Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

PMPRB Framework Modernization

TELUS Health Annual Conference

March & April 2019

Canada

Patented Medicines Prices Review Board

The PMPRB is an independent quasi-judicial body established by Parliament in 1987 under the *Patent Act*.

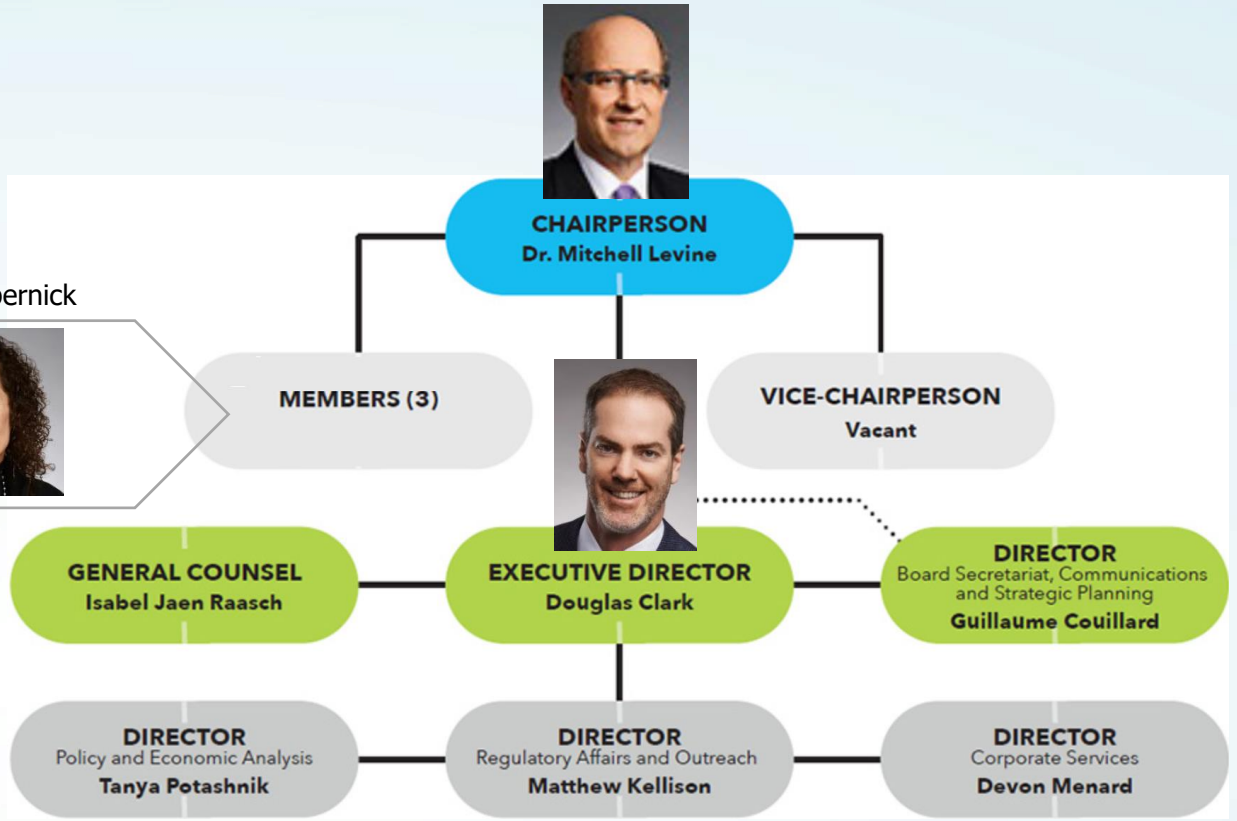
Mandate: The PMPRB has a dual role:

- to ensure that prices at which patentees sell their patented medicines in Canada are not excessive;
- to report on pharmaceutical trends of all medicines and on research and development spending by patentees.

Although the PMPRB is part of the Health Portfolio, it carries out its mandate at arm's length from the Minister of Health. It also operates independently of other bodies such as Health Canada.

The PMPRB has regulatory jurisdiction over the prices that patentees charge, at the factory-gate level price, for both prescription and non-prescription patented medicines sold in Canada to wholesalers, hospitals or pharmacies, for human and veterinary use.

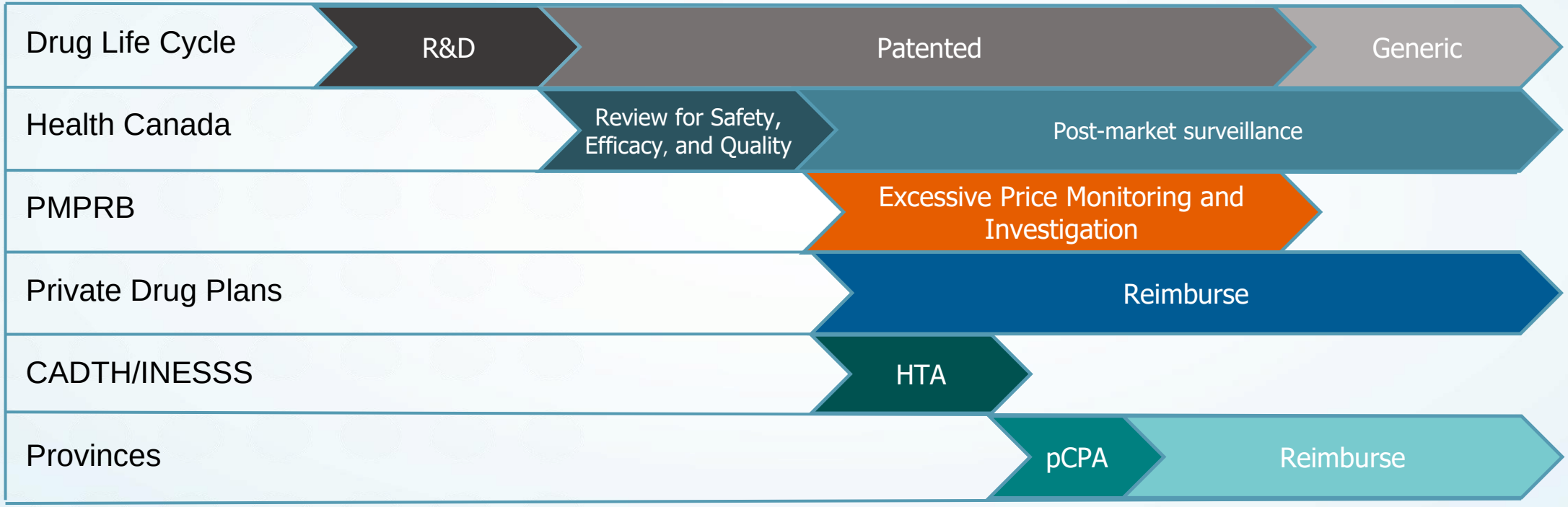
Organizational structure



- The Board consists of up to 5 part-time members, including a Chairperson and a Vice-Chairperson. All members are appointed by the Governor-in-Council.
- The Chairperson is designated under the *Patent Act* as the Chief Executive Officer of the PMPRB, with the authority and responsibility to supervise and direct its work.
- PMPRB Staff is composed of approximately 70 public servants with a budget of approx. $15M.

PMPRB regulatory role in context

The PMPRB is part of a complex regulatory and reimbursement ecosystem:



CADTH: Canadian Agency for Drugs and Technologies in Health
INESSS: Institut national d'excellence en santé et services sociaux
pCPA: pan-Canadian Pharmaceutical Alliance

30 years ago

In 1987, Canada enacted a two-fold reform of its medicine patent regime (Bill C-22) that sought to balance competing industrial and social policy objectives:

- Incentivize R&D expenditure through stronger patent protection;
- Mitigate the economic impact of stronger patent protection on the health system.

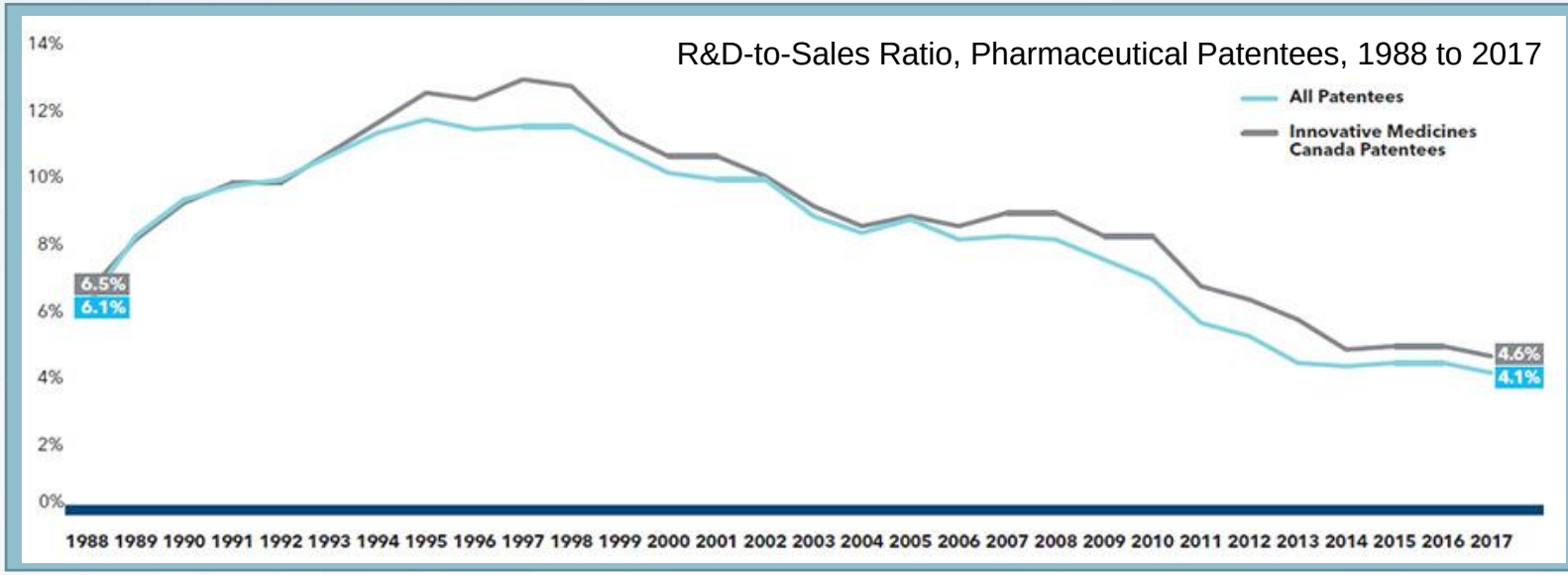
The PMPRB was conceived as C-22's "consumer protection pillar", to ensure that prices of patented medicines remain "reasonable" and "affordable".

The intent was to double R&D in Canada (to 10% of revenues) while keeping prices in line with high R&D countries (the "PMPRB7*) on the assumption we would come to emulate their level of investments.

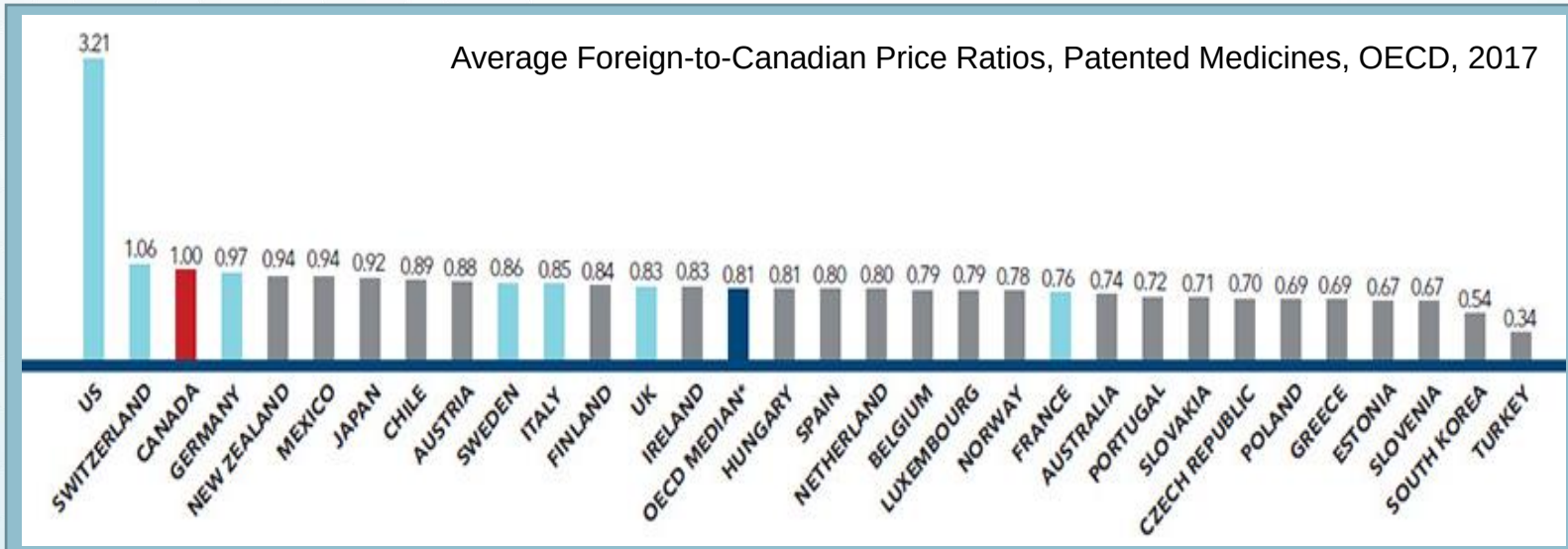
*Countries in the PMPRB7 are France, Germany, Italy, Sweden, Switzerland, the UK, and the US.

30 years later

The policy objectives sought by the Patent Act have not been met



R&D are at a 30-year low: **4.1%**



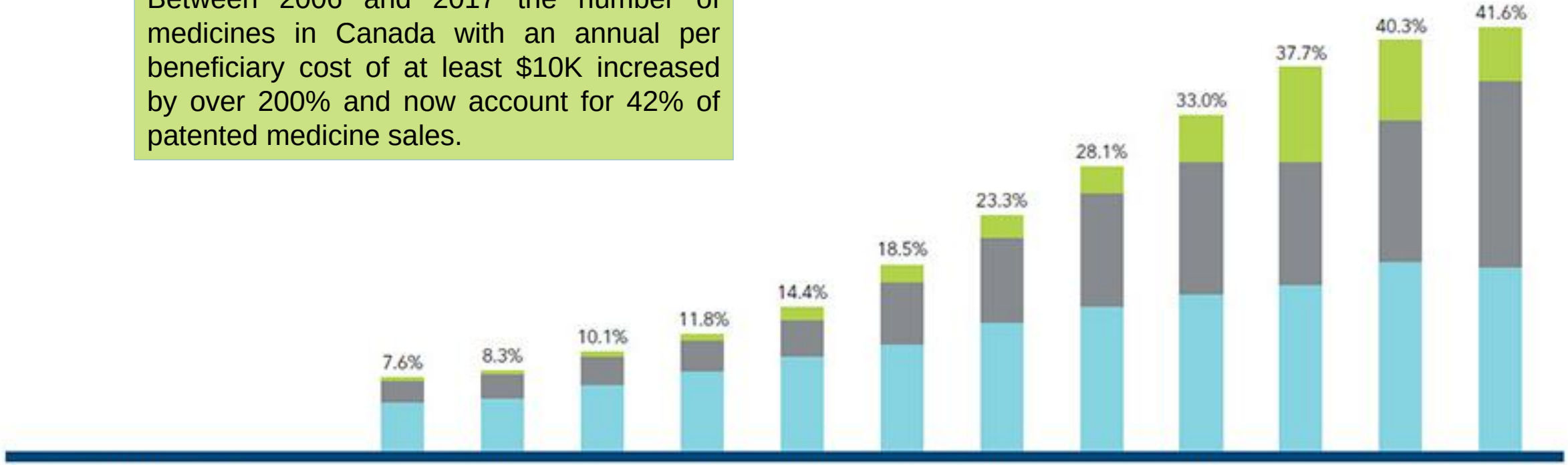
Canadian prices are **3rd** highest

Figure source:
PMPRB Annual Report, 2017

Data source:
PMPRB, MIDAS™ database, 2017, IQVIA. All rights reserved.

Number of high-cost medicines is rising

Between 2006 and 2017 the number of medicines in Canada with an annual per beneficiary cost of at least $10K increased by over 200% and now account for 42% of patented medicine sales.

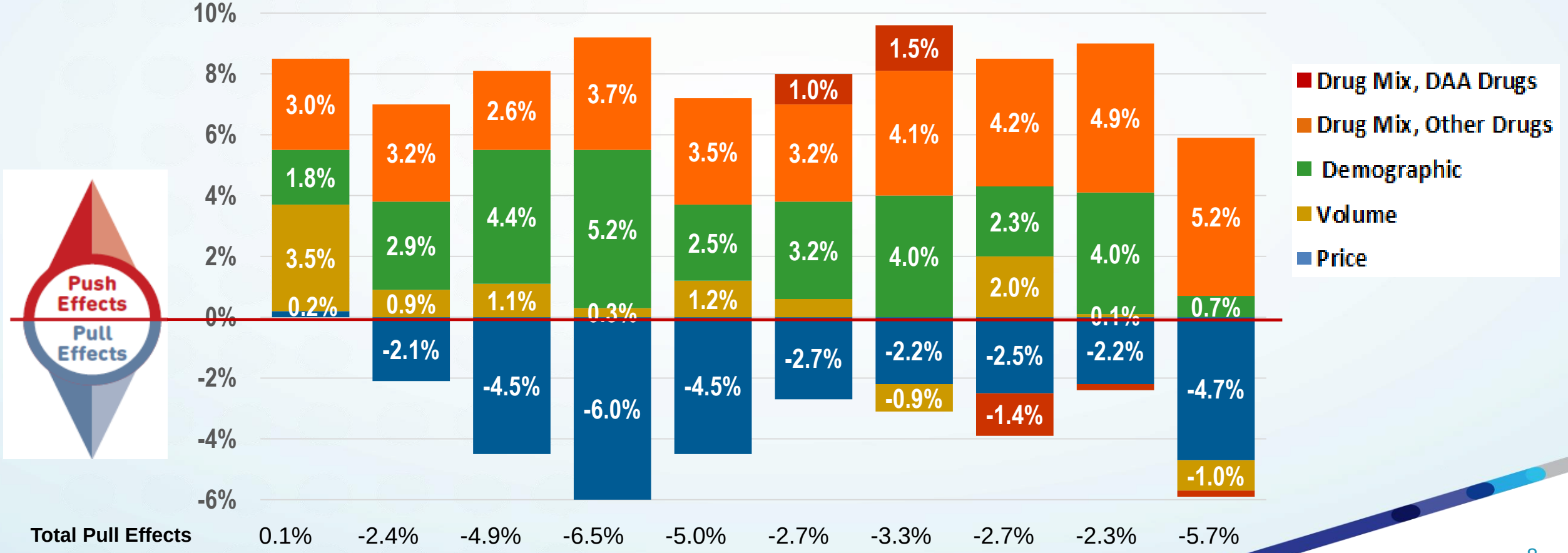


SHARE OF SALES %	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
50K+	0.3	0.4	0.5	0.7	1.3	1.7	2.2	2.7	4.5	9.2	7.8	5.3
20K-50K	2.1	2.4	2.7	3.0	3.5	6.0	8.2	10.9	12.9	12.0	13.8	18.1
10K-20K	5.2	5.5	6.9	8.1	9.6	10.8	12.9	14.5	15.6	16.5	18.7	18.2
Total	7.6	8.3	10.1	11.8	14.4	18.5	23.3	28.1	33.0	37.7	40.3	41.6

Figure source: PMPRB Annual Report, 2017
Data source: PMPRB; IQVIA Private Pay Direct Drug Plan Database, 2006–2017

Drug cost drivers in private drug plans, 2009 to 2018

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Net Change	8.3%	4.6%	3.3%	2.7%	2.2%	5.8%	6.2%	4.4%	6.4%	0.6%
Total Push Effects	8.3%	6.9%	8.1%	9.2%	7.1%	8.5%	9.5%	7.1%	8.8%	6.3%
Total Pull Effects	0.1%	-2.4%	-4.9%	-6.5%	-5.0%	-2.7%	-3.3%	-2.7%	-2.3%	-5.7%



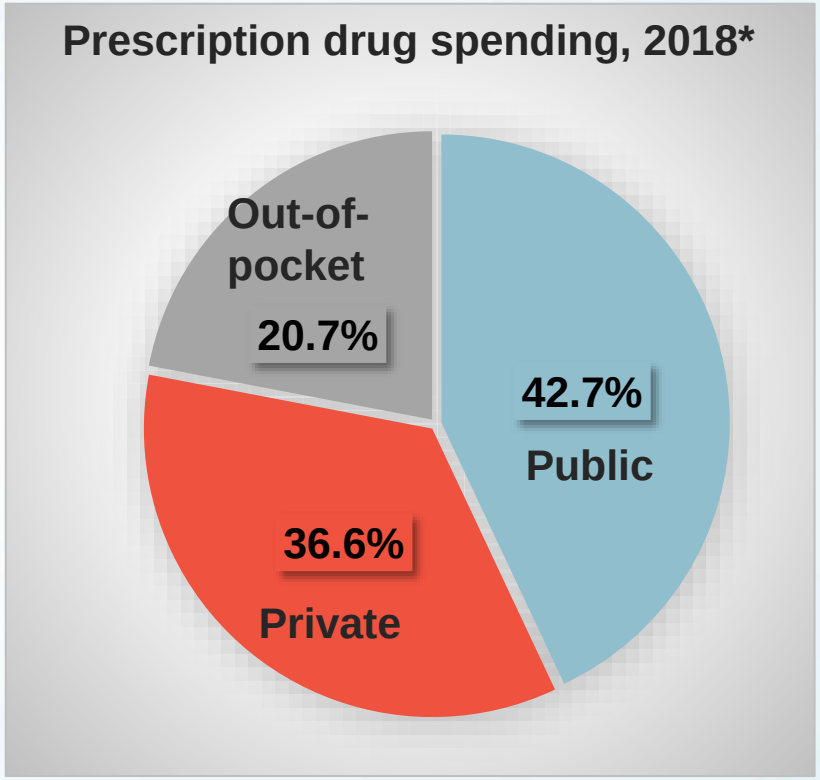
Data source: IQVIA™ Private Pay Direct Drug Plan Database.

Challenges faced by payers

Canadian payers struggle to cope with the influx of high-cost drugs and often have to ration access.

Given the systemic fragmentation, Canada is unable to leverage the national buying power in the same way as other countries.

- pan-Canadian Pharmaceutical Alliance (pCPA) negotiates rebates off of the list price for public plans only.
- Private insurers have recently started to negotiate prices for drugs, but not as a buying group – they pay higher prices than provinces.
- The uninsured pay the highest prices for drugs, the list prices.

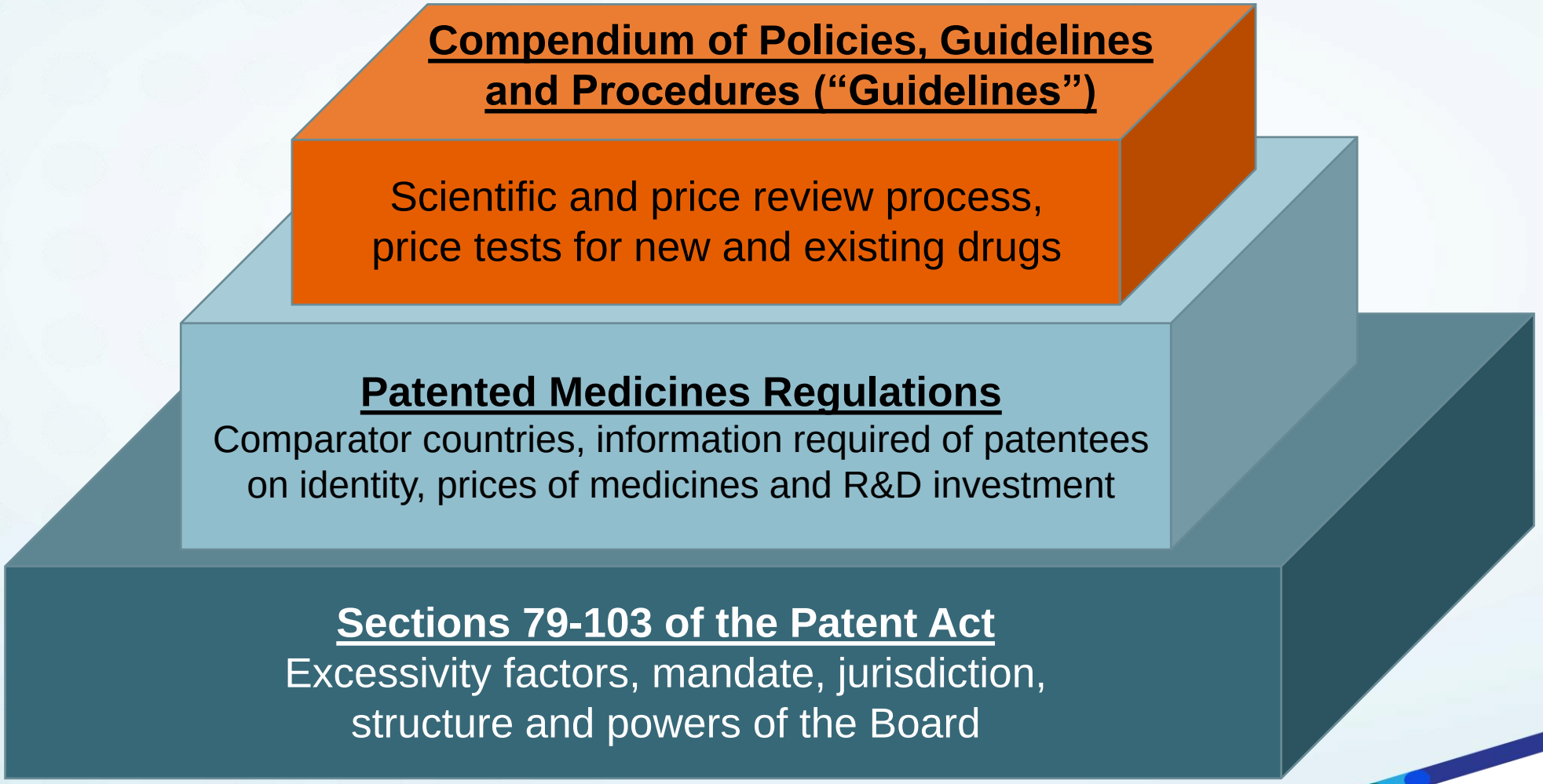


All payers, national or international, have little leverage in negotiating for the drugs that have few or no therapeutic options.

*Data source: Canadian Institute for Health Information, Prescribed Drug Spending in Canada, 2018

PMPRB regulatory framework

The PMPRB's authority to regulate patented medicine prices reposes on three legal instruments



How the PMPRB sets ceiling prices today

New patented medicines are assessed for level of therapeutic benefit relative to existing therapies and are assigned a ceiling price that is based on either:

1. The median international price based on the **PMPRB7**;
2. The highest price in the domestic therapeutic class; or
3. Some combination of the two.

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, 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.

Q: Main problem with the current framework?
A: Designed at a time before the internet or cell phones

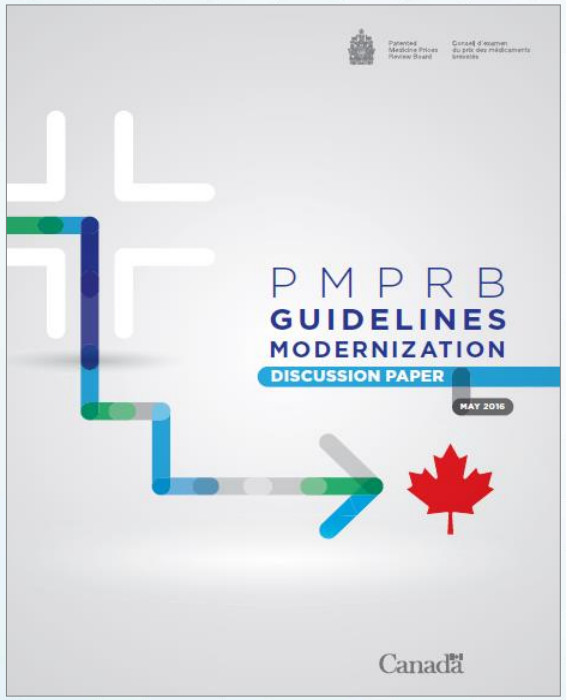
Designed to respond to realities of the mid-1980s

No longer effective in the 21st century

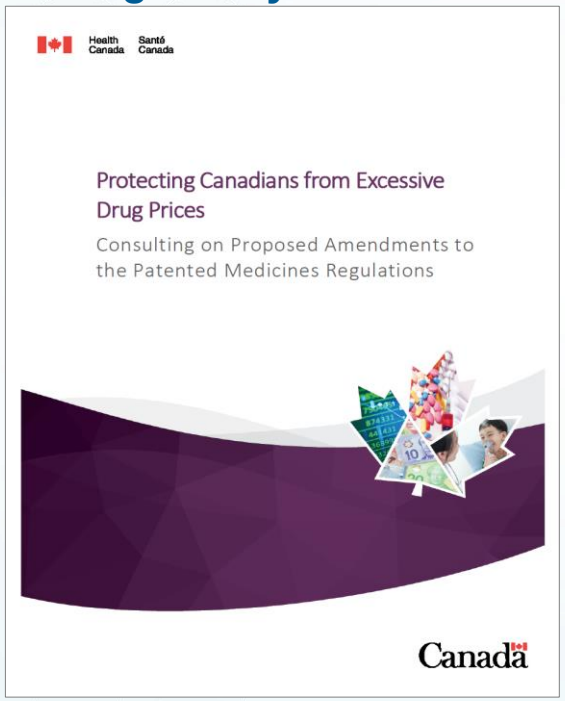
Strengthen IP regime while controlling prices and increasing domestic R&D investment	Further strengthen IP regime, higher prices and lower domestic R&D investment
Price ceilings based on public list prices that reflect market prices	Inflated list prices and non-transparent rebates
Market dominated by small molecules indicated for more common ailments	Speciality therapies increasingly dominating the drug landscape
Effective price control factors: internal and external price referencing	Medicines priced for value, a factor not currently in PMPRB toolbox
Level of regulatory scrutiny irrespective of market power	A risk-based approach required for medicines with the most market power
Comparator countries who's R&D investments Canada would emulate	Premium priced comparator countries, including the US

PMPRB and Health Canada have been consulting since June 2016

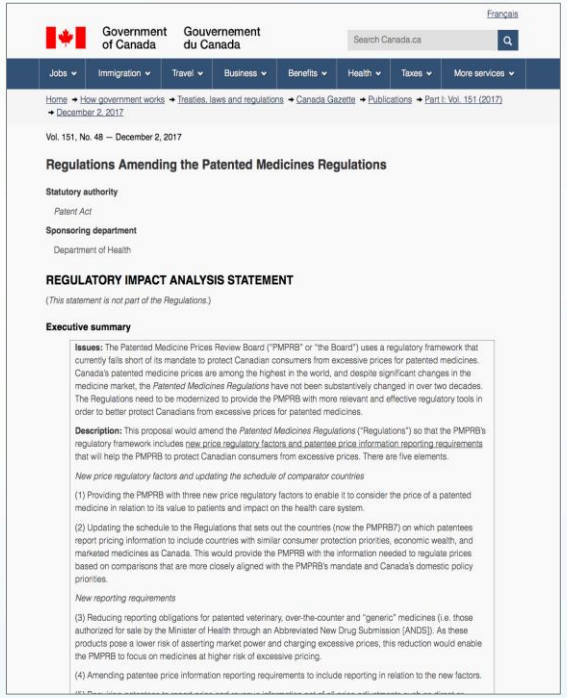
PMPRB Discussion paper on Guideline reform



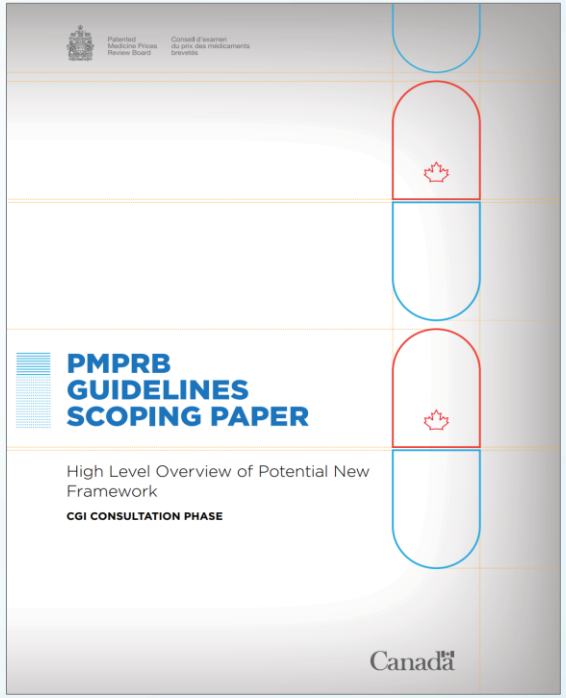
Health Canada pre-consultation on regulatory amendments



Health Canada Canada Gazette I



PMPRB Guidelines scoping paper



Proposed changes to the Patented Medicines Regulations

Would give the PMPRB the 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. **Regulating at the level of the actual prices being paid in Canada** and not just the non-transparent manufacturer list prices

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

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

Changing the basket of countries

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

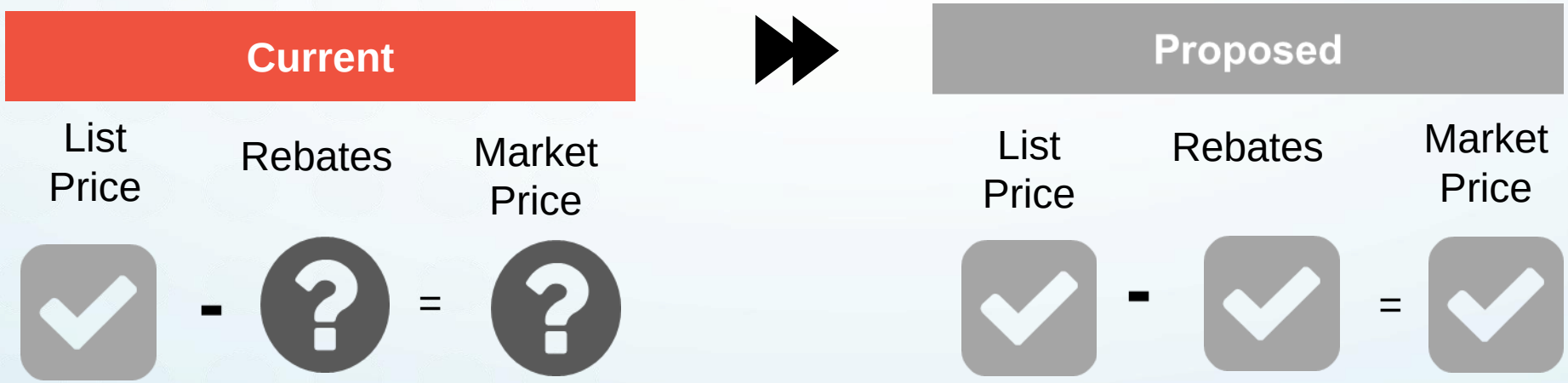
PMPRB-12 (new basket)			
Country ([2]added to new basket)	**CDN Price Ratio**	**Country** ([2]added to new basket)	**CDN Price Ratio**
Australia[2]	0.78	Norway[2]	0.75
Belgium[2]	0.80	South Korea[2]	0.54
France	0.78	Spain[2]	0.80
Germany	1.00	Sweden	0.89
Italy	0.83	United Kingdom	0.84
Japan[2]	0.92	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

The Government proposes to include additional comparator countries and to drop 2 outliers:

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

Regulating true prices

- When the PMPRB was created, actual prices paid in the market matched 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 left to set its domestic price ceilings based on inflated prices.

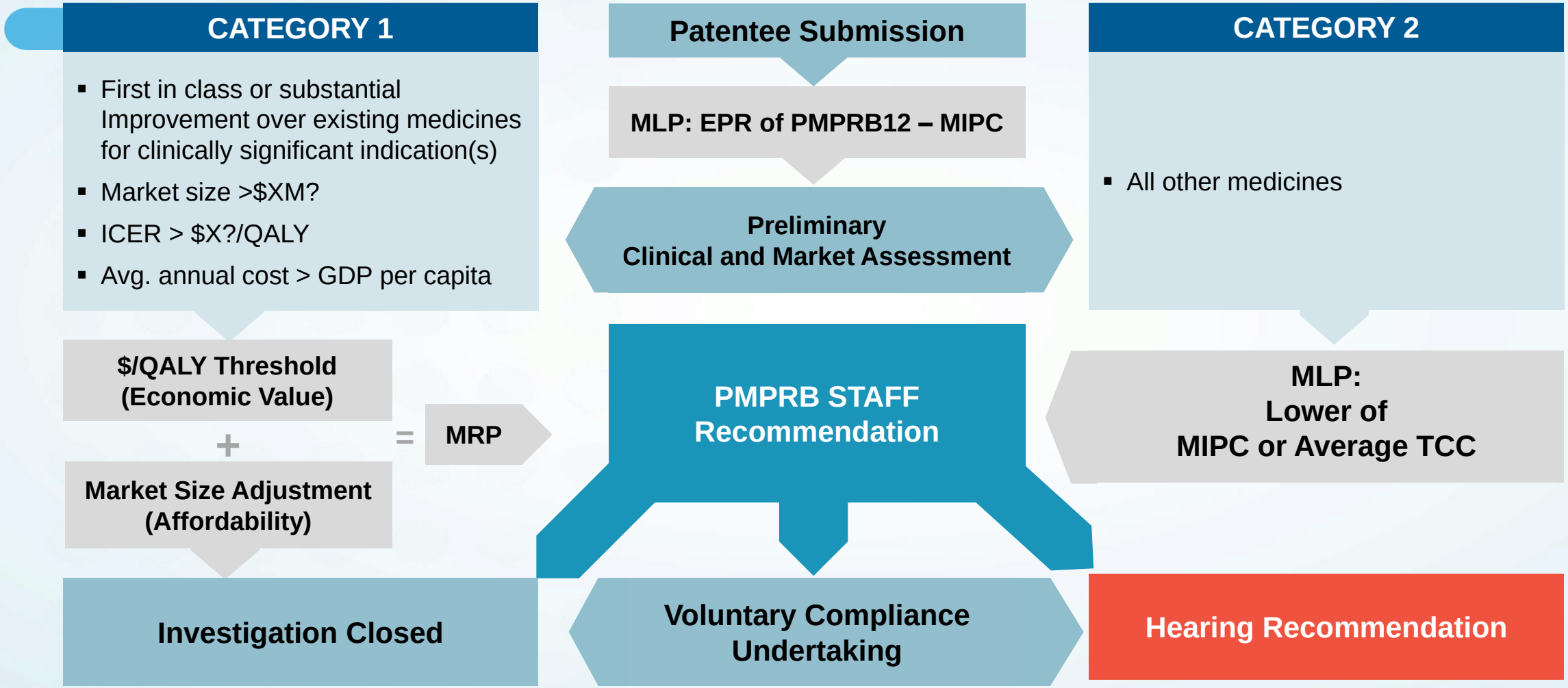


New price review factors

Most regulators consider additional factors beyond simply comparing prices paid in other countries.

Factor	Description	Comparator countries using the factor
Value for Money	Comparison of the costs and benefits of a drug to patients and the healthcare system ▪ **A country should not pay for a drug more than the value it offers, expressed in monetary terms**	
Size of the market	Consideration to the market size and its re-assessment over time ▪ **A drug should not be priced at a level that may result in rationing by payers.**	
GDP and GDP per capita	The assessment of the affordability of a drug for a country and an individual based on the GDP and the GDP capita, respectively ▪ **A medicine should not be priced at a level that patients and/or payers cannot afford.**	

Proposed PRICE review schematic



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 International Price Comparison (MIPC) of the PMPRB12
- **Part II:** Screening of medicines 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 Comparison (ATCC) for Category 2 medicines
- **Part V:** Re-benching

The Maximum List Price would be a transparent ceiling based on public list prices, while the Maximum Rebated Price (Category 1 medicines only) will be confidential.

To comply with the Maximum Rebated Price, patentees of Category 1 medicines would be required to submit information on undisclosed rebates to third parties.

Re-benching

Possible re-benching for both MLP and MRP to be 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 Health Canada lifting the conditions for the Notice of Compliance)
- Significant changes in international prices (e.g. MIPC* < MIPC at intro by more than 25%)

Patentees could apply for a re-benching with evidence of increased cost-effectiveness, smaller market, or a significant increase in the Consumer Price Index

*Median International Price Comparison

Guidelines Consultations

The PMPRB is consulting with its stakeholders on changes to its non-binding guidelines

PMPRB Steering Committee (SC)

- Comprised of representatives from public and private payers, health technology assessment bodies, industry and industry associations, patient groups, as well as medical and pharmacist associations.
- Mandate: to assist the PMPRB in synthesizing stakeholder views on key technical and operational modalities of new draft Guidelines which will serve the following dual objectives:
  1. Operationalize amendments to the Patented Medicines Regulations designed to lower patented medicine prices; and
  2. Support a risk-based approach to regulating medicine prices that simplifies and streamlines compliance for patentees.
- In deliberating on the above, the SC should seek to strike a balance between the following guiding principles: Sustainability, Predictability, Consistency, Functionality, and Fairness

Working Group (WG)

- Assists the SC with expertise in health technology assessment and economic and scientific matters.
- The analysis and recommendations of the WG will inform the work of the SC.

Technical Working Group: 6 areas of focus

1. Options for determining what medicines fall into ‘Category 1’
2. Application of supply-side cost effectiveness thresholds in setting ceiling prices for Category 1 medicines
3. Medicines with multiple indications
4. Accounting for uncertainty
5. Perspectives
6. Application of the market size factor in setting ceiling prices

Next steps

Winter 2019 / Analysis and Recommendations

- Technical Working Group to produce a report in March
- Steering Committee deliberations will be summarized in a report produced by the PMPRB Staff
- The PMPRB Board to consider in the spring the analysis and recommendations emanating from the reports of the Working Group and the Steering Committee's deliberations.

Spring 2019 / Release Guidelines – Depending on Canada Gazette II (CG II)

- Board to produce draft guidelines for consultations following the final publication of the proposed amendments as part of CG II.
- Any changes to the CG II amendments may warrant changes to the proposed framework and/or a further round of consultations on the Guidelines.
- Stakeholders' information and outreach sessions to be organized.
- Release of Published Guidelines – consultations in accordance with the *Patent Act*.

Thank You