About the PMPRB
The PMPRB is an independent, quasi-judicial, consumer protection agency.

It was established by Parliament in 1987 through patent legislation intended to balance stronger patent protection for pharmaceuticals with a mechanism to ensure their prices remained reasonable.

The PMPRB regulatory framework reposes on three legal instruments:

- **Patent Act** Sections 79-103
  - Excessivity factors, mandate, jurisdiction, structure and powers of the Board

- **Patented Medicines Regulations**
  - Comparator countries and reporting requirements: e.g. prices of medicines, R&D investment

- **Guidelines** (non-binding)
  - Scientific and price review process, price tests for new and existing drugs
The PMPRB is part of a complex regulatory and reimbursement ecosystem.
How the PMPRB sets ceiling prices

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.
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.

- International and domestic price referencing alone is not sufficient for regulating the prices of the many high-cost medicines that are driving growth in spending in public and private plans.

- All medicines are subject to the same level of regulatory scrutiny, regardless of market dynamics.

- PMPRB sets ceiling prices for medicines at introduction and does not reassess over time to ensure that the prices continue to remain reasonable/non-excessive.
Changes in the pharmaceutical market
Drug affordability has become a global issue, even for the richest countries.
Canada is not immune
Rapid growth in high-cost* drugs is accounting for an increasingly significant share of spending but covers only a small minority of claimants

In the last 5 years, the fastest growing segment of the market is high cost drugs at 13%, or which EDRDs are growing at 33%.

High-cost patented drug are used by only 1% of Canadians but accounted for 30% of 2017 sales, up from only 8% in 2006.

In 2017, 5 of top 10 selling drugs had an average annual treatment cost exceeding $10K.

* High-cost is defined as average annual cost exceeding $10,000

Evolving Pharmaceutical Market – Patented Medicines

Share of Sales for High-Cost Patented Medicines, 2006 to 2017

Source: Annual Report 2017, PMPRB

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<tr>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>50K+</td>
<td>0.3</td>
<td>0.4</td>
<td>0.5</td>
<td>0.7</td>
<td>1.3</td>
<td>1.7</td>
<td>2.2</td>
<td>2.7</td>
<td>4.5</td>
<td>9.2</td>
<td>7.8</td>
<td>5.3</td>
</tr>
<tr>
<td>20K-50K</td>
<td>2.1</td>
<td>2.4</td>
<td>2.7</td>
<td>3.0</td>
<td>3.5</td>
<td>6.0</td>
<td>8.2</td>
<td>10.9</td>
<td>12.9</td>
<td>12.0</td>
<td>13.8</td>
<td>18.1</td>
</tr>
<tr>
<td>10K-20K</td>
<td>5.2</td>
<td>5.5</td>
<td>6.9</td>
<td>8.1</td>
<td>9.6</td>
<td>10.8</td>
<td>12.9</td>
<td>14.5</td>
<td>15.6</td>
<td>16.5</td>
<td>18.7</td>
<td>18.2</td>
</tr>
<tr>
<td>Total</td>
<td>7.6</td>
<td>8.3</td>
<td>10.1</td>
<td>11.8</td>
<td>14.4</td>
<td>18.5</td>
<td>23.3</td>
<td>28.1</td>
<td>33.0</td>
<td>37.7</td>
<td>40.3</td>
<td>41.6</td>
</tr>
</tbody>
</table>
Despite small patient populations, EDRDs are a rapidly growing market, gaining sizeable sales through high prices.

While EDRDs are rare by definition, collectively they represent a substantial portion of Canadian population.

“Rare diseases affect one in 12, or approximately 2.8 million Canadians” (CORD)

<table>
<thead>
<tr>
<th>Year</th>
<th>Non-cancer</th>
<th>Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>$0.1B</td>
<td>$0.3B</td>
</tr>
<tr>
<td>2013</td>
<td>$0.3B</td>
<td>$0.3B</td>
</tr>
<tr>
<td>2014</td>
<td>$0.4B</td>
<td>$0.4B</td>
</tr>
<tr>
<td>2015</td>
<td>$0.2B</td>
<td>$0.5B</td>
</tr>
<tr>
<td>2016</td>
<td>$0.3B</td>
<td>$0.7B</td>
</tr>
<tr>
<td>2017</td>
<td>$0.8B</td>
<td>$1.0B</td>
</tr>
<tr>
<td>2018</td>
<td>$1.4B</td>
<td>$1.4B</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Cumulative number of EDRDs approved</th>
<th>EDRD share of total Pharma market</th>
<th>Sales per capita</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>26</td>
<td>1.9%</td>
<td>$11</td>
</tr>
<tr>
<td>2013</td>
<td>31</td>
<td>2.2%</td>
<td>$13</td>
</tr>
<tr>
<td>2014</td>
<td>37</td>
<td>2.8%</td>
<td>$16</td>
</tr>
<tr>
<td>2015</td>
<td>48</td>
<td>3.6%</td>
<td>$23</td>
</tr>
<tr>
<td>2016</td>
<td>61</td>
<td>4.3%</td>
<td>$28</td>
</tr>
<tr>
<td>2017</td>
<td>71</td>
<td>5.5%</td>
<td>$38</td>
</tr>
<tr>
<td>2018</td>
<td>79</td>
<td>7.0%</td>
<td>$50</td>
</tr>
</tbody>
</table>
EDRDs, despite lower populations, are likely to generate greater revenues than lower-cost drugs.

### Distribution of patented drugs by highest sales* in the first 3 years

<table>
<thead>
<tr>
<th>Share of drugs with sales in</th>
<th>$10M-$50M</th>
<th>$50M-$100M</th>
<th>$100M+</th>
<th>$10M+ in sales</th>
<th>Share of total sales</th>
<th>Avg. sales per drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower-cost drugs</td>
<td>33%</td>
<td>5%</td>
<td>6%</td>
<td>44%</td>
<td>92%</td>
<td>$24M</td>
</tr>
<tr>
<td>&lt;$10K annually</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Higher-cost drugs</td>
<td>31%</td>
<td>18%</td>
<td>12%</td>
<td>61%</td>
<td>97%</td>
<td>$58M</td>
</tr>
<tr>
<td>≥$10K annually</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EDRDs</td>
<td>40%</td>
<td>5%</td>
<td>9%</td>
<td>54%</td>
<td>94%</td>
<td>$28M</td>
</tr>
</tbody>
</table>

* In 2018 dollars; drugs introduced since 2005. Data source: PMPRB and MIDAS™ database, IQVIA. All rights reserved.

** EDRDs include drugs with at least 2 years of sales.

Note: Results not reflective of managed entry agreements.
Canada pays third-highest list prices on patented medicines in OECD and has the second-highest sales per capita.
Example of impact of high Canadian prices: drugs for age-related macular degeneration (AMD)

- AMD is the leading cause of visual impairment in Canadians over 50.

- The top-selling drugs used in the treatment of AMD – Lucentis and Eylea – cost Canadian public drug plans around $8,000/year per patient, twice as much as lower-priced countries such as the UK and Sweden.

- If Canada paid the lowest available prices for these drugs in the PMPRB7, it would have saved $356 million in 2017.

- If Canada paid median prices for these drugs, it would have saved $168 million in 2017.
Spending on patented medicines is outpacing other healthcare categories and economic growth, 2013-2017

<table>
<thead>
<tr>
<th>Category</th>
<th>Growth Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPI</td>
<td>1.5%</td>
</tr>
<tr>
<td>GDP</td>
<td>2.4%</td>
</tr>
<tr>
<td>Patented medicines</td>
<td>5.8%</td>
</tr>
<tr>
<td>High-cost medicines</td>
<td>13.0%</td>
</tr>
<tr>
<td>EDRDs</td>
<td>33.0%</td>
</tr>
<tr>
<td>Drugs</td>
<td>3.1%</td>
</tr>
<tr>
<td>Physicians</td>
<td>4.0%</td>
</tr>
<tr>
<td>Hospital</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

Growth in patented medicine spending has been twice as high as that in GDP and almost 4 times that of inflation.

Lower due to savings from generic price reductions

Growth in physician and hospital spending was much lower than that in patented medicine spending.
For many Canadians, prescription drugs are simply unaffordable

- 21% of prescription drug spending in 2018 was out-of-pocket
- 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

<table>
<thead>
<tr>
<th>Percentage of Canadians without prescription drug coverage</th>
<th>Percentage of Canadians who had to forego filling a prescription because of cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>20%</td>
<td>8.2%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Canadians who used additional health services as a result of foregoing a prescription drug in the past year</th>
<th>Canadians who had to forego other spending, including basic necessities, to pay for prescription drugs in the past year</th>
</tr>
</thead>
<tbody>
<tr>
<td>374K</td>
<td>1.4M</td>
</tr>
</tbody>
</table>

Sources: CIHI
Challenges faced by public and private payers

1. Inadequate evidence around drug efficacy, safety, and cost-effectiveness to support drug coverage decisions;

2. Extremely high drug prices and rapid growth in spending on a minority of patients.

- Both the pan-Canadian Pharmaceutical Alliance (pCPA) and the Canadian Life and Health Insurance Association (CLHIA) have called for stronger federal support in dealing with high cost medicines.

- All payers, public, private, national or international, have little leverage in negotiating for medicines that have few or no therapeutic options.

- Many developed countries with universal health care systems are considering “new tools” to level the playing field with industry.

Prescription drug spending, 2018*

- Public: 43%
- Private: 37%
- Out-of-pocket: 21%
The changing regulatory environment for pharmaceuticals in Canada

- **High-cost drugs for rare diseases**
  - Up to $1 billion over two years, from 2022–23
  - Up to $500 million per year ongoing

- **Canadian Drug Agency (CDA)**
  - A new national drug agency that would build on recent trend towards greater alignment and integration and facilitate adoption of national pharmacare

- **PMPRB reforms**
  - Amending regulations to provide new tools and information to better protect Canadian consumers from excessive prices

- **Regulatory Review of Drugs & Devices (R2D2) CADTH parallel processes**
  - Streamlining regulatory processes, expedited approval of new and innovative products, and reducing unnecessary delay

- **National Formulary**
  - A comprehensive, evidence-based list of nationally reimbursed drugs

* Foundational element of the Advisory Council on the Implementation of National Pharmacare
PMPRB Reforms
The path to PMPRB framework reform

- PMPRB Discussion paper on Guideline reform
- Health Canada pre-consultation on regulatory amendments
- Health Canada Canada Gazette I
- PMPRB Guidelines scoping paper
- Health Canada Canada Gazette II
- PMPRB Draft Guidelines

May 2016
May 2017
December 2017
December 2017
August 2019
November 2019
August 2019: Canada announces “…biggest step to lower drug prices in a generation.”

Canada makes drug-price crackdown official over industry opposition

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

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

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 paid 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
Will apply to all patented medicines as of July 2020

<table>
<thead>
<tr>
<th>Previous comparator countries: PMPRB7</th>
<th>Foreign-to-Canadian price ratio</th>
<th>New comparator countries: PMPRB11</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>0.75</td>
<td>France</td>
</tr>
<tr>
<td>Germany</td>
<td>1.12</td>
<td>Germany</td>
</tr>
<tr>
<td>Italy</td>
<td>0.95</td>
<td>Italy</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>0.94</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>Sweden</td>
<td>0.93</td>
<td>Sweden</td>
</tr>
<tr>
<td>Switzerland</td>
<td>1.12</td>
<td>Australia</td>
</tr>
<tr>
<td></td>
<td>0.74</td>
<td>Belgium</td>
</tr>
<tr>
<td></td>
<td>0.79</td>
<td>Japan</td>
</tr>
<tr>
<td>Switzerland</td>
<td>1.12</td>
<td>Australia</td>
</tr>
<tr>
<td></td>
<td>0.74</td>
<td>Belgium</td>
</tr>
<tr>
<td></td>
<td>0.79</td>
<td>Japan</td>
</tr>
<tr>
<td>United States</td>
<td>3.36</td>
<td>Netherlands</td>
</tr>
<tr>
<td></td>
<td>0.80</td>
<td>Norway</td>
</tr>
<tr>
<td></td>
<td>0.80</td>
<td>Spain</td>
</tr>
</tbody>
</table>
New excessive price factors
Will apply to patented medicines approved after August 21, 2019

<table>
<thead>
<tr>
<th>Factor</th>
<th>Description</th>
<th>Comparator countries using the factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value for Money</td>
<td>The PMPRB will consider the opportunity cost of a medicine in the health system.</td>
<td></td>
</tr>
<tr>
<td>Size of the market</td>
<td>The PMPRB will consider the economic impact of paying for the medicine for everyone who needs it when evaluating if a price is excessive.</td>
<td></td>
</tr>
<tr>
<td>GDP and GDP per capita</td>
<td>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</td>
<td></td>
</tr>
</tbody>
</table>
Reporting true market prices:
Patentees must provide information on direct and indirect rebates

Current:
List Price - Rebates = Market Price

Amended:
List Price - Rebates = Market 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.
Schematic of proposed new Guidelines

**iMLP**
- MIP of available PMPRB11 prices
  
  *Calculated yearly until MLP set*

**CATEGORY I**
- Above annual cost threshold
- Above estimated market size threshold

**CATEGORY II**
- All patented medicines not in Category I

**MRP**
- Pharmacoeconomic Value (PV) test
- Market size adjustment
- If no PV available, lower of LIP, dTCC or iTCC

**MLP**
- MIP or TCC or LIP but not lower than LIP

*Calculated once unless reassessed*

**IF iMLP < LIST PRICE**

**IF MRP < ATP OR MLP < LIST PRICE**

**INVESTIGATION**

**VCU**

**HEARING**

**CLOSURE**

---

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
Transparent price ceilings – iMLP and MLP

• List prices of all patented medicines that are above the median of the PMPRB11 countries will be reduced – draft Guidelines propose a six month grace period for coming into compliance

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)

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

*Based on current draft Guidelines, subject to change following consultation
How the new Guidelines will work in practice
Case 1: New medicine for chronic disease, large patient population (200,000 in Canada)

Category 1

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

**iMLP**
MIP of available PMPRB11 prices
$2.00

**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
FAQs
Addressing concerns about the impact of the reforms – FAQs

1. Will the reforms make Canada an outlier in how it deals with high cost patented medicines?
2. Will lower prices delay or reduce the availability of new medicines in Canada?
3. Will these changes lead to a loss of R&D, including clinical trials, and manufacturing?
4. Will the reforms exacerbate drug shortages in Canada?
5. Will Canada be seen as a “free-rider” on pharmaceutical innovation?
6. Doesn’t the pCPA have the buying power to deal with high cost drugs already?
7. Will the PMPRB duplicate CADTH and INESSS HTA processes?
8. What if private insurers have a higher willingness to pay for some medicines?
Factors used by national pricing authority

<table>
<thead>
<tr>
<th></th>
<th>Not used</th>
<th>Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTA / Value</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The most common and effective tool used by national and regional pricing and reimbursement authorities is health technology assessment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Budget impact / Market size</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Governments have increasingly added affordability measures by capping total drug expenditures to predetermined levels, establishing budget impact thresholds, and negotiating treatment envelops for entire populations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual market prices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canada is also unique in lack of domestic transparency into pricing for the pricing authority</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Will the reforms make Canada an outlier in how it deals with high cost patented medicines?

- Canada is already an outlier in the sense that it is the only developed country with a publicly funded health care system that doesn’t cover prescription drugs.

- As Canada lacks the ability to harness its national buying power to negotiate lower prices for new medicines, it is unique in needing a regulator to ensure patented medicines aren’t excessive.

- By having the PMPRB consider value and affordability, Canada is adopting the latest best practices internationally for ensuring sustainable access to clinically effective new medicines.
Will the reforms delay the availability of new medicines in Canada?

- In addition to these reforms, the Government is streamlining its regulatory processes for new drugs by allowing the health and safety and HTA review processes to run concurrently.

- This will enable new drugs to enter the Canadian market faster, benefiting patients and boosting revenues for drug companies.

---

**Old**

<table>
<thead>
<tr>
<th>Health Canada Review</th>
<th>CADTH Review</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 days*</td>
<td>180 days</td>
<td>Up to 480 days</td>
</tr>
<tr>
<td>Health Canada reviews all new prescription drugs to ensure safety, efficacy and quality</td>
<td>The Canadian Agency for Drugs and Technologies in Health (CADTH), a federal-provincial-territorial agency, evaluates drugs for cost-effectiveness</td>
<td>pCPA negotiates listing of drug on public drug plans</td>
</tr>
</tbody>
</table>

**New**

<table>
<thead>
<tr>
<th>Health Canada Review</th>
<th>CADTH Review</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>300 days*</td>
<td>180 days</td>
<td>pCPA negotiation</td>
</tr>
<tr>
<td>Health Canada and CADTH reviews are conducted concurrently to shorten the time it takes new drugs to reach market</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*as little as 180 days for priority drugs
Will lower prices reduce the availability of new drugs in Canada?

- Price is a very weak determinant of availability - all the PMPRB7 countries have greater new drug availability than Canada, yet many have lower drug prices.

- Stronger determinants are: i) the wealth of a country, (ii) how much it spends on drugs and (iii) the size of its market.

- Even with reduced prices, Canada will continue to be a top 10 market for pharmaceuticals and our spending per capita and as a percentage of GDP will remain high.

<table>
<thead>
<tr>
<th>Country</th>
<th>New Drugs (relative to Canada)</th>
<th>Price Discount (relative to Canada)</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom</td>
<td>↑ 36%</td>
<td>↓ 16%</td>
</tr>
<tr>
<td>Sweden</td>
<td>↑ 22%</td>
<td>↓ 11%</td>
</tr>
<tr>
<td>Italy</td>
<td>↑ 18%</td>
<td>↓ 17%</td>
</tr>
<tr>
<td>Norway</td>
<td>↑ 12%</td>
<td>↓ 25%</td>
</tr>
<tr>
<td>France</td>
<td>↑ 2%</td>
<td>↓ 22%</td>
</tr>
<tr>
<td>Canada</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>
Will these changes lead to a loss of R&D and manufacturing?

- Most of Canada’s peer countries enjoy far greater levels of R&D investment despite having considerably lower drug pricing.

- For example, Belgium enjoys 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 per capita spending countries and yet pharmaceutical R&D and manufacturing have been steadily decreasing long before the PMPRB reforms.

### Comparison of R&D Spending Relative to Pricing

<table>
<thead>
<tr>
<th>Country</th>
<th>R&amp;D Spending per Resident (relative to Canada)</th>
<th>Price Discount (relative to Canada)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>↑ 1215%</td>
<td>↓ 20%</td>
</tr>
<tr>
<td>Sweden</td>
<td>↑ 546%</td>
<td>↓ 11%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>↑ 408%</td>
<td>↓ 16%</td>
</tr>
<tr>
<td>France</td>
<td>↑ 292%</td>
<td>↓ 22%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>↑ 115%</td>
<td>↓ 21%</td>
</tr>
<tr>
<td>Canada</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>
Will the reforms exacerbate drug shortages in Canada?

- Drug shortages are a complex, global problem that arise from any number of possible causes, including production issues, sole source contracting, unexpected surges in demand and difficulties accessing raw ingredients.

- The majority of drug shortages in Canada are for generic drugs, which the PMPRB will no longer be actively regulating under the new framework.

- As in the past, we expect drug companies will refuse to sell patented drugs to Canadian wholesalers who wish to export cheaper Canadian drugs to the US.

- Currently, Americans need a prescription from a physician licensed in Canada to buy Canadian pharmaceuticals.

Source:

Canada’s contribution to global spending on pharmaceuticals (2.06%) is the same as its contribution to global GDP (2.06%) in 2017.

The US is an outlier, paying the highest patented drug prices in the world.
- Prices in the US are 3 times higher than the next highest country (Switzerland) and nearly 4 folds above the OECD median (PMPRB Annual Report Figure 21).
- Canada pays the third highest patented drug prices in the world, 19% above the OECD median prices.

R&D in Canada is at a 30-year low despite Canadian patented prices being some of the highest in the world.
Will the PMPRB duplicate CADTH and INESSS HTA processes?

- The PMPRB is not mandated to conduct health technology assessments and will not duplicate the work of the existing publicly funded bodies.

- The PMPRB will leverage the existing work of Canada’s world class HTA bodies to operationalize the pharmacoeconomic factors provided in the amended regulations.

- The PMPRB is consulting CADTH and INESSS on the operational aspects of the Guidelines to ensure that processes are aligned and that the price reviews can rely on the information provided in the pharmacoeconomic reports.
Doesn’t the pCPA have the buying power to deal with high cost drugs?

- The pCPA often negotiates under very challenging circumstances, starting with extremely high list prices, severe untreated disease, no competing products, and high patient and care provider expectations to conclude negotiations quickly.

- The pCPA has stated on the record that the prices it has achieved through negotiation remains largely unfair, excessive and not cost-effective and that it needs stronger federal support.*

- Only a half of drugs for rare or ultra-rare disorders have been successfully negotiated through pCPA.

- Payers grapple with difficult funding decisions and their opportunity costs: fund expensive drugs for a few and not be able to fund something else for the multitude.

*Brief to House of Commons' Standing Committee on Barriers to Access Treatment and Drugs for Canadians Affected by Rare Diseases and Disorders Submitted by pan-Canadian Pharmaceutical Alliance (Public Drug Plans) December 7, 2018.
What if private insurers have a higher willingness to pay for some medicines?

- The amended regulations require the PMPRB to consider the cost utility analysis produced by a publically funded health technology assessment body, with the policy intent for the PMPRB to take a public system perspective when applying the pharmacoeconomic factor in its price review.

- The PMPRB regulates prices at a national level and not by payer. This allows for price differentials across payers depending on the willingness to pay, as long as the national average transaction price does not exceed the confidential maximum rebated price ceiling.

- Private payers have expressed strong support for strengthening the PMPRB’s regulatory framework to deal with high cost medicines, which now account for 30% of their spending on prescription pharmaceuticals in Canada.

“Insurers believe that a strengthened PMPRB is a vital step towards modernizing the regulatory environment around drug prices in Canada…We believe the approach outlined today strikes the right balance between lowering prices across Canada over time while ensuring that Canadians continue to have access to the innovative medicines that they need.”

Canadian Life and Health Insurance Association
Next steps
We recognize that our regime is complex and that civil society has varying levels of familiarity/capacity when seeking to provide the consumer perspective on the proposed Guidelines.

We hope that civil society would be particularly interested and engaged by the following questions:

1. What aspect(s) of the proposed Guidelines do you agree with and why?
2. What aspect(s) of the proposed Guidelines do you disagree with and why?
3. What impact do you hope these reforms will achieve for you, your organization and Canadian patients?
4. If you had to design a price test using the new factors to ensure Canadian prices are fair and affordable, what price test would you suggest?

Interested parties can provide their views on the proposed Guidelines by writing to PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca by no later than January 31, 2020.
Consultation period deadline: January 31, 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
Interested stakeholders who have submitted written feedback can request to participate in a policy forum and make their views known to the PMPRB’s Board

Final Guidelines – Expected in the spring of 2020

Monitoring and Evaluation – PMPRB will develop a comprehensive plan for assessing the impact of the new regime on prices, access, R&D etc. summer 2020.

Coming into force – July 2020
Thank You