Patented Medicine Prices Review Board Canada

Conseil d'examen du prix des médicaments brevetés Canada

PMPRB GUIDELINES MODERNIZATION

SEPT 2016

Canada

Strategic Plan 2015-2018

High patented drug prices and record low pharmaceutical R&D in Canada have rise to public questioning of the effectiveness of the PMPRB. Accordingly, in 2014 the PMPRB initiated a year-long strategic planning process to chart a fresh course for the next quarter century.

Accordingly, strategic Plan 2015-2018 was published in December 2015. It identified four strategic objectives, as well as a new vision and mission for the organization.

1. Consumer-focused regulation and reporting
2. Framework modernization
3. Strategic partnerships and public awareness
4. Employee engagement

Much of our activities over the past year have been in response to the adoption of these objectives.

PMPRB Vision

Vision

- A sustainable pharmaceutical system where payers have the information they need to make smart reimbursement choices and Canadians have access to patented drugs at affordable prices.

Mission Statement

- We are a respected public agency that makes a unique and valued contribution to sustainable spending on pharmaceuticals in Canada by:
  - Providing stakeholders with price, cost and utilization information to help them make timely and knowledgeable drug pricing, purchasing and reimbursement decisions
  - Acting as an effective check on the patent rights of pharmaceutical manufacturers through the responsible and efficient use of its consumer protection powers.

PMPRB Regulatory Framework

The PMPRB's legal authority is derived from three primary sources:

- *Patent Act*: establishes the PMPRB with a mandate to regulate the prices of patented medicines sold in Canada to ensure that they are not excessive; and to report to Parliament annually through the Minister of Health. The PMPRB operates within sections 79 to 103 of the Act.
- Patented Medicines Regulations: specify the information patentees must provide and the countries for comparison.
- Compendium of Policies, Guidelines and Procedures: articulate the core administrative concepts which give effect to the PMPRB's consumer protection mandate.

Regulatory Environment in 1987

At the time of the PMPRB's creation, little was known about the relationship between price, intellectual property (IP) protection and R&D investment.

Efforts by public and private payers to control prescription drug costs were in their relative infancy, including the concept of "international reference pricing" (i.e. benchmarking prices in one country to prices in other countries).

Industry R&D efforts were focused on bringing medicines to market which treated the most common diseases and conditions, such as high cholesterol, high blood pressure and depression, and which were generally priced within reach of consumers and payers

Official "list" prices for medicines approximated the true price paid in the market and did not vary significantly between different types of payers (e.g. public vs. private).

Finally, the government believed pharmaceutical companies would generally seek to avoid abusing their newly strengthened patent rights out of consideration for the political capital that had been spent securing passage of the underlying legislation.

Sales of Patented Drugs

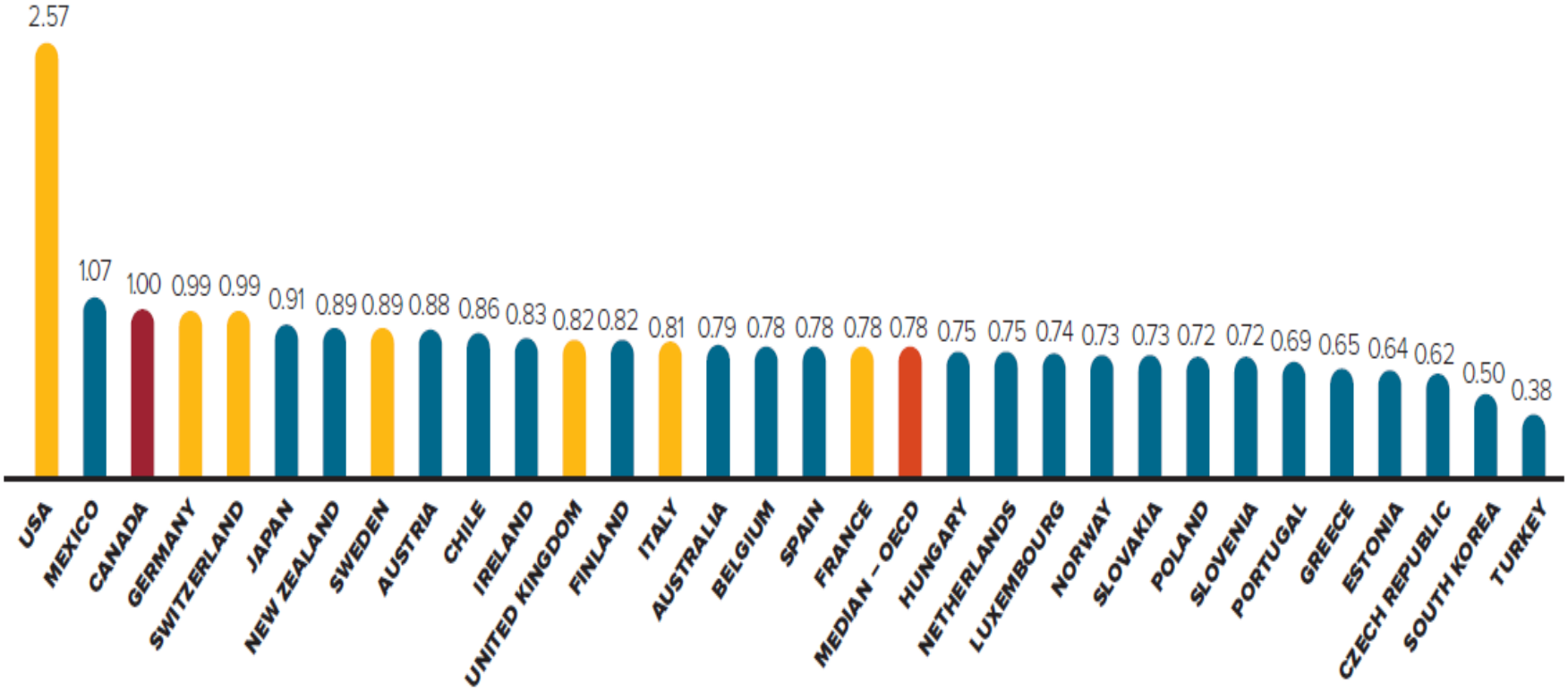
In 2015 total sales had highest growth rate in more than 10 years.

TABLE 7. Sales of Patented Drug Products, 1990–2015

YEAR	PATENTED DRUG PRODUCTS		SALES OF PATENTED DRUG PRODUCTS AS A SHARE OF ALL DRUG SALES (%)*
	SALES ($BILLIONS)	CHANGE (%)	
2015	15.2	9.5	61.8
2014	13.8	3.1	59.9
2013	13.4	4.2	60.7
2012	12.9	0.1	59.2
2011	12.9	3.5	58.3
2010	12.4	-4.3	55.8
2009	13.0	2.9	59.6
2008	12.6	4.6	61.7
2007	12.1	3.2	63.2
2006	11.7	7.4	67.8
2005	10.9	4.2	70.6
2004	10.5	7.8	72.2
2003	9.7	9.0	72.7
2002	8.9	17.5	67.4
2001	7.6	18.9	65.0
2000	6.3	16.7	63.0

OECD Comparisons

FIGURE 10. Average Foreign-to-Canadian Price Ratios, Patented Drugs, OECD, 2015



Drug Expenditure in Canada

One way to examine this issue in a way that limits the influence of exchange rates is to focus on local currency drug expenditure over time.

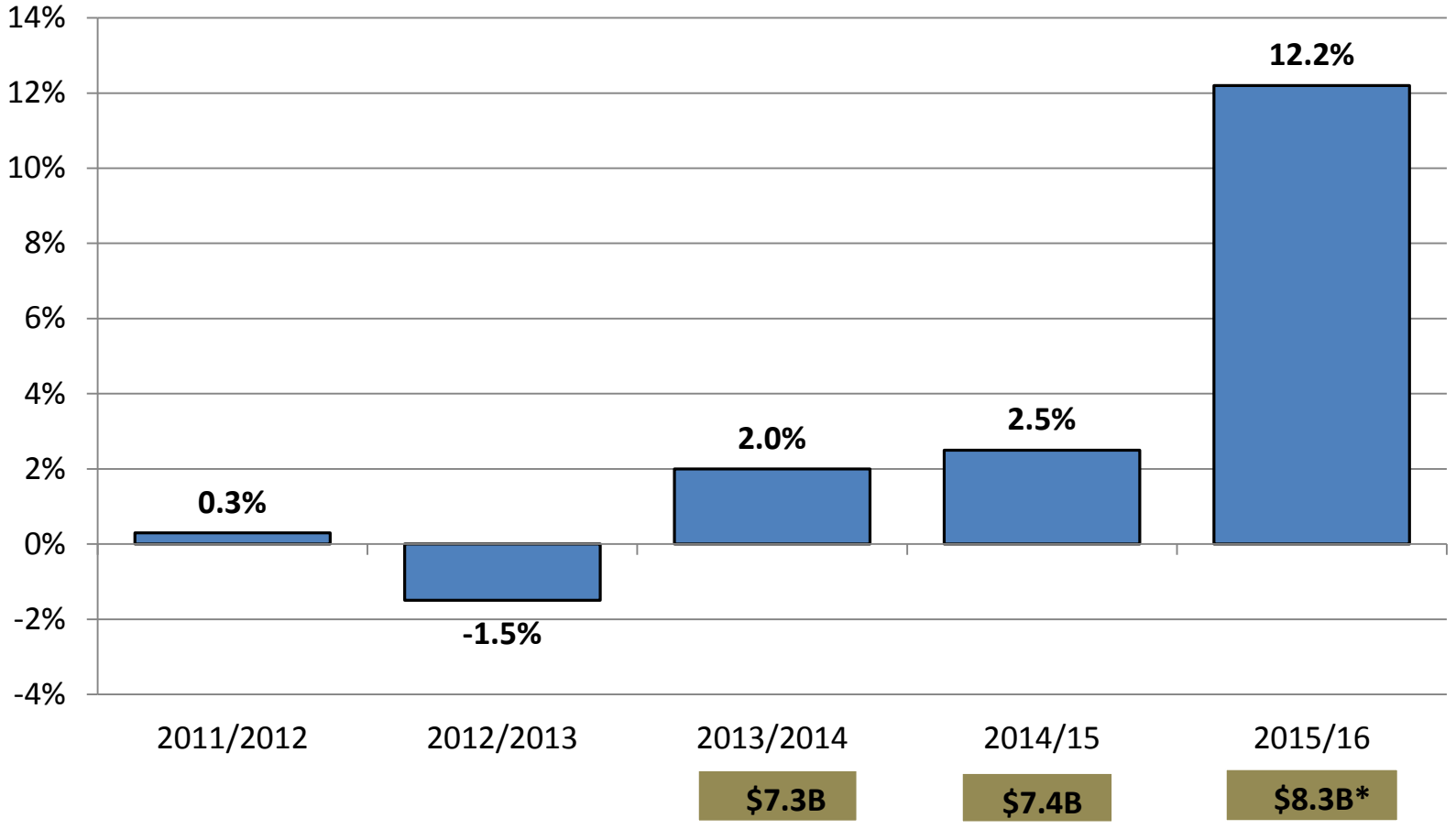
	Drug Expenditures/GDP 2013 (%)	Drug Expenditures/GDP 2005 (%)	GDP 2005-2013 (%)	Drug Spending Per Capita ($US PPP)
Canada	1.78	1.64	33.3	761
France	1.65	1.79	34.6	622
Germany	1.55	1.58	36.7	678
Italy	1.63	1.70	25.1	572
Sweden	1.11	1.15	39.6	496
Switzerland	1.22	1.09	64.9	696
UK	1.04	1.00	19.9	367
USA	1.95	1.88	27.3	1034

With the most recent data available, Canada has the second highest drug expenditure as a share of GDP in the PMPRB7 (behind only the US). Though Canada's GDP growth over that period is average, Canada has one of the highest increases in drug expenditure as a share of GDP over that same period.

This has resulted in Canada having the 2nd highest drug spending per capita among the PMPRB7.

Sharp increase in public drug plan costs in 2015/16…

Annual rates of change in drug expenditures, select public drug plans, 2011/12 to 2015/16



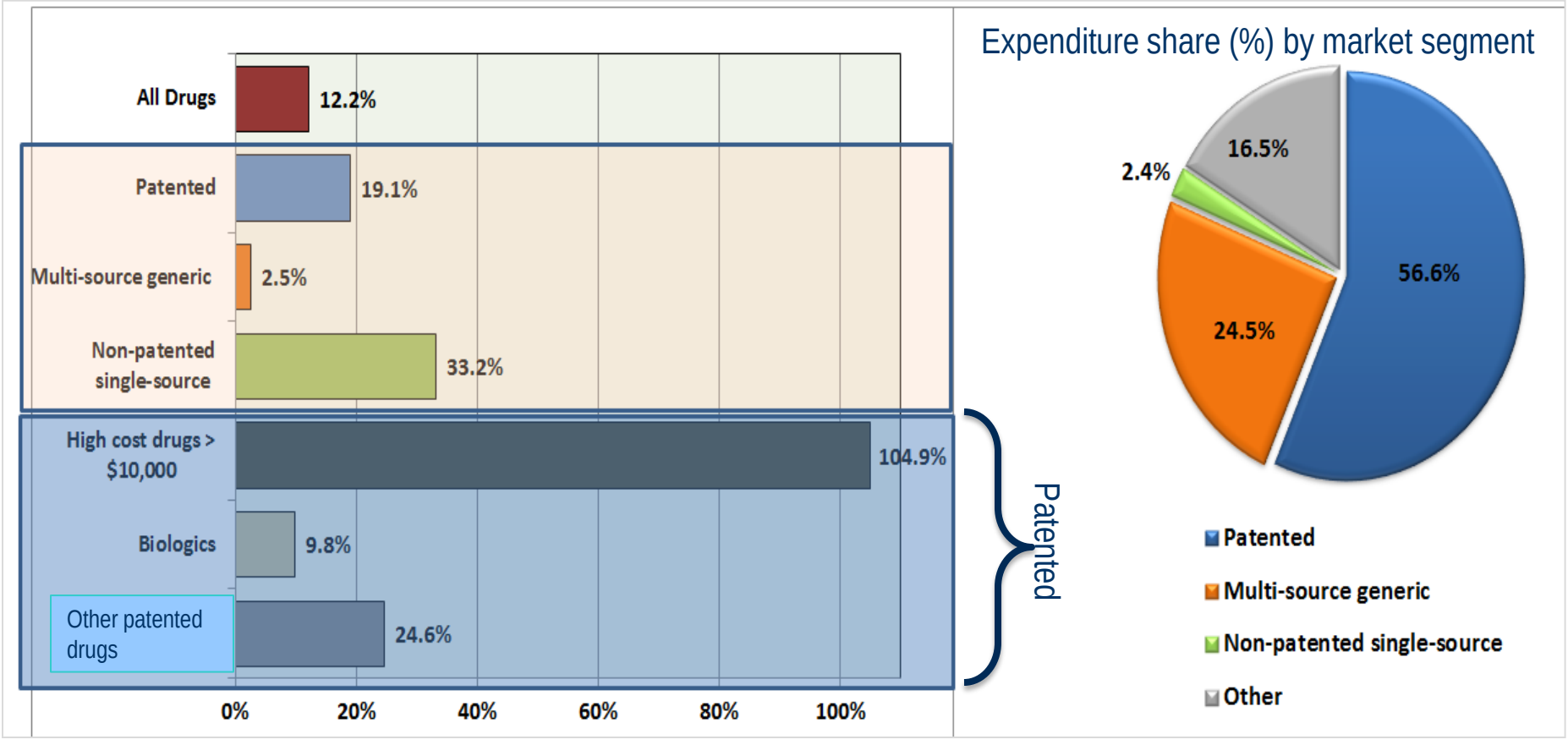
*Estimate

Data source: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

Public Plans

Costs double for high-cost drugs in 2015/16

Annual rates of change in drug costs by market segment, NPDUIS public drug plans, 2014/15 to 2015/16

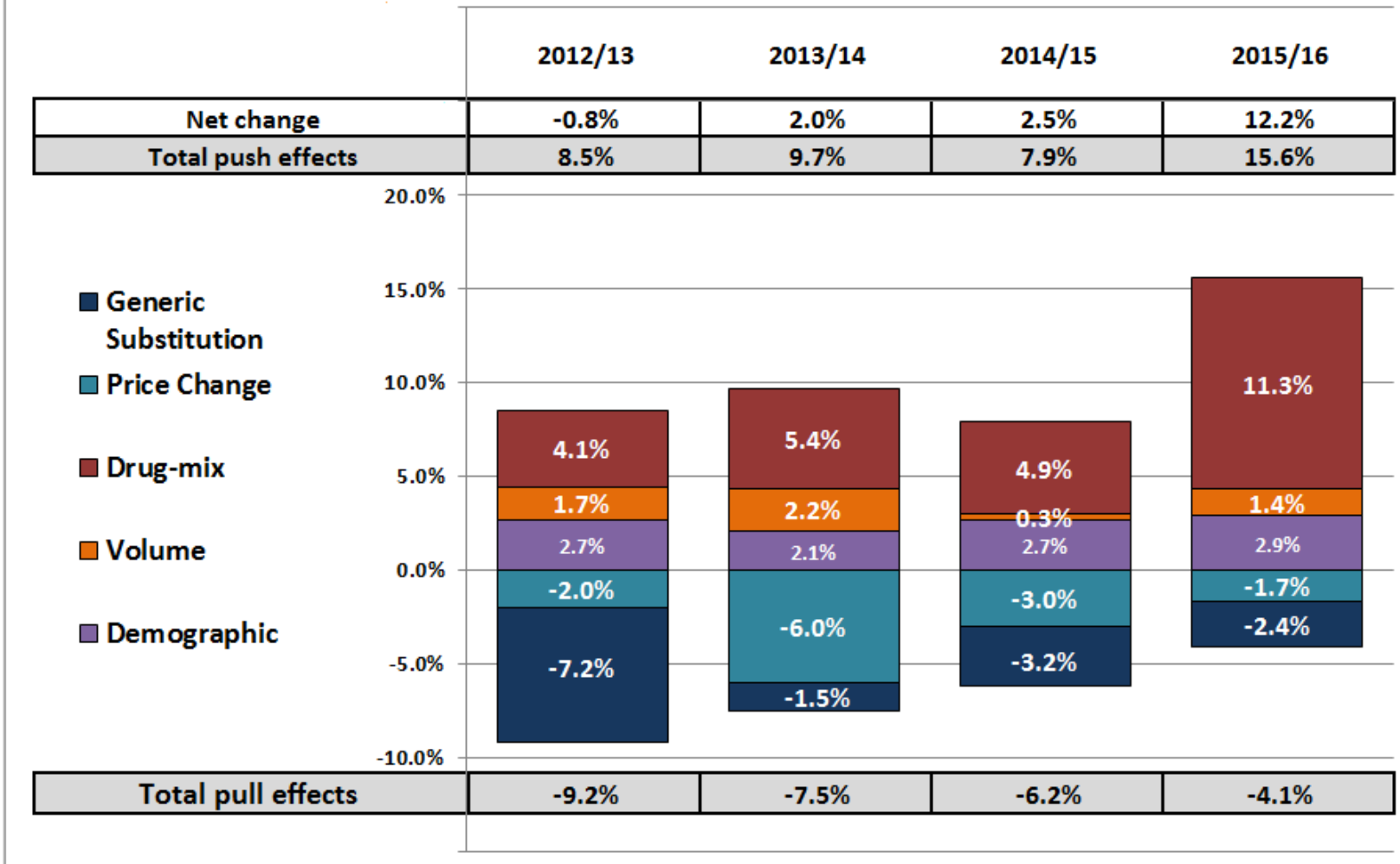


Data source: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

Cost drivers in public plans

....drug mix dominates, gradual decline in price effects

	2012/13	2013/14	2014/15	2015/16
Net change	-0.8%	2.0%	2.5%	12.2%
Total push effects	8.5%	9.7%	7.9%	15.6%



Total pull effects	-9.2%	-7.5%	-6.2%	-4.1%

Data source: National Prescription Drug Utilization Information System Database, Canadian Institute for Health Information.

Policy Ecosystem

"The Panel therefore recommends that the federal government review and strengthen the PMPRB… so as to ensure that the Board will provide more effective consumer protection against high patented drug prices."

Report of the Advisory Panel on Healthcare Innovation 2015

"We will also develop a pan-Canadian collaboration on health innovation, and will improve access to necessary prescription medications. We will join with provincial and territorial governments to buy drugs in bulk, reducing the cost Canadian governments pay for these drugs, and making them more affordable for Canadians."

Liberal Platform 2015

"[I]mprove access to necessary prescription medications. This will include joining with provincial and territorial governments to buy drugs in bulk, reducing the cost Canadian governments pay for these drugs, making them more affordable for Canadians."

Minister of Health Mandate Letter (November 2015)

"We need to explore new ways to focus our regulatory system upon the review of drugs that actually deliver a better standard of care and increase value for money. We also need to re-examine the role of the regulatory body whose job it is to protect Canadians from excessive brand name drug prices. And this, some of you may know, is called the Patented Medicine Prices Review Board."

Minister of Health Jane Philpott (September 2016)

Changes In Regulatory Environment

Today, the empirical evidence is that high prices are not especially effective policy levers for attracting pharmaceutical R&D.

Confidential discounts off the list price have become the industry standard. In Canada, this is resulting in a growing price gap between public payers, private payers, and cash customers, who have no ability to negotiate.

The era of mass-marketed, so-called “blockbuster” medicines has evolved towards one where the most profitable return on investment is made from very high cost specialty medicines. These “nichebusters”, as the most successful are often called, target less common, untreated, and severe illnesses and conditions but at a price even the most well-funded payers struggle to afford.

The present day reality is that the only meaningful constraints on what pharmaceutical companies can charge for their products is what the market will bear or regulators can effectively impose.

Why Are We Consulting?

Canadian prices for patented drugs are now among the highest in the world, and R&D is near record low levels. Accordingly, the effectiveness of the PMPRB has come into question.

In order to ensure that we can effectively fulfill our consumer protection role, the Guidelines through which Board Staff operationalize the Regulations and Patent Act must be regularly brought up to date with the reality of the ever-evolving Canadian pharmaceutical landscape.

The Guidelines Discussion Paper has the following objectives:

1. to stimulate an informed discussion of the changes that have taken place in the PMPRB's operating environment;

2. to identify areas of the Guidelines that may be particularly in need of reform in light of these changes;

3. to encourage public participation to obtain a diverse array of viewpoints on the direction of Guideline reform; and,

4. to support the PMPRB in its continuing efforts to protect consumers from excessively priced patented medicines.

Guidelines Modernization

An update to the Guidelines is required to ensure that they remain effective in the face of changes that have taken place since the PMPRB was created.

The following areas have been identified as potential areas of change:

1. Therapeutic Benefit
2. International Price Comparisons
3. Domestic Price Comparisons Price
4. Price change and the Consumer Price Index
5. Frequency of Reviews
6. Any Market Price Review

Therapeutic Benefit

The rationale for categorizing new patented drugs based on perceived therapeutic benefit is to attempt to align price ceilings with innovation.

While this approach makes some sense from an industrial and intellectual property policy perspective, it appears to conflict with recent Supreme Court jurisprudence which says that the PMPRB's mandate is to "balance the monopoly power held by the patentee of a medicine, with the interests of purchasers of those medicines".

Categorizing drugs based on indicators of potential for abuse of statutory monopoly (rather than clinical evidence of therapeutic superiority) may be more in keeping with the Supreme Court's interpretation of the PMPRB's purpose.

Despite the Supreme Court's reasoning and the changes in the pharmaceutical marketplace described above, the PMPRB's current approach to categorizing medicines by therapeutic benefit is not geared to questions of market dynamics.

This results in undue regulatory burden on patentees and frustrates the ability of the PMPRB to prioritize its enforcement resources on cases where payers are most in need of regulatory relief.

What alternatives to the current approach to categorize new patented medicines could be used to address the questions of high relative prices, market dynamics and affordability?

International Price Comparisons

Most wealthy countries engage in some form of international price comparison to limit drug costs, although increasingly as an adjunct to other forms of cost containment.

The PMPRB's longstanding benchmark for determining evaluating the effectiveness of our mandate is that, on average, Canadian prices should not exceed median PMPRB7 prices.

The policy rationale for practicing international price referencing should guide the discussion of how international price referencing is applied.

However, the current reality is that the actual prices being paid in European countries are below the public prices that the PMPRB is constrained to use for international comparison purposes. In 2015, Canadian prices were 28% higher than the OECD average for the same drugs.

To put this differential in perspective, there were C$15.2 billion in sales of patented medicine products in Canada in 2015. If Canadians paid the OECD average for these medicines, consumers would have saved nearly $3.3 billion.

How should international prices be considered in evaluating whether the price of a patented medicine in Canada is excessive?

Domestic Price Comparisons

Currently, new patented drugs that fall into the “slight or no improvement” category are permitted to price at the top of the therapeutic class. This is problematic for two reasons:

1. It is out of step with how many other countries regulate the pricing and reimbursement of so-called “me-too” drugs.

2. The prices upon which the PMPRB relies for domestic comparison purposes do not reflect confidential discounts and rebates.

If the goal of therapeutic class comparison is to protect Canadians from the risk that new medicines will raise treatment costs to excessive levels, then referencing the highest price in a therapeutic group pushes price ceilings in the wrong direction.

At the same time, the fact that me-too drugs face competition argues in favour of less regulatory oversight of this class of drugs, not more.

One solution to these competing considerations would be to introduce lower price ceilings for me-too drugs in the Guidelines at introduction, but take a more relaxed approach to monitoring them on a go-forward basis having regard to the lower risk of abuse.

How should the Guidelines reference other drugs in the same therapeutic classes for the purpose of a domestic price comparisons? Should the price be re-assessed periodically to reflect evolving market conditions?

Consumer Price Index

Every country has an interest in ensuring that pharmaceutical prices are stable and predictable over time. This is reflected in the current Guidelines to the extent that patented drug prices cannot increase by more than average inflation (as measured by CPI).

This practice is generally seen as achieving its goals: the average rate of change for patented pharmaceutical prices in Canada has been less than CPI since 1992.

However, other countries, such as France, Sweden and Switzerland, are more stringent, in that pharmaceutical prices either cannot increase or must decrease at specified intervals. This makes sense given that, over time, both the marginal cost of producing a drug should be expected to decrease and price competition from subsequent drugs make itself felt.

For example, between 2008 and 2014, the prices of 64% of patented medicines sold in both Canada and Switzerland decreased in Switzerland but increased in Canada. This pattern is similar among the other non-US PMPRB7 comparators.

How should the PMPRB use the consumer price index?

Frequency of Reviews

The PMPRB practice of reviewing all patented medicines annually relative to CPI and against the highest international price, but only once (at introduction) relative to therapeutic category is out of step with the approach in many other countries.

For instance, Switzerland completely reassesses the prices of one-third of prescription medicines every year (such that the entire portfolio is reassessed every three years). France reassesses medicines at a minimum of 2 years, and maximum of 5 years, depending on whether additional clinical or observational data have been developed.

It may therefore be appropriate to instantiate a more regular review of drug prices against *all* the factors in the Patent Act, triggered at a certain frequency, new indication, rapid increase in sales, or some other means.

How often should the PMPRB review the price of a drug?

Any Market Price Review

The lack of price transparency in the Canadian pharmaceutical system allows patentees to discriminate between different classes of consumers.

The Act empowers the PMPRB to evaluate whether the price of a patented medicine is excessive “in any market” in Canada. The current Guidelines give effect to this authority by scrutinizing prices at the wholesaler, pharmacy and hospital level and in each province and territory.

However, this is only done at introduction and in subsequent years, “any market” reviews only take place if a medicine is already under investigation.

Given that the Act contemplates an assessment of price in “any market”, consideration of equity between customer classes, whether by region or payer type, could play a more prominent role in determining whether the price of a patented medicine is excessive.

How should the Guidelines treat sales to different markets and payers/consumers?

Consultation Process

At this initial stage in consultations, the PMPRB is seeking generalized feedback, in the form of responses to a series of broadly framed questions.

Throughout the process, stakeholders and members of the public who wish to submit their views are respectfully requested to give due consideration to the following issues:

- the Supreme Court's interpretation of the PMPRB's consumer protection mandate
- affordability
- market power
- price transparency
- Canada's price gap with European countries
- price differentials between public and private payers
- regulatory burden
- R&D trends
- international best practices.

3 Phases of Consultations

Phase	Steps	Timelines
Phase 1: Consult with Stakeholders on Issues	• Publish Discussion Paper • Meet with various stakeholder groups across Canada. • Obtain written comments from stakeholders and the public on questions in the discussion paper • Gather and analyze all results from Phase 1 of consultation	Summer/Fall 2016
Phase 2: Engage Stakeholders and Gather Expert Input	• Public Policy Hearing – invite stakeholders to appear before the Board and make representations in support of their written submissions	Fall/Winter 2017
Phase 3: Presentation of Proposed Changes	• Publication of proposed changes to Guidelines for comment through Notice and Comment Process • Strike multi-stakeholder forum(s) on specific issues and explore options for specific changes to the Guidelines	Spring/Summer 2017

Submitting Comments

Written comments must be submitted by e-mail, letter mail or fax by October 24, 2016 to:

Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Fax: 613-952-7626
E-mail: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

PMPRB GUIDELINES MODERNIZATION

DISCUSSION PAPER

JUNE 2016