grandfathering**

   Medicines with DINs issued prior to August 21, 2019 are not subject to the new excessive pricing factors

2. **Demarcated filing requirements**

   Patentees are not required to file cost utility analyses for medicines for which annual treatment costs are less than 50% of GDP per capita

3. **Schedule of comparator countries**:

   South Korea was removed from the schedule

PMPRB Draft Guidelines

Released Nov 21, 2019

Breakdown of proposed new Guidelines

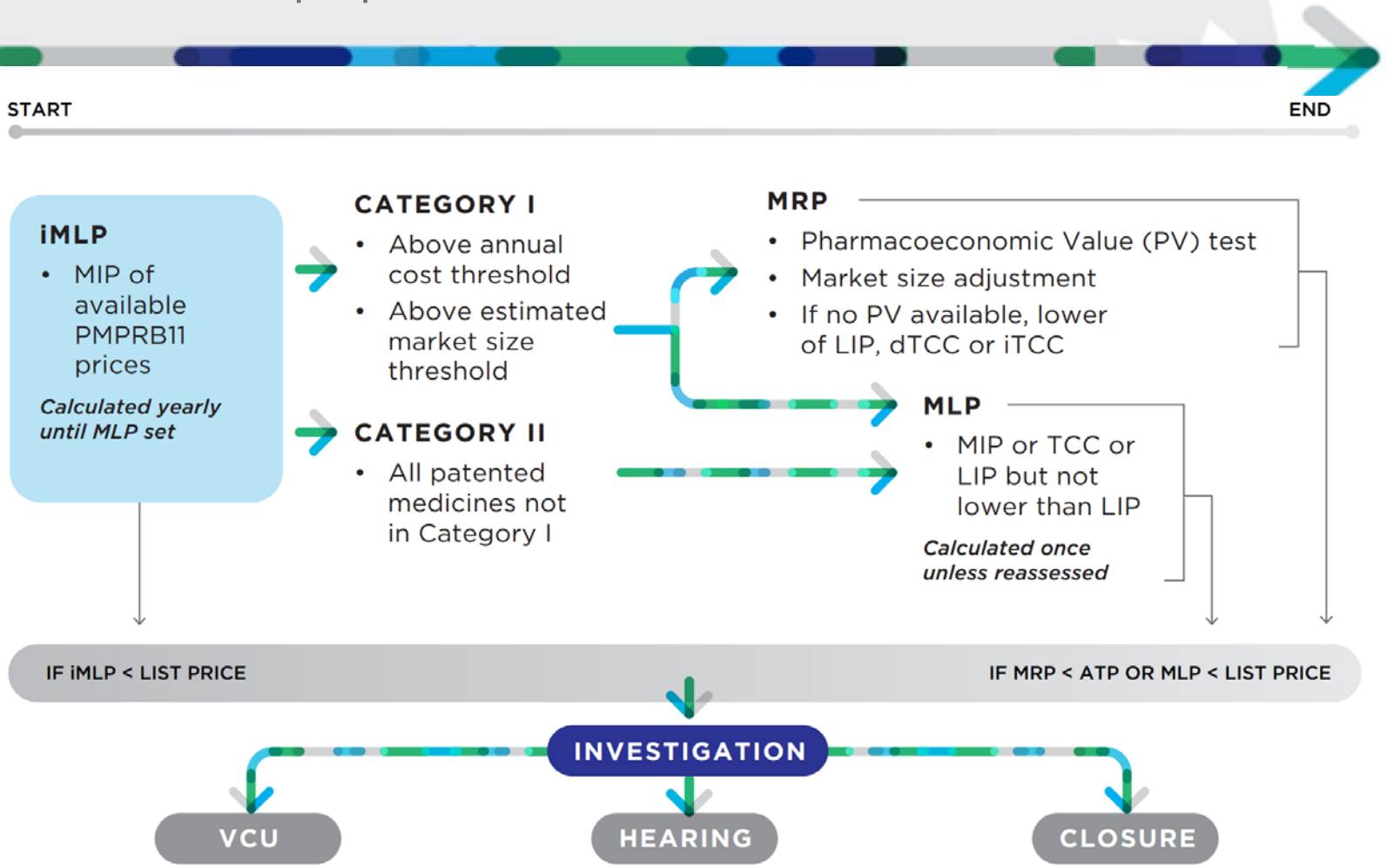
A risk-based approach to price regulation that considers value and affordability, in addition to list prices in other like-minded countries.

- Price review process

1. **STEP 1: iMLP (ALL PATENTED MEDICINES)**
2. **STEP 2: MLP (ALL PATENTED MEDICINES)**
3. **STEP 3: MRP (CATEGORY I PATENTED MEDICINES ONLY)**
4. **STEP 4: IDENTIFICATION OF RELEVANT INDICATION**

- Reassessment
- Filing requirements

Schematic of proposed new Guidelines



iMLP – interim Maximum List Price

MLP – Maximum List Price

MRP – Maximum Rebated Price

MIP – Median International Price

LIP – Lowest International Price

dTCC – domestic Therapeutic Class Comparison

iTCC – international Therapeutic Class Comparison

ATP – Average Transaction Price

STEP 1: interim Maximum List Price (iMLP) – all patented medicines

Previous Guidelines	Proposed Guidelines: iMLP
The interim ceiling is calculated annually	
Interim period ends after 3 years or the point at which the same medicine is sold in at least 5 countries	

1. STEP 1: iMLP (ALL PATENTED MEDICINES)

37. At introduction, an **interim maximum List Price** ceiling is set (the "**iMLP**") for the sale of the patented medicine. The iMLP is set at the median international list price ("**MIP**") for the PMPRB11 countries for which the patentee has provided information during the interim period. Patentees must ensure that the patented medicine's gross[9] publicly available Canadian ex-factory price ("**List Price**") is no higher than the iMLP for the period during which it is applicable, failing which the price may be subject to additional review or investigation by Staff.

38. The iMLP will be recalculated annually and will apply until the ***earlier of***: (i) three (3) years from the date of the introduction of the patented medicine in Canada; or (ii) the date when the patentee has filed international price information for at least five (5) of the PMPRB11 countries. At the end of the interim period, the MLP will be set (see Step 2) and the iMLP will cease to apply.

Step 2: Maximum List Price (MLP) – all patented medicines

Previous Guidelines: MAPP	Proposed Guidelines: MLP
Approach differs across the four categories of therapeutic improvement:	Same approach applies to all drugs, irrespective of the category:
One, or a combination of the following approaches apply depending on the • Median International Price Comparison (MIPC) • Midpoint • Therapeutic Class Comparison (TCC) • Reasonable Relationship (RR) • Highest International Price Comparison (HIPC)	• Median International Price (MIP) • Therapeutic Class Comparison (TCC) • Lowest International Price Comparison (LIP) • Reasonable Relationship (RR) The MLP is set by the lowest of the MIP and the TCC, but not lower than LIP
The MAPP may fluctuate	The MLP is frozen after the interim period, and may change only if MIP changes by +/- 10%
Assessed at the Average Transaction Price (ATP)	Assessed at list price level (highest price if multiple list prices)
More complex List price ceiling is determined by applying five tests depending on the level of therapeutic improvement. Ceilings can fluctuate over time. Any market.	**Less complex** MLP applied in the same way to all patented medicines irrespective of the categorization. List to List assessment. Ceilings are frozen, greater predictability.

Domestic Therapeutic Class Comparison (dTCC)

Previous Guidelines	Proposed Guidelines
Highest of the highest The highest list price for each comparator, and then consider the highest treatment cost across all comparators.	**Median of the lowest** The lowest list price for each comparator, and then consider the median treatment cost across all comparators.
Lowest list price across domestic prices sources	
Application varies based on the level of therapeutic improvement. Not applied to Breakthrough medicines.	Applies to all medicines in the same way

dTCC test

Following the identification of medicines for comparison purposes and of their lowest public price for each medicine, the cost of comparable courses of treatment for each medicine will be calculated. These costs of treatment will be ordered and the median identified. In the event of an even number of medicines used for comparison purposes, the median will be the simple average of the middle two costs of treatment. This median cost of treatment will then be divided by the constituent units of the comparable course of treatment for the medicine under review to establish a per-unit price.

STEP 3: Maximum Rebated Price (MRP) – Category I patented medicines only

- Confidential, non-transparent price celling
- MRP assessed at the Average Transaction Price (ATP) level: patentees must ensure that the 'Net Price' of a Category 1 medicine in Canada is no higher than the MRP.

3. STEP 3: MRP (CATEGORY I PATENTED MEDICINES ONLY)

48. Patented medicines will be classified as either **Category I** or **Category II** based on certain market characteristics. In addition to the iMLP/MLP, Category I patented medicines are also subject to a "**Maximum Rebated Price**" ceiling ("**MRP**"). The MRP takes into account therapeutic value and affordability measures (e.g. the pharmacoeconomic value and market size for the patented medicine). Patentees must ensure that the patented medicine's **Net Price**[12] in Canada, (e.g., its average transaction price or "**ATP**") is no higher than the MRP, failing which the price may be subject to additional review or investigation by Staff.

Less complex
MRP assessed against National ATP rather than current any market approach (52 markets). Patentees are able to exercise discretion as to how to allocate rebates/discounts as long as on average the net price is below the MRP.

Classifying patented medicines

Previous Guidelines	Proposed Guidelines
Four categories depending on the level of therapeutic improvement: • Breakthrough • Substantial improvement • Moderate improvement • Slight/No improvement	Two categories related to the treatment cost and market size • Category I • Category II
Categorization for the purpose of choosing the approach that will establish the list price ceiling	While all products get a list price ceiling (MLP), the categorization is for the purpose of identifying the medicines that also warrant a rebated price ceiling (MRP)

More complex
Requires a scientific review of the level of therapeutic improvement

Less complex
Based on a calculation of treatment cost and the reporting of market size

Criteria for classifying a patented medicine as Category I

CGII: *The Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements) [the Amendments] update the PMPRB's regulatory framework to* ***a risk-based approach*** *that includes new price regulatory factors and patentee information reporting requirements to protect Canadian consumers from excessive prices.*

- ***12-month treatment cost greater than 50% of GDP per capita:*** following the filing of introductory period pricing information, the medicine's 12-month treatment cost will be calculated by Staff based on the maximum dosage per course of treatment listed in the product monograph; the maximum number of courses of treatment per 12 months, based on the nature of the condition, clinical practices, and other relevant criteria; and the highest Canadian List Price. If a List Price is not available, the national Net Price will be used.
- ***Estimated or actual market size (revenue) exceeds annual Market Size Threshold:*** the annual Market Size Threshold will initially be set at $25 million.[13]

Simplified categorization criteria compared to the Technical Working Group recommendation

The following criteria have been identified as supporting a Category 1 classification:

- ⊗ *A. The medicine is 'first in class' or a 'substantial' improvement over existing options;*
- ⊗ *B. The medicine's opportunity cost exceeds its expected health gain;*
- ✓ *C. The medicine is expected to have a high market impact;*
- ✓ *D. The medicine has a high average annual treatment cost.*

STEP 4: Identification of ‘Relevant Indication’

56. For patented medicines with more than one approved indication, the Relevant Indication for which the MLP (and MRP, if applicable) will be assessed will be determined by Staff. This could occur at introduction, or as part of a reassessment if additional indications are approved during the life cycle of the patented medicine (see section VI).

57. For Category I medicines, the Relevant Indication will be the indication triggering the Category I classification criteria for annual treatment cost in these Guidelines. For Category I medicines where more than one, or no, indications meet this threshold, and for Category II medicines, the Relevant Indication will be the indication treating the condition with the highest prevalence (i.e., the largest patient population).

Proposed MRP calculation

The **MRP** would be calculated as follows:

- The Incremental Cost-Effectiveness Ratio ("**ICER**") measured in cost per quality-adjusted life years ("**QALYs**") for each indication of the patented medicine will be identified from the cost-utility analyses filed by the patentee.
- The ICER will be compared against the applicable Pharmacoeconomic Value Threshold ("**PVT**") of $60,000 per QALY
- The price at which the patented medicine's ICER would be equivalent to the PVT will be identified (the "Pharmacoeconomic Price" or "**PEP**").
- The MRP may be further adjusted for market size if the patented medicine realizes annual quantities such that, if priced at the MRP set by the PEP, revenues would be in excess of $25 million
- For patented medicines with an estimated total prevalence no greater than 1 in 2,000 across all approved indications, the MRP will be set at 50% above the PEP, but will be further adjusted for market size if the patented medicine realizes annual revenues in excess of $12.5 million

If the procedure above results in an MRP that exceeds the MLP, the MRP will be set at the same level as the MLP.

Pharmacoeconomic Price: sources of information

CGII: *The patentee shall provide to the Board every cost-utility analysis prepared by a publicly funded Canadian organization, if published and communicated to the patentee, for which the outcomes are expressed as the cost per quality-adjusted life year for each indication that is the subject of the analysis.*

Perspectives

- Policy intent is a public payer perspective: CADTH will be the primary source, however INESSS may also be considered

Regulatory Impact Assessment Statement (RIAS): *the policy intent is for the PMPRB to adopt the perspective of the public health care system and favour a supply-side cost-effectiveness threshold in estimating opportunity cost.*

Cost-utility analysis

- Calculations will rely on the base-case reanalysis conducted by CADTH and INESSS, as opposed to the analysis conducted with the base case model submitted by the patentee.

List prices

- PMPRB will rely on ICER derived based on list prices unless the patentee can substantiate different prices

Pharmacoeconomic Price: indications and patient populations

- Multiple indications (triggering category 1 classification)
  - Draft Guidelines: "…*the Relevant Indication will be the indication treating the condition with the highest prevalence (i.e., the largest patient population)*."
- Multiple patient populations
  - Extending the Technical Working Group recommendations, a single ceiling price will be specified for each medicine that applies across all patient populations

Technical Working Group:
The Technical Working Group recommended to "Specify a single ceiling price for each medicine that applies across all indications

Pharmacoeconomic Price:
medicines with insufficient pharmacoeconomic evidence

53. If a patentee does not file a cost-utility analysis prepared by a publicly funded Canadian organization for a Category I patented medicine, or if the analysis submitted does not allow for the determination of the MRP as described above, the MRP may be set by using alternative methods. Such methods may include, but are not limited to:

-> The MRP being set by the LOWER of the LIP, the dTCC, or the iTCC, with further adjustments based on the Market Size Adjustment Methodology.

54. Because these scenarios are expected to be rare and fact dependent, they will be dealt with on a case by case basis.

55. Once set, the MRP will be only reassessed at a later point in time if it meets the criteria set out in section VI.

International Therapeutic Class Comparison (iTCC)*

Current Guidelines	Proposed changes
The iTCC test is not a primary price test. It is conducted in order to provide information in the context of an investigation into apparent excessive prices.	The iTCC test may be used as part of the calculation of a patented medicine's MRP.

ITCC test

Following the identification of medicines for comparison purposes and of the lowest public price for each medicine, the cost of comparable courses of treatment for each comparator medicine in each comparator country will be calculated. These costs of treatment will be ordered and the median identified for each country. In the event of an even number of comparator medicines used for comparison purposes, the median will be the simple average of the middle two costs of treatment. These medians will be ordered in a "median of the medians" will be identified. This median cost of treatment will then be divided by the constituent units of the comparable course of treatment for the medicine under review to establish a per-unit price. Local currencies will be converted to Canadian dollars using the methodology described in section V of these Guidelines.

Market size adjustment for Category I medicines

- A market size adjustment is applied to medicines with quantities sold such that annual revenues would exceed $25 million when priced at the MRP(s) set by the PEP
- Incremental adjustment based on units sold in each tier* over $25 million and this adjustment will be applied annually to determine the MRP

RIAS: *The impact of an excessive price is a function of both price and volume; the larger the size of the market for the medicine in Canada, the greater the impact of its price.*

Market size adjustment for Category I medicines

Annual revenues	Incremental adjustment factor	MRP	
		Medicines with a PEP	Medicines without a PEP
<$25M	0%	PEP	Lower of LIP, dTCC, iTCC
$25M–$50M	-10%	PEP adjusted by applicable factor	Lower of LIP, dTCC, iTCC adjusted by applicable factor
$50M–$75M	-20%		
$75M–$100M	-30%		
$100M–$125M	-40%		
$125M+	-50%		

*These tiers may also be adjusted from time to time, and at least every five years, to reflect changes in CPI and GDP.

Market size adjustment for Category I medicines that treat rare diseases

- For category 1 medicines with an estimated total prevalence no greater than 1 in 2,000 across all approved indications
- The adjusted ceiling prices for the Net Price of these drugs will be higher than those for more common conditions to allow for the even application of the pharmacoeconomic value factor across all Category I patented medicines
- Allow to 50% increase of PEP as a start and then apply incremental adjustment based on units sold in each tier* over $12.5 million and this adjustment will be applied annually to determine the MRP

Market size adjustment for Category I rare disease or disorder patented medicines

Annual revenues	Incremental adjustment factor	MRP	
		Medicines with a PEP	Medicines without a PEP
<$12.5M	+50%	1.5 * PEP	Lower of LIP, dTCC, iTCC
$12.5M-$25M	0%	PEP	
$25M–$50M	-10%	PEP adjusted by applicable factor	Lower of LIP, dTCC, iTCC adjusted by applicable factor
$50M–$75M	-20%		
$75M–$100M	-30%		
$100M–$125M	-40%		
$125M+	-50%		

*These tiers may also be adjusted from time to time, and at least every five years, to reflect changes in CPI and GDP.

How did the PMPRB arrive at the $25M market size threshold?

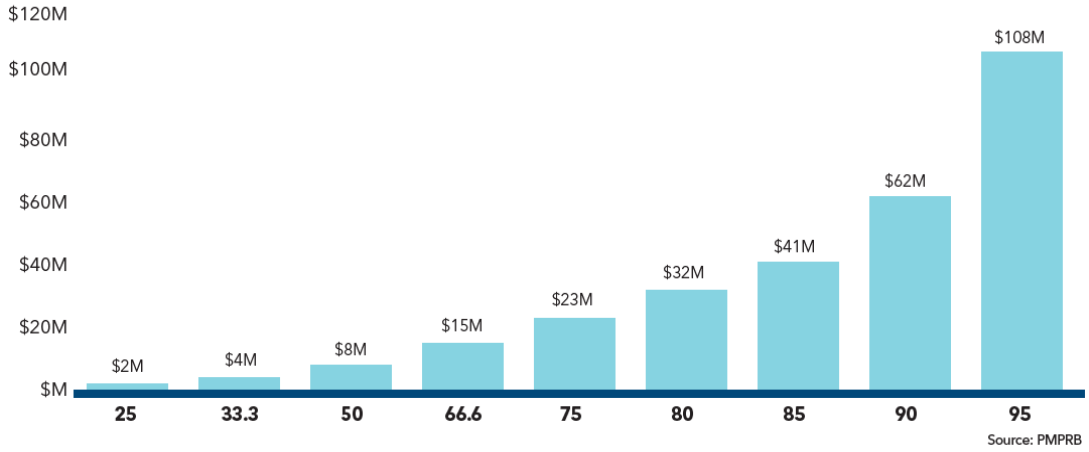
Affordability calculation: top-down approach to identify

Average annual patented medicines sales, 2014 to 2018 ($B)	**$14.9B**
Average annual growth in patented medicine sales, in line with the growth rate in GDP	**$432MB**
Average number of new patented medicines introduced per year, 2014 to 2018	**36**
Average annual affordability threshold per medicine	**$12M**

- $25M is approximately double of avg. annual affordability per medicine

Market analysis: bottom-up approach to support

Percentiles analysis of patented medicines by maximum revenues by 3rd year (639 medicines introduced since 1998)



- Medicines earning $25M as annual sales outperform over 75% of medicines in the pharma market

Reassessment

63. For non-grandfathered patented medicines, a reassessment may be conducted if any of the following situations arise:

- A patented medicine (Category I or Category II) is approved for a new indication;
- A Category II patented medicine has sales exceeding the Market Size Threshold (see Appendix D), contrary to the initial estimate filed by the patentee; or
- A Category I patented medicine's total prevalence across all approved indications, as estimated by Staff, increases above 1 in 2,000; or
- A Category I patented medicine's cost-utility analysis is updated; or

How the new Guidelines will work in practice

Case 1 : New medicine for chronic disease, large patient population (200,000 in Canada)

iMLP
MIP of available PMPRB11 prices
$2.00

Category 1

- ✗ Annual Treatment cost: $1000<50%GDP/capita
- ✓ Estimated Revenues $200M>Market size threshold

MRP: $1.34

- ✗ Pharmacoeconomic Price
- ✓ Market size adjustment = $1.34

MLP: $1.80
MIP=$2.00, LIP=$1.80, dTCC=$1.40
The MLP is the lowest of the MIP and the dTCC with the LIP as a floor

Revenues at MLP ↘ **$180M**

Revenues at MRP ↘ **$134M**

MAPP – Maximum Average Potential Price
iMLP – interim Maximum List Price
MLP – Maximum List Price

MRP – Maximum Rebated Price
MIP – Median International Price
LIP – Lowest International Price

dTCC – domestic Therapeutic Class Comparison
iTCC – international Therapeutic Class Comparison
ATP – Average Transaction Price

How the new Guidelines will work in practice

Case 2 : New medicine for rare disease, small patient population (2,000 in Canada)

iMLP
MIP of available PMPRB11 prices
$1,000

Category 1

- Annual Treatment cost: $100,000>50%GDP/capita
- Estimated Revenues $200M>Market size threshold

MRP: $431

- Pharmacoeconomic Price (50%) = $500
- Market size adjustment = $431

MLP: $1,000

MIP=$1,000, LIP=$900, dTCC not available
The MLP is the lowest of the MIP and the dTCC with the LIP as a floor

Revenues at MLP
$200M

Revenues at MRP
↘ **$86M**

MAPP – Maximum Average Potential Price
iMLP – interim Maximum List Price
MLP – Maximum List Price

MRP – Maximum Rebated Price
MIP – Median International Price
LIP – Lowest International Price

dTCC – domestic Therapeutic Class Comparison
iTCC – international Therapeutic Class Comparison
ATP – Average Transaction Price

Filing under the amended Regulations

By July 30, 2020: 1st filing period under the amended regulations

All medicine need to file the following information:

- **Existing** forms are being **updated** to reflect the amended regulations
  - ✓ Form 1 – Identification of Medicine
  - ✓ Form 2 – Information on the identity and Prices of the Medicine
    - o Block 4 – Information related to the price in relevant markets (provinces) for Canada
    - o Block 5 – Information related to the price in the PMPRB 11
  - ✓ Form 3 – Revenues and R&D Expenditures. The reporting of revenues needs to be compliant with the new reporting requirements and the provisions related to the adjustments made by the patentee or any party
- **New** form is being **added** to reflect amended regulations
  - Form 4 – National Market Size Estimate of Medicine
- **All forms** – original and amended - will be submitted through the **on-line filing tool**
- **Assistance** on how to complete the forms will be available via the **help feature** of the on-line fling tool
- **Documents** as required by the amended regulations will also be submitted using the on-line filing tool

Medicines with a DIN issued starting with August 21, 2019, and with an annual treatment cost greater than half of the GDP per capita

- File unredacted cost utility analysis from CADTH and INESSS

Filing Requirements

	Previous regulations	Amended regulations
Net revenues	Excluding: rebates, discounts, refunds, free goods, free services, gifts or other benefit of a like nature	Excluding: reductions given to any party in the form of free goods, free services, gifts or any other benefit of a like nature (e.g. rebates and discounts provided to third party insurers)
Patented OTC/ veterinary/ generics	√	Reduced reporting obligations for medicines at the lowest risk of excessive pricing
Pharmaco-economic info*	X	Cost-utility analyses from a publicly funded Canadian organization.
Market size information**	X	Estimated maximum use of the medicine in Canada, based on the prevalence of the approved therapeutic use of the medicine in Canada

Previous Guidelines	Proposed Guidelines
• Hospital, Pharmacy, Wholesaler, Other • Provinces/Territories	• Provinces/Territories
More complex Requires the reporting by multiple classes of customers and Provinces/Territories	**Less complex** Only requires the reporting by Provinces/Territories

Patentee's Guide to Reporting

- All filings and document submission are being transitioned to an online filing tool
- Any assistance related to filing will be embedded in the online filing tool
- The PMPRB plans to publish guidance as to the Market Size Estimation

Price ceilings – transitional provisions – Grandfathered and Gap

Establishment of the MLP

For medicines with a MAPP prior to July 1, 2020 (Grandfathered and "Gap"):

- The MLP will be determined as the lowest of the existing ceiling and the MIP of the PMPRB11
- The MLP will be communicated post July 30, 2020 filing
- The new MLP/or iMLP ceiling will be enforced starting with January 1, 2021

For new medicines, without a MAPP by July 1, 2020 - Gap

- The MLP will be determined based on the full application of the MLP provisions as per the new Guidelines (iMLP, dTCC, LIP)
- The MLP will be communicated post July 30, 2020 filing
- The new ceiling will be enforced starting with January 1, 2021

Gap Medicines ONLY - Establishment of the MRP – For new medicines with a DIN issued starting with August 21, 2019, and that screen in Category I:

- MRP will be determined based on the application of the MRP provisions as per the new Guidelines
- The MRP ceiling will be enforced once determined, and no earlier than January 1, 2021

What to expect after July 2020 coming into force
Notwithstanding transitional provisions

Transparent price ceilings – iMLP and MLP

- List prices of all patented medicines that are above the median of the PMPRB11 countries will be reduced – to be enforced starting with January 1, 2021

Confidential price ceilings – MRP (new Category 1 medicines only)

- Net Price must be below the price ceiling established by the new factors ($60K/QALY threshold + further price reductions if revenues exceed $25M/year)
- Medicines for rare diseases to be afforded a ceiling price that is 1.5 times the cost-effective price (i.e. price at $60K/QALY)

- To be enforced starting with January 1, 2021

iMLP – interim Maximum List Price
MLP – Maximum List Price
MRP – Maximum Rebated Price
QALY – Quality Adjusted Life Years

Next steps in the PMPRB Guideline Consultation

Consultation period deadline: February 14, 2020

Stakeholders and the public are invited to provide feedback including written submission before the end of the consultation period, at PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Policy Forum

Stakeholders who have submitted written feedback may be invited to participate in a policy forum and present their views to the Board in person

Final Guidelines

Implementation – July 2020, notwithstanding the transitional provisions

Commitment to Evaluate - Framework Modernization and Evaluation Plan (FMEP)

Thank You

PMPRB
GUIDELINES
2019

Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés