THE GRADUATE INSTITUTE GENEVA

GLOBAL HEALTH CENTRE

Regulating Drug Prices

National and Global Implications of Canada's Recent Reforms

Tuesday, 17 December 2019 | 4:00pm-5:00pm CET

Webinar

P M P R B

GUIDELINES

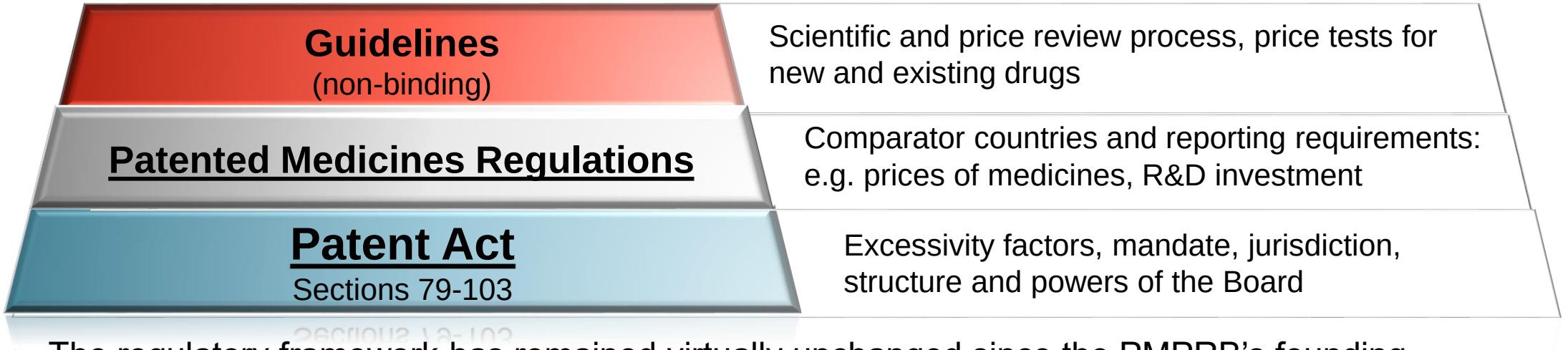
2019

Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

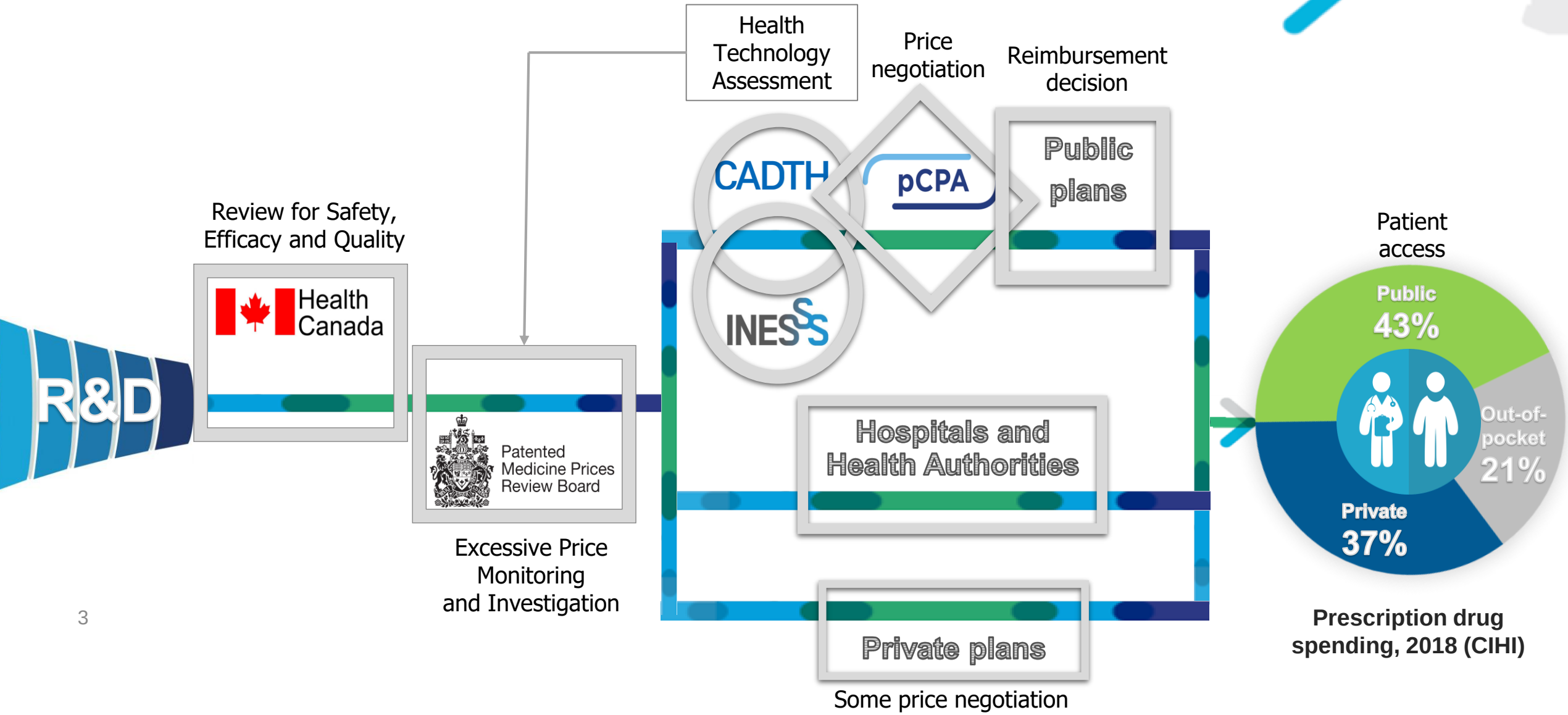
About the PMPRB

- The PMPRB is an independent, quasi-judicial, consumer protection agency that carries out it's mandate at arm's length from the Minister of Health.
- It was established by Parliament in 1987 under the Patent Act (Act), to ensure that the prices of patented medicines sold in Canada are not excessive.
- PMPRB is a "consumer protection pillar" established as a counter-balance to the market exclusivity afforded to patent medicines through the Act, which eliminated compulsory licensing.
- The PMPRB regulatory framework reposes on three legal instruments:



- The regulatory framework has remained virtually unchanged since the PMPRB's founding.

The PMPRB is part of a complex regulatory and reimbursement ecosystem



How the PMPRB sets ceiling prices currently

New patented medicines are assessed for level of therapeutic benefit relative to existing therapies and are assigned a ceiling price that is based on one, or a combination of the following:

1. The median international price based on the **PMPRB7**;
2. The highest price in the domestic therapeutic class;

After entering the market, the price of a medicine can increase in keeping with the Consumer Price Index (CPI) but never to the point of becoming highest of the **PMPRB7**.

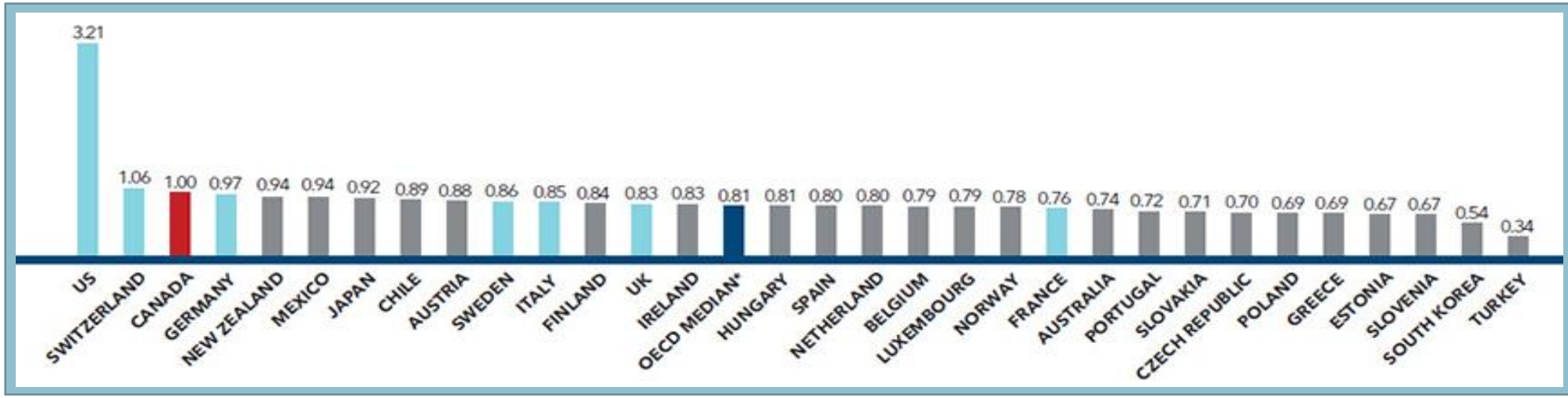
Where PMPRB staff and a patentee disagree on whether a medicine is excessively priced, a hearing may be held before PMPRB Board Members.

If the Board decides a medicine is excessively priced, the patentee is ordered to reduce its price and/or pay back excess revenues.

Given the significant changes in the pharmaceutical environment in recent years, it has been increasingly challenging for the PMPRB to fulfill its consumer protection mandate under the current regulatory framework.

Main problems with current framework

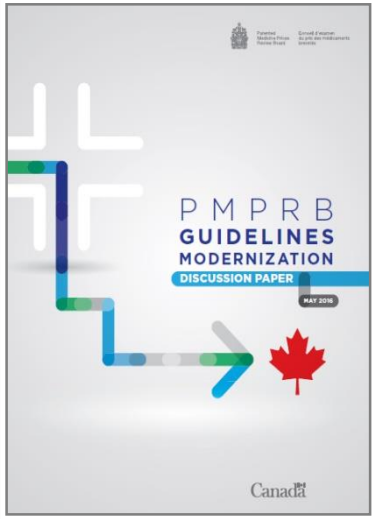
- Our basket of comparators – the PMPRB7 – is made up of premium priced countries and includes the US, an international outlier.
- PMPRB price review is based on publicly available list prices, which are increasingly divorced from the true price net of confidential rebates/discounts.
- Internal and external price referencing are insufficient tools to regulate the new wave of very high-cost medicines that is coming to dominate the market.
- All medicines are subject to the same level of regulatory scrutiny, regardless of the risk of excessive pricing.
- PMPRB sets ceiling prices for medicines at introduction and does not reassess over time to ensure that they remain reasonable/non-excessive.



Canadian prices are **3rd** highest in the OECD

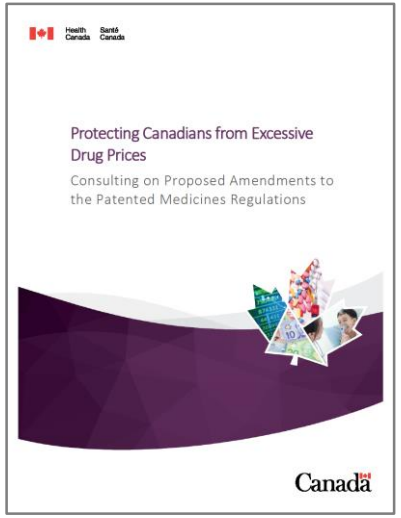
The path to framework reform

PMPRB Discussion paper on Guideline reform



May 2016

Health Canada pre-consultation on regulatory amendments

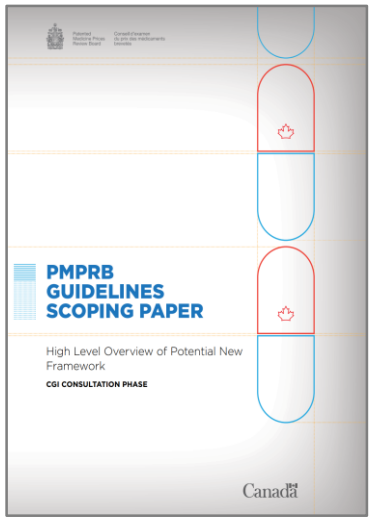


May 2017

Health Canada Canada Gazette I

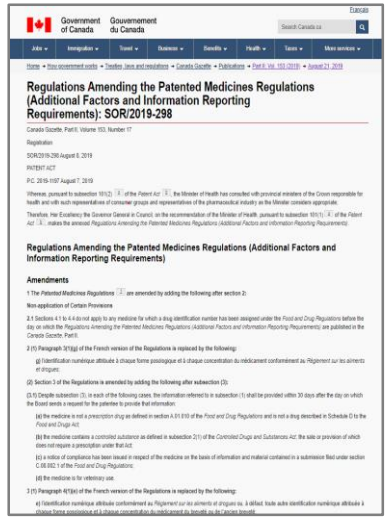
December 2017

PMPRB Guidelines scoping paper



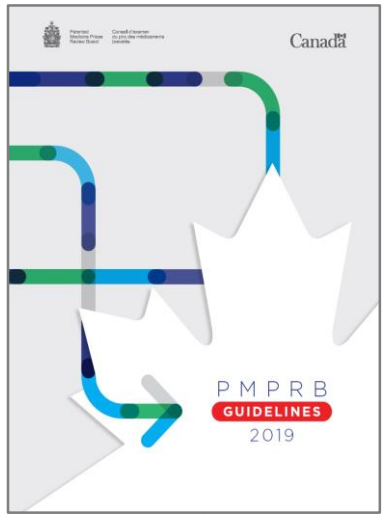
December 2017

Health Canada Canada Gazette II



August 2019

PMPRB Draft Guidelines



November 2019

August 2019: Canada announces "…biggest step to lower drug prices in a generation."

CANADIAN LABOUR CONGRESS

Take Action What We Care About What Unions Do Who We Are

Canada makes drug-price crackdown official over industry opposition

Reuters
Published: Aug 09 at 8:42 a.m.
Updated: Aug 09 at 9:49 a.m.

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Government of Canada Announces Changes to Lower Drug Prices and Lay the Foundation for National Pharmacare

Health Canada says drug pricing changes will save Canadians billions

By Allison Martell Reuters

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B.C. Applauds Federal Government For Modernizing Drug Pricing Regulations

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Proposed new drug regulations will hurt all Canadians — and Ottawa has been warned

Opinion: Changes which aim to make prescriptions more affordable could shut off entry of new drugs

Drug policy experts accuse industry and patient groups of 'fearmongering' with concerns about new drug-pricing rules

Canadians currently pay among the highest patented drug prices in the world, behind only the United States and Switzerland

Amendments to Regulations
Coming into force on July 1, 2020

Provide the PMPRB with modern tools and information it needs to protect Canadians from excessive medicine prices:

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

2. **Considering the value and the overall affordability of a medicine** when setting the maximum price.

3. **Regulating at the level of the actual prices being charged by patentees in Canada** and not just the non-transparent manufacturer list prices.

Although Canada is the only country with a regulator that caps patented medicine prices, it is adopting best practices in most other developed countries by considering value and affordability

New basket of countries
Applies to all patented medicines

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

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

New factors

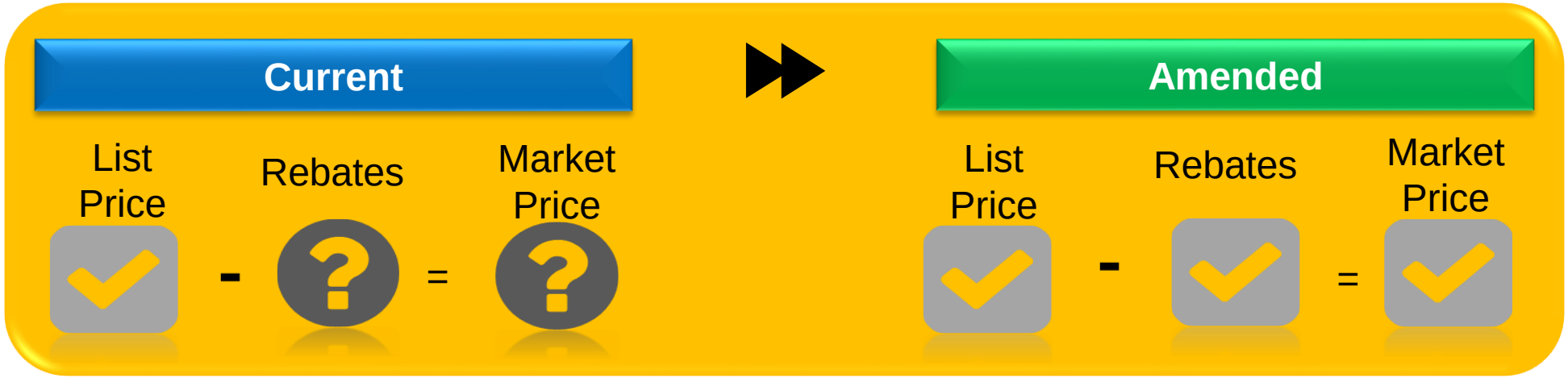
Apply to new patented medicines approved starting with August 21, 2019

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 that consider these same factors
Value for Money	The PMPRB will consider the opportunity cost of a medicine in the health system when evaluating if a price is excessive.	
Size of the market	PMPRB will consider the economic impact from the sales for the medicine when evaluating if a price is excessive.	
GDP and GDP per capita	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	

Modernized reporting requirements for patentees
Providing information relating to third-party 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;*

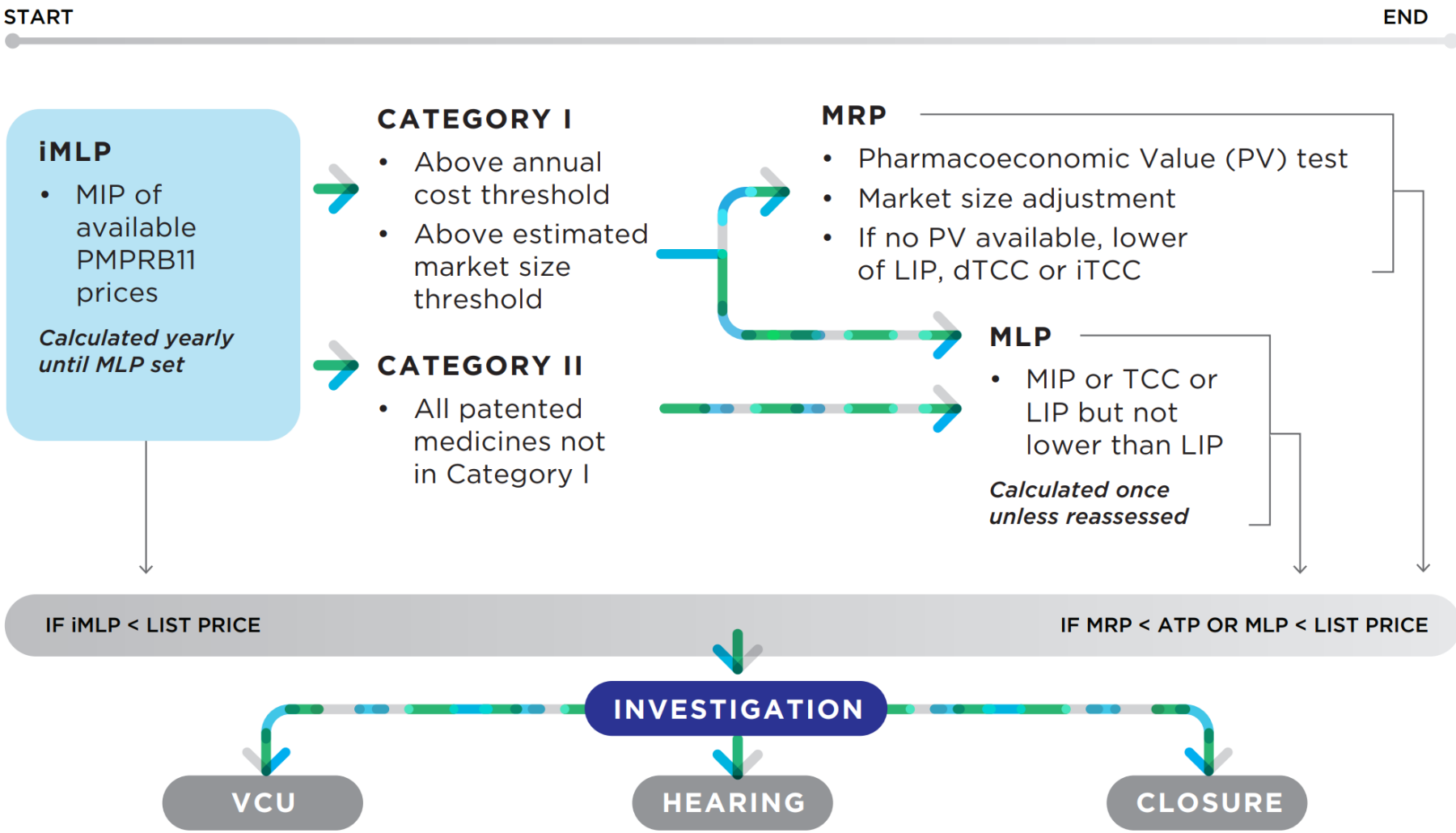


Overview of the new PMPRB regulatory framework

Regulations come into force on July 1, 2020

		Previous regulations	Amended regulations
Existing factors (as per the Patent Act)	**CPI changes**	√	√
	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
New factors (as per the amended 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)
	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

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

Overview 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.

Basic process:

I. Interim Maximum List Price (iMLP) for all medicines at introduction based on Median International Price (MIP) of the PMPRB11

II. Screening of medicines into high-priority (**Category I**) or low-priority (**Category II**)

III. Maximum Rebated Price (MRP) for Category I drugs based on new pharmacoeconomic, market size, and GDP factors

IV. Maximum List Price (MLP) is the lower of MIP and the median domestic Therapeutic Class Comparison ("dTCC") but is subject to a price floor set by the lowest international price ("LIP")

V. Reassessment

The MLP would be a transparent ceiling based on public list prices, while the MRP (Category I medicines only) would be confidential.

Patentees must ensure that the 'Net Price' of a Category 1 medicine in Canada is no higher than the MRP. To comply, patentees would be required to report revenues net of rebates to third-parties.

Criteria for classifying a patented medicine as Category I

Canada Gazette Part II: *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]

Proposed Maximum Rebated Price (MRP) calculation for Category I medicines

Medicines with treatment cost greater than 50% of GDP per capita

- 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 of $60,000 per QALY
- The price at which the patented medicine's ICER would be equivalent to the pharmacoeconomic value threshold will be identified as the Pharmacoeconomic Price, or "PEP"
- In the absence of a PEP, the lower of the (i) Lowest International Price, (ii) the domestic Therapeutic Class Comparison, or the (iii) international Therapeutic Class Comparison will be considered
- 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

Medicines with treatment cost lower than 50% of GDP per capita, triggering the Market Size Threshold

- The Maximum Rebated Price will be derived by adjusting the Maximum List Price for market size when revenues exceed $25 million.

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

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 Pharmacoeconomic Price, 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 Maximum Rebated Price

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 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

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

64. A patented medicine receiving a new indication may have its Relevant Indication changed

What to expect after July 2020 coming into force

Base on the draft Guidelines and 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

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)

Enforcement

- Both transparent and confidential ceilings 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

THANK YOU

http://www.pmprb-cepmb.gc.ca/

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