Amendments to the Patented Medicines Regulations

Cost-Benefit Analysis

Strategic Policy Branch
Health Canada
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Executive Summary

Objective and Context

This document provides the cost-benefit analysis (CBA) of the amendments to the *Patented Medicines Regulations* to modernize the Patented Medicine Prices Review Board's (PMPRB) Regulatory Framework.

The PMPRB is an independent, quasi-judicial body established by Parliament in 1987 under the *Patent Act* (*Act*). The PMPRB is mandated to protect Canadian consumers by ensuring that the prices of patented medicines sold in Canada are not excessive. It does so by establishing the maximum price at which a patented medicine can be sold in Canada and monitoring the price that patentees charge. If a price is believed to be excessive, either the PMPRB can negotiate with the patentee to voluntarily lower the price or induce the patentee to repay any excess revenues, or the PMPRB can hold public hearings to determine whether the price is excessive. If it is found to be excessive, the PMPRB can order price reductions and/or collect revenues from the patentees to offset excessive charges to Canadian consumers. The PMPRB is also responsible for reporting to Parliament on trends in medicine sales and on research and development expenditures by patentees.

To strengthen the PMPRB's consumer protection mandate, Health Canada is amending the *Patented Medicine Regulations* (PMRs) to:

- introduce new, economics-based price regulatory factors that will enable the PMPRB to ensure non-excessive prices reflect value-for-money and Canada's willingness and ability to pay for patented medicines;
- update the Schedule of countries used by the PMPRB for international price comparisons (currently 7 countries, termed the PMPRB7) to better align with the PMPRB's consumer protection mandate;
- provide reduced reporting obligations for patented veterinary, over-the-counter and 'generic' medicines;
- set out the patentee price information reporting requirements to enable the PMPRB to operationalize the new price regulatory factors; and,
- require patentees to report on all price adjustments (such as direct or indirect third party discounts or rebates).

The amendments will modernize the PMPRB's Regulatory Framework to enable a risk-based approach to price regulation. Central to this approach is the recognition that patented medicines have differing potential to exert market power and charge excessive

prices. This potential is largely shaped by the characteristics of the market for each medicine, such as the availability of comparator products and the size of the patient population. Under the amendments, medicines with higher potential to exert market power will face a higher degree of regulatory scrutiny while medicines with lower risk of excessive prices will face lower oversight.

Costs and Benefits

Lower overall spending on patented medicines in Canada is anticipated to result from lower prices. Costs relate to

1. reduced industry profits due to lower prices for patented medicines; and,
2. the net impact of new and reduced administrative industry reporting requirements.

The amendments are expected to result in 10-year total savings to public, private and out of pocket-payers of $8.8 billion present value (PV) because of lower patented medicine costs. Lower prices will alleviate financial pressures on public and private insurers and improve affordable access for Canadians paying out-of-pocket. Costs to industry include lost profits, as well as administrative and compliance costs as described below.

Table 1: Cost-Benefit Statement.

	Base Year (Year 1 PV)	Final Year (Year PV)	Total (PV)	Annualized Average
		Benefits		
Lower Medicine Expenditure	$219,993,857	$1,513,601,539	$8,786,998,457	$1,251,067,609
New Factors	$33,443,984	$761,063,624	$3,796,634,596	$535,792,273
Updated Schedule	$138,187,980	$418,977,091	$2,926,192,236	$396,948,040
3rd-Party price adjustments	$48,361,892	$333,560,824	$2,064,171,625	$287,005,201
Total Benefits	$219,993,857	$1,513,601,539	$8,786,998,457	$1,251,067,609
		Costs		

Industry	$219,993,857	$1,513,601,539	$8,787,062,280	$1,251,076,677
Loss in profits	$219,993,857	$1,513,601,539	$8,786,998,457	$1,251,067,609
Administrative Cost			$34,717	$4,924
Compliance Cost			$29,106	$4,144
Government	$4,981,481	$8,025,361	$61,716,822	$8,787,064
PMPRB Program Expenditure	$3,849,215	$5,680,633	$43,361,629	$6,173,704
Special Purpose Allotment	$981,481	$2,025,361	$16,119,394	$2,295,033
Accommodation Requirements	$143,085	$304,667	$2,131,142	$303,425
IT Services	$7,700	$14,700	$104,657	$14,900
Total costs (PV)	$224,975,338	$1,521,626,900	$8,848,779,102	$1,259,863,741
Net benefits (NPV)			-$61,780,645	-$8,796,132

Qualitative impacts

Other Benefits

- Greater population health and increased savings to the health care system due to fewer acute care incidents. Lower prices could result in lower patient cost-related non-adherence to needed medicines (for example, not filling prescriptions or skipping doses).
- Opportunity to improve access to medicines and reallocate resources to other important areas of the healthcare system.
- Reduction in the burden placed on price negotiating bodies (e.g. the pan-Canadian Pharmaceutical Alliance) to ensure system affordability.

Other Costs

- Potential impact on wholesalers, distributors, pharmacies, and generic medicine manufacturers whose markups and prices are often expressed as a percentage of patented medicines prices.

Once compliance and administrative costs to industry and implementation costs to government are factored in, the total net benefit of these amendments is estimated to be negative $62 million net present value (NPV) over 10 years. However, a number of

benefits have not been monetized and are not reflected in this equation. In addition to the qualitative impacts listed in Table 1, the amendments are likely to reduce welfare losses attributable to the monopolistic nature of the industry.

Benefits

Lower Patented Medicine Prices

Anticipated quantitative benefits were calculated based on reduced overall spending on patented medicines. The projected baseline of future spending (2017–2028) was calculated using current growth trends and anticipated launches from the current medicine pipeline. It also includes the expected loss of patent protection of medicines that are currently under the PMPRB's jurisdiction.

The total quantitative benefits of the amendments are estimated at $8.8 billion (PV) over 10 years and consist exclusively of the direct benefits of lower prices for patented medicines. The impact on patented medicine prices in Canada is limited to the three primary elements of the amendments, namely:

1. introducing new price regulatory factors;
2. updating the Schedule of countries used by the PMPRB; and
3. requiring patentees to report price and revenues net of all adjustments.

The impact is expected to be progressive, representing a 1.1% reduction in revenues in the first year, growing to a 10.8% reduction, by year 10. With these amendments, the total spending on patented medicines in Canada over the next 10 years is expected to be $141.8 billion (PV), down from $150.6 billion (PV), for an overall reduction of 5.8%.

The introduction of the new price regulatory factors is expected to have the biggest impact on patented medicine expenditure ($3.8 billion), followed by the revised Schedule ($2.8 billion) and the reporting of price and revenues net of all adjustments ($2.0 billion).

Not all medicines will see a reduction in prices, as most existing products are still expected to be priced below the non-excessive price ceilings, even after the coming into force of these amendments. The CBA assumes that the PMPRB will take a risk-based approach to price regulation, whereby it will place a higher degree of regulatory scrutiny on medicines with a higher potential to exert market power ("high-priority medicines"), such as those medicines that have few or no therapeutic alternatives. It is assumed that medicines with a lower risk of excessive prices ("low-priority" medicines) will receive less oversight. For example, low-priority medicines will not be required to report on the new pharmacoeconomic value factor, while others will be exempt entirely from actively

reporting any information to the PMPRB. The new price regulatory factors do not apply to medicines that obtained a Drug Identification Number (DIN) in Canada prior to the publication of the amendments in the *Canada Gazette, Part II.*

Lowered Administrative Burden

The amendments remove the need for patented veterinary, over-the-counter, and generic medicines to file identity and price information to the PMPRB, unless that information is requested by the PMPRB. 96 medicines (out of PMPRB's 1359) fall under these categories and are currently required to file information to the PMPRB. Given that the Federal Court of Appeal only recently clarified and upheld the PMPRB's jurisdiction over these medicines, the PMPRB has not historically reported on the rate of compliance for the reporting on these medicines. Assuming full compliance, the administrative burden reduction is estimated to be $8,656 (PV) over 10 years.

Costs

Lost Revenues to the Medicine Industry

It is estimated that the amendments will result in reduced industry revenues of approximately $8.8 billion (PV) over 10 years, due to reduced non-excessive price ceilings in Canada.

Any price reduction and repayment of excess revenues will be pursuant to a voluntary compliance undertaking (VCU), or pursuant to a Board Order made following a public hearing where the Board determined that the medicine has been sold at an excessive price. A price reduction will not occur without voluntary compliance or a ruling by the Board, meaning that lost revenues from these amendments will only occur due to voluntary compliance by patentees or because of prices being deemed "excessive" under the *Act*.

For the purpose of this CBA, national treatment of revenue was given to all patented medicine manufacturers in Canada, despite the fact that 90% of the companies that report to the PMPRB are multinational enterprises (MNEs). While this deviates from Treasury Board Secretariat (TBS) Guidance, which only requires consideration of impact on domestic firms, it was decided to acknowledge the full impact on industry given its economic footprint in Canada. Doing so resulted in the lost revenue calculations being several times higher than it would have normally been for a CBA whose purpose is to ensure the greatest overall benefit to current and future generations of Canadians.

Increased Reporting Obligations and Costs

Patentee price information reporting requirements already exist under the current regulatory framework. For the most part, the types of information to be reported and the reporting frequencies remain unchanged. The increased administrative burden on the industry is to report on the new price regulatory factors of pharmacoeconomic value and market size. The amendments also include the benefit of reduced administrative burden for certain types of patented medicines (including some over-the-counter (OTC), veterinary, and generic medicines) but this reduction does not fully offset the new reporting requirements.

Increased Industry Costs

- Reporting requirements in relation to the new price regulatory factors. Patentees will need to ensure that the information is updated as new analyses are undertaken. The total administrative costs to report in relation to the new price regulatory factors are estimated to be $6,175 annually or $43,373 in (PV) over 10 years.
- Compliance costs to update existing reporting systems to comply with the new Schedule and domestic prices and revenues net of all adjustments. Patentees already have reporting systems in place for domestic and international prices - the amendments only modify the type of information to be reported. Total compliance costs are estimated to be $4,144 annually or $29,106 in (PV) over 10 years.

Government of Canada Costs

The total costs to the Government of Canada are anticipated to be $61.7 million in (PV) over 10 years. These costs are to increase the PMPRB's capacity and legal resources. These are the costs specifically allocated for these purposes as outlined in Budget 2017.

Increasing the PMPRB's Capacity

Costs to the Government of Canada include increasing the PMPRB's capacity to regulate excessive patented medicine prices. The PMRPB will need to hire additional staff to support the expected increase in enforcement-related activities. Staff with expertise in cost-effectiveness analysis will also be required to administer the new factors. The base (2018–19), second (2019–20), third (2020-21), and fourth years (2021-22) are anticipated to cost $3.8 million, $5.7 million, $6.7 million, and $7.7 million respectively. From the fifth year onwards, it is anticipated that costs to the Government of Canada will be $5.7 million per year to maintain the PMPRB's increased capacity.

Increasing Special Purpose Allotment (SPA) Funding

With the amendments in place, patentees might be less willing to accept a VCU. A VCU is a written commitment by a patentee to comply with the Board's *Compendium of Policies, Guidelines, and Procedures* (Guidelines), including adjusting the price of the patented medicine in question to a non-excessive level and offsetting any excess revenues that may have been received as a result of having sold the medicine at an excessive price. Instead of agreeing to a VCU, patentees may press for formal and potentially prolonged hearings should the PMRPB find excessive prices based on the amendments. In Federal Court, patentees will likely challenge the PMPRB's constitutional authority to regulate based on the new price regulatory factors as well as conceptual and methodological aspects of their implementation. The PMPRB will require additional funding for its SPA to cover the costs of outside legal counsel and expert witnesses. The base (2018–19), second (2019–20), third (2020-21), and fourth years (2021-22) are anticipated to cost $1.0 million, $1.8 million, $2.8 million, and $3.8 million respectively. From the fifth year onwards, it is anticipated that costs to the Government of Canada will be $2.0 million per year to maintain the PMPRB's increased SPA funding.

Offsetting Costs to Public Services and Procurement Canada and Shared Services Canada

Increasing the PMPRB's staffing levels will increase the costs of accommodation and information technology (IT) services. Combined, the base (2018–19), second (2019–20), third (2020-21), and fourth years (2021-22) will be anticipated to cost $151,000, $305,000, $328,000, and $331,000 respectively. From the fifth year onwards, it is anticipated that costs to the Government of Canada will be $319,000 per year to offset Public Services and Procurement Canada's accommodation costs and Shared Services Canada's IT services costs.

The total cost to the Government of Canada will be $61.7 million (PV) over 10 years.

1.0 Introduction

The Cabinet Directive on Regulatory Management issued by the TBS states that departments and agencies are responsible for assessing the costs and benefits of regulatory and non-regulatory measures, including government inaction, when determining whether and how to regulate.

This document presents the CBA of the amendments to the *Patented Medicines Regulations* (PMR) to modernize the operations of the PMPRB. Modernization of the PMPRB is needed to strengthen its consumer protection mandate to reduce the risk of excessive patented medicine prices.

To address the fast rising cost and increasing unaffordability of patented medicines in Canada, the amendments will enable a risk-based approach to price regulation in Canada. These amendments include adding new factors that the Board must consider when assessing excessive prices, revising the Schedule of countries used for international price comparison, and requiring patentees to report price and revenues net of all adjustment.

This analysis is predicated on a reduction in the predicted level of the public risk of having excessive patented medicine prices in the healthcare system. The objective of the amendments is to advance the overall health of Canadians by reducing the risk that consumers may face poor access to care due to excessively priced patented medicines and/or financial detriment.

2.0 Approach and Methodology

TBS requires medium and high impact proposals to conduct a comprehensive CBA that quantifies and monetizes costs and, where data is readily available, benefits. A qualitative analysis is undertaken to fill in the benefit gaps for each stakeholder group where necessary.

The objective of this analysis is to estimate the costs and benefits of the amendments to the *Patented Medicine Regulations* of adding new price regulatory factors, changing the Schedule of comparator countries and modifying reporting requirements.

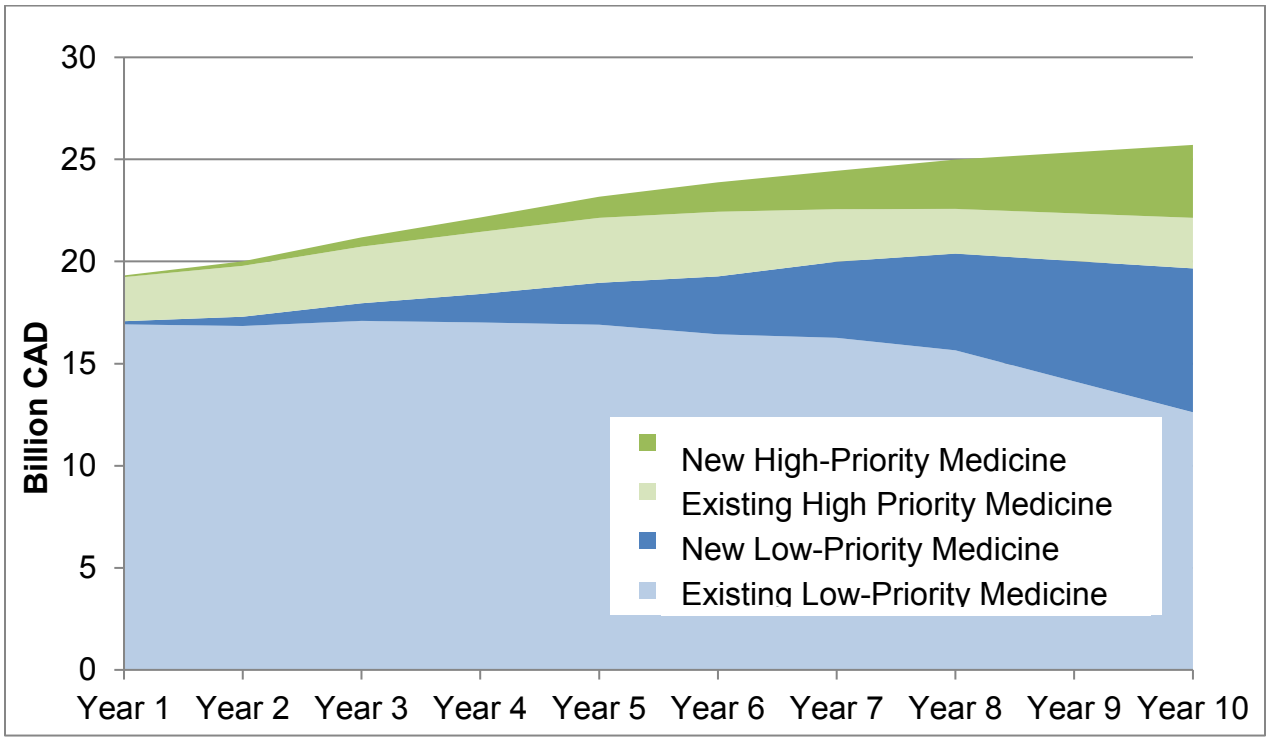
The amendments will be compared against the current scenario without any regulatory revisions or changes.

The modeling for the CBA can be described as follows. First, a baseline forecast was created. This baseline was built using recent patented medicine information and projects future aggregated medicine expenditure into four segments:

3. New High-Priority Medicines
4. Existing High-Priority Medicines
5. New Low Priority Medicines
6. Existing Low Priority Medicines

"New" represents all medicines that are expected to be introduced after the publication of the amendments in the *Canada Gazette, Part II*, whereas "existing" refers to all medicines that are introduced prior to that date. "High-priority" and "low-priority" represent the new medicine categorization system meant to replace the current PMPRB system that sorts medicines based on therapeutic benefit. High-priority medicines are medicines that have few therapeutic alternatives, are indicated for conditions that have a high prevalence in Canada, or have a high annual cost of treatment (i.e. exceeding $30,000).

Graph 1: Forecasted Patented Medicines Expenditure



Second, from this baseline, tests were applied to each element of the amendments that will affect the total expenditure for these four classes of medicines. Three elements of the amendments are expected to affect medicine expenditure in Canada:

1. new price regulatory factors;
2. updated Schedule of price comparator countries; and
3. information on price adjustments.

This CBA assumes that the PMPRB will take a risk-based approach to price regulation and will apply different tests to high-priority medicines and low-priority medicines. High-priority medicines possess greater market power and are therefore more at risk of being priced excessively. Because of this, the CBA assumes that the PMPRB will place greater scrutiny on high-priority medicines, while lessening its oversight of low-priority medicines.

The impacts of all three elements are aggregated and compared to the baseline. For calculating the PV, a 7% discount rate will be used as currently recommended by TBS guidelines. Other discount rates are provided in the sensitivity analysis.

3.0 Sector Overview

3.1 Canadian Medicine Sector

There are over 9,000 medicines on the Canadian market today. The Canadian Institute of Health Information (CIHI) estimated that Canadians spent in excess of $39 billion on prescription medicines.

Innovation, Science and Economic Development Canada (ISED) indicates that Canada represents 1.9% of global medicine sales and ranks 10th in the world in terms of total expenditure. Since 2011, the sector has had a compound annual average growth rate of 2.8%

Statistics Canada indicates there are approximately 30,000 Canadians employed in the domestic pharmaceutical industry.

3.2 Patented Medicine Sector

The PMPRB regulates the factory gate ceiling prices for all patented medicines sold in Canada. Although patentees are not required to obtain approval of the price before a medicine is sold, patentees are required to comply with the Act to ensure that the prices of patented medicines sold in Canada are not excessive. In 2017, the PMPRB held

jurisdiction over 1,391 patented medicines sold in Canada. The average Canadian spends $1,074 per year on medicines, with a total of $16.8 billion spent on patented medicines in 2017. There are currently 77 patented medicine manufacturers in Canada.

4.0 Parties Affected by the Regulatory Amendments

4.1 Patented Medicine Prices Review Board

Canada has some of the highest patented medicine prices in the world. This outcome demonstrates the PMPRB's limited effectiveness as an excessive price regulator given the evolution of the market since its inception in 1987. Modernizing the PMRs will bolster the PMPRB's ability to carry out its consumer protection mandate, as established in sections 79 -103 of the *Act.*

Many of the administrative concepts and price tests that form the operational foundation of the PMPRB are found in the Guidelines While Section 101 of the *Act* only authorizes the Governor in Council to amend the PMRs, the PMPRB is authorized under section 96 (4) of the *Act* to change its Guidelines. Unlike the PMRs, the Guidelines do not possess the force of law. There amendments will support a modernization of the PMPRB's Guidelines and strengthen the Board's ability to regulate excessive patented medicine prices.

4.2 Provincial and Territorial Governments

Provincial and territorial (PT) governments deliver health care services. PTs are greatly affected by any amendments that impact overall expenditures for medicines in the health care system, as each PT maintains public medicine insurance schemes. Any change in the overall Canadian price level for patented medicines will impact PT expenditures.

4.3 Government of Canada

Under the *Canada Health Act*, the Government of Canada provides direct healthcare funding and services to several key groups, including: First Nations people living on reserves, serving members of the Canadian Forces, eligible veterans, inmates in federal penitentiaries, and some groups of refugees. The Government of Canada's overall expenditure on patented medicines is expected to decrease due to lower prices for patented medicines.

4.4 Canadian Consumers

Twenty-two percent of all medicine expenditure in Canada comes directly out of the pockets of Canadians. These out-of-pocket payments are based on the publicly listed prices that are subject to the PMPRB's excessive price ceilings. As such, regulatory modernization and lower price ceilings will have a significant impact on Canadian consumers, even if they have some form of medicine coverage.

Lower patented medicine prices could also increase the health of Canadians. It is estimated that nearly three million Canadians do not fill prescriptions due to high cost. Removing the cost barriers could increase the access to essential medicines and lower the overall morbidity of Canadians.

4.5 Industry

The amendments will affect several industries. First and foremost, patented medicine manufacturers will be subject to lower non-excessive price ceilings. This does not mean reduced revenues for all companies since many patented medicines are priced below the current maximum price ceilings, and are expected to still be priced below the new price ceilings. The new ceilings will only descend to a level that is comparable to prices already found in many other jurisdictions with comparable wealth and pharmaceutical markets to Canada.

Domestic research and development (R&D) investment and production levels are not expected to be impacted by the amendments. Cross-country analysis demonstrates that domestic price levels do not correlate with R&D-to-sales ratios. If anything, lower prices should result in greater quantities of medicines demanded and higher domestic production.

Other industries that rely on the price of patented medicines include generic medicine manufacturers, whose price levels are often derived as a percentage of the patented reference product, and pharmacies and wholesalers, which often derive their markups from a percentage of the patented product. A decrease in patented medicine prices could impact the revenues generated in these industries if they do not correspondingly alter the way in which they calculate their prices and markups. At the same time, manufacturers of patented generics will benefit from a reduction in regulatory burden by no longer being required to report identify and price information.

5.0 Scope and Baseline Scenario

5.1 PMPRB's Current Regulatory Framework

The PMPRB's current regulatory framework is largely focused on domestic and international price comparisons. The current elements of this framework as specified in section 85(1) of the *Act* are:

- the prices at which the same medicine has been sold in the relevant market;
- the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
- the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada; and,
- changes in the Consumer Price Index ("CPI").

The PMPRB's regulatory framework is operationalized by Board staff who investigate medicines that appear to be priced excessively. They apply the tests and thresholds specified in the Guidelines to each patented medicine sold in Canada, notify the patentee that they are under investigation if the prices fail those tests and thresholds, and try to negotiate a VCU by the patentee based on the compliant price level as set out in the Guidelines. A VCU is a written commitment by a patentee to comply with the PMPRB's Guidelines.

If an acceptable VCU is not concluded, the case proceeds to a public adversarial hearing in front of a panel comprised of members of the Board. During a hearing, the Board Panel acts as a neutral arbiter between the parties (Board staff and the patentee). The Board Panel must consider every factor under section 85(1) of the *Act* in determining whether the price of a medicine sold in Canada is excessive. The Board Panel is not bound by the Guidelines during a hearing, although the Board staff, when presenting evidence in front of the Board, often relies on tests and methods that appear in the Guidelines as part of its case that a medicine has been sold at an excessive price. If the Board Panel determines that a medicine was sold at an excessive price, it may issue a Board Order to enforce a non-excessive price and order the patentee to repay any excess revenue that resulted from selling the medicine at the excessive price. A ruling by the Board Panel has the same weight as a Federal Court.

Most patented medicines that trigger an investigation never reach the level of a hearing. VCUs, which are based on Guidelines interpretations, are by far the most common resolution. As a result, how the PMPRB decides to interpret the *Act* and *Regulations* through its Guidelines has a significant impact on patented medicine prices in Canada.

5.2 Scope of the Analysis

The amendments to the *Patented Medicine Regulations* consist of the following changes:

- Adding the following three factors to assist the Board in determining price excessiveness for the purposes of s.85(1) of the *Act*:
  1. the medicine's pharmacoeconomic value
  2. the size of the market for the medicine in Canada; and
  3. gross domestic product (GDP) in Canada and per capita GDP
- Updating the Schedule of Countries
- Setting out the reporting requirements needed to operationalize the new price regulatory factors:
  1. the cost utility analysis of the medicine;
  2. the estimated maximum use of the medicine in Canada; and
  3. the price and revenue net of all price adjustments, such as direct or indirect third party discounts or rebates.
- Modifying the reporting requirements for some patented over-the-counter (OTC), veterinary, and generic[1] medicines

This CBA analyzes the impact of these amendments on total patented medicine expenditure for the 10 years following their coming into force.

When possible, the assumption was made that current Guidelines will be maintained. This was done in order to isolate the impact of the regulatory amendments, excluding any broader Guidelines changes that could occur.

5.3 Baseline Scenario

There are two reasons why the PMPRB's current regulatory framework is ill equipped to control patented medicine prices.

- There is a growing discrepancy between public list prices and lower actual market prices due to the increased use of confidential price adjustments. As the PMPRB's current regulatory framework is almost entirely based on domestic and international price comparisons of public list prices that no longer match the prices actually paid

[1] Patented medicines that have been approved by the Minister through an abbreviated new medicine submission (ANDS).

for the medicine, the PMPRB does not have access to the information it needs to be effective in its role as a regulator.

- There is an emergence of high cost medicines, such as biologics and genetic therapies, that are putting an increased pressure on medicine spending. This hinders the PMPRB's effectiveness since the Board currently has no means to measure whether the products it regulates can justifiably charge these high prices. The PMPRB can assess whether the prices demanded are similar to the ones demanded elsewhere but it cannot assess whether the prices are excessive based on the value that the medicine brings to the system or the ability of consumers to pay for the medicine.

The CBA estimated a baseline scenario of future patented medicine sales in Canada that are expected to occur in the absence of any regulatory changes. The PMPRB's Compliance Information Management System (CIMS) data was used to create the baseline, which reflects the actual price and revenue information of patentees as reported to the PMPRB every 6 months. It contains sales figures that include rebates, discounts, and free goods given at the first point of sale.

The baseline is built on the revenues of patented medicines that were under the PMPRB's jurisdiction as of June 30, 2016, the most recent data available at the time of the analysis.

Publically available pricing and revenue information is expected to reproduce the general trends found in the baseline, but the results will not be identical, given the lack of rebate information in publically available data.

Table 2 below summarizes the baseline projection of patented medicine sales in Canada for the first ten years after the coming into force of the amendments. The methodology used to populate this table is outlined in section 5.4. The highest predicted growth occurs in the market segments where the PMPRB's current regulatory framework is particularly ineffective (i.e. biologics, medicines for rare diseases, and oncology medicines) in ensuring that the monopoly power held by the patentee is in balance with the interests of purchasers.

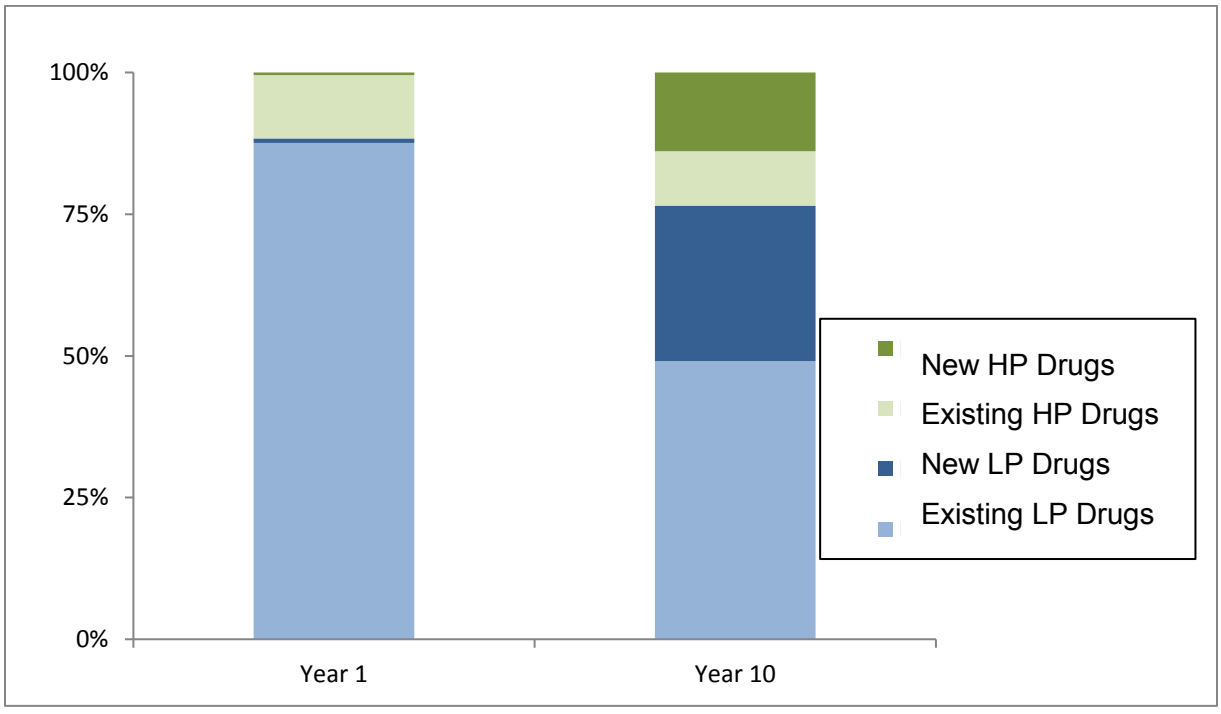
Table 2: Baseline Expenditure Summary by Medicine Type (Billion CAD)

	Year 1	***Year 2***	***Year 3***	***Year 4***	***Year 5***	***Year 6***	***Year 7***	***Year 8***	***Year 9***	***Year 10***
New High-Priority Medicines	0.1	0.2	0.5	0.7	1.0	1.4	1.9	2.4	3.0	3.6

Existing High-Priority Medicines	2.2	2.5	2.8	3.0	3.2	3.2	2.6	2.2	2.3	2.5
New Low-Priority Medicines	0.2	0.5	0.9	1.4	2.1	2.8	3.7	4.7	5.9	7.1
Existing Low-Priority Medicines	16.9	16.8	17.1	17.0	16.9	16.4	16.3	15.6	14.1	12.6
Total Medicine Spending	19.3	20.0	21.2	22.2	23.2	23.9	24.4	25.0	25.3	25.7

As observed in Table 2, expenditure for high-priority medicines is expected to represent an increasing share of total spending in the coming years. Overall patented medicine spending is estimated to reach $25.7B by Year 10, representing an average annual growth of 4.5%. In comparison, high-priority medicines are anticipated to exhibit an average annual growth of 10.4%, while low-priority medicines are anticipated to exhibit an average annual growth of 1.4%.

Graph 2: Share of Baseline Spending by Medicine Type



5.4. Baseline Methodology

Medicine Selection

All medicines under the PMPRB's jurisdiction by June 30, 2016 (time of analysis) was considered in the baseline calculation. Medicines were then ranked on a 3-year average based on revenues reported to the PMPRB. The top 200 molecules by revenue in Canada were selected to form the baseline projections. These 200 molecules represent over 87% of all patented medicine expenditures. All remaining molecules were combined and forecasted as a group. This means that the forecast was projected from n=201 (n=200 individual molecules, n=1 for all the others), which represented the total patented medicine sales as reported to the PMPRB in the first half of 2016.

Table 3: Summary of Medicine Selection

	2015[2]	
Medicine Groups	Revenues	Share of total
All patented medicines (n=868)	15,131M	
Patented medicines with reported sales in 2016 (n=558)	14,833M	98%
Selected patented medicines for line-by-line forecast (200)	13,238M	87%

Table 4: Historical Data of Selected Medicines (n=200)

Description	2010[3]	2011	2012	2013	2014	2015
Selected patented medicines for line-by-line forecast (200)	9,231M	9,524M	10,137M	10,925M	11,913M	13,238M
Growth rates	0%	3%	6%	8%	9%	11%
Rest of the medicines (358)	2,368M	2,147M	1,820M	1,688M	1,548M	1,595M
Growth rates	-3%	-9%	-15%	-7%	-8%	3%
Total	11,599M	11,671M	11,957M	12,612M	13,461M	14,833M
Growth rates	-1%	1%	2%	5%	7%	10%

Modeling – Forecast for Each Individual Existing Molecule (n=200)

Revenue of existing patented molecules were based on the revenue already reported to the PMPRB for all 200 molecules from 2006-2015. As described in the methodology below, the future revenue for all 200 molecules was forecasted independently from one another. All remaining molecules were grouped together and forecasted as one. This

[2] Since only half of 2016 had reported data, the analysis was based from the sales up to end of 2015

[3] The forecast was based on the sales from 2006-2015. In the interest of space, the table reproduced here only includes 2010-2015.

means that the entirety of the revenue reported to the PMPRB at the end of 2015 was forecasted to 2028.

Calculating the time of loss of exclusivity:

Revenue of existing patented molecules is highly contingent on a medicine's market exclusivity. Once a patented medicine loses market exclusivity (i.e. once a generic or biosimilar version of a medicine enters the market) patented revenues tend to fall significantly. The CBA assumes that current single sourced patented medicines will lose patent exclusivity and their sales will decline at rates already observed for medicines on the market.

The loss of exclusivity period was estimated based on the earlier of these two events:

1. last patent expiry date in PMPRB's database

   OR

2. average patent duration as observed for the medicines already genericized
   - 11 years for small molecules
   - 13 years for biologics

Once loss of exclusivity occurred, the forecasted revenue for all individual molecules (n=200) was subject to an erosion curve to simulate competition and the entry of a generic in the Canadian market. A different erosion curve was used for small molecules and biologics. For small molecules, the erosion curve was derived from aggregate historical data as reported in the PMPRB360 reports. For biologics, the erosion curve was based on the actual and forecasted median OECD price discounts for adalimumab (Humira).

Table 5: Erosion Curve by Medicine Type

	Year										
Medicine Type	1	2	3	4	5	6	7	8	9	10	11
Small Molecule	50%	12%	12%	12%	12%	12%	12%	12%	12%	12%	12%
Biologics	95%	90%	85%	80%	76%	71%	66%	61%	56%	52%	48%

It is important to note that the baseline calculation did not model the loss of a medicine's patented status, which will reduce patented revenues to zero rather than erode it. A medicine remains under PMPRB's jurisdiction as long as there remains at least one active patent. Medicine manufacturers increasingly file many patents for the same molecule; this is especially the case for top selling medicines, which were the basis of this analysis. Therefore, the expiration of the "main patent" (i.e. the patent that

guarantees market exclusivity) usually does not represent the expiration of all patents. Most medicines retain additional patents even after being genericized and will have to continue to report (reduced) revenue to the PMPRB. In this CBA, it was assumed that all medicines under analysis will retain at least one patent and will have to continue to report to the PMPRB for the duration of the analysis

Example of the forecast used for existing medicines:

Medicine A is a biologic with a first sale reported to the PMPRB in 2011.

The forecast function was used on medicines that had at least a 5-years' worth of reported data to form the baseline, since there tends to be a ramp up in sales during the first 5 years. For medicines with less than 5-years worth of reported data, an equation of best fit using the available data points was used and then projected to populate the 5 year trend upon which the forecast calculation was then applied.

Erosion calculation:

Calculating the loss of market exclusivity:

2011 (First sale) + **13** (market exclusivity for biologics) = **2024**

The last patent year reported to the PMPRB is **2030**. Since the calculated loss of market exclusivity (2024) is less than the last patent year reported to the PMPRB (2030), the erosion curve will begin in 2024.

The erosion curve applied to molecule A will follow the same curve as the one outlined in Table 5.

Table 6 below provides an example of molecule A with projected sales following a five-year trend line, and then with the erosions applied once the molecule losses market exclusivity in 2024 and a biosimilar enters the market. By contrast, if molecule A will be a generic, loss of market exclusivity will have a bigger impact and will occur in 2022 (shown in Table 6 for comparison).

Table 6: Example of Baseline Projected Sales for a Biologic

Molecule A	Sales	With Biosimilar Erosion	With Generic Erosion
2012	1,729,322	1,729,322	1,729,322
2013	2,689,872	2,689,872	2,689,872
2014	4,155,120	4,155,120	4,155,120
2015	6,360,026	6,360,026	6,360,026

2016	8,920,800	8,920,800	8,920,800
2017	10,186,961	10,186,961	10,186,961
2018	11,992,272	11,992,272	11,992,272
2019	13,797,583	13,797,583	13,797,583
2020	15,602,894	15,602,894	15,602,894
2021	17,408,205	17,408,205	17,408,205
2022	19,213,516	19,213,516	9,606,758
2023	21,018,827	21,018,827	2,522,259
2024	22,824,138	21,614,459	2,738,897
2025	24,629,449	22,144,612	2,955,534
2026	26,434,760	22,501,855	3,172,171
2027	28,240,071	22,686,191	3,388,809
2028	30,045,382	22,697,617	3,605,446

This forecast was done for all 200 molecules, and once aggregated, this formed the foundation of the baseline projections. For the remaining 13% of medicine spending, actual data reported to the PMPRB was simply projected to 2028 without any erosion curves applied.

Separating Existing Medicines into High and Low Priority

Since individual forecasts were available for a majority of the medicines, they can be reported by different categories Independent from the baseline forecast, 70 molecules were isolated to form the basket of molecules that formed the basis of the analysis. Revenue information from these 70 molecules, if reported to the PMPRB and part of the 200 individual forecast, were then isolated from the rest and became the "**existing high-priority medicines**" forecasted revenues, while the remaining of the revenues was marked as "**existing low-priority medicines,**" as shown in Graph 2.

Table 7: List of High-Priority Medicines used in the Cost-Benefit Analysis

ABIRATERONE ACETATE	COLLAGENASE CLOSTRIDIUM HISTOLYTICUM	IDELALISIB	PERTUZUMAB	TALIGLUCERACE ALPHA
AFATINIB	CRIZOTINIB	INTERFERON GAMMA-1B	PIRFENIDONE	TEDUGLUTIDE
ALANYL-GLUTAMINE	DABRAFENIB	IPILIMUMAB	PLERIXAFOR	TELAPREVIR
ANIDULAFUNGIN	DIMETHYL FUMARATE	IVACAFTOR	POMALIDOMIDE	TEMOZOLOMIDE
AXITINIB	ELTROMBOPAG	LEVODOPA	PONATINIB	TERIFLUNOMIDE

BELIMUMAB	ENZALUTAMIDE	LIRAGLUTIDE	POSACONAZOLE	TOCILIZUMAB
BIMATOPROST	EPOPROSTENOL	LOMITAPIDE	REGORAFENIB	TRABECTEDIN
BOCEPREVIR	EVEROLIMUS	MACITENTAN	RIFAXIMIN	USTEKINUMAB
BOCEPREVIR/RIBAVIRINPLUS/PEGINTERFERON ALPHA	FAMPRIDINE	NINTEDANIB	RIOCIGUAT	VACCINE, NEISSERIA MENINGITIDIS GROUP B
BOSUTINIB	FENTANYL	OBINUTUZUMAB	ROMIDEPSIN	VALSARTAN
BRENTUXIMAB VEDOTIN	FLUOCINOLONE ACETONIDE	OCRIPLASMIN	RUFINAMIDE	VANDETANIB
CABAZITAXEL	FUMAGILLIN	PALIFERMIN	RUXOLITINIB	VELAGLUCERASE ALFA
CANAKINUMAB	HEXAMINOLEVULINIC ACID	PASIREOTIDE	SAPROPTERIN	VEMURAFENIB
CERITINIB	IBRUTINIB	PEMBROLIZUMAB	SOFOSBUVIR	VISMODEGIB

Modeling – New Medicines

All new medicines that entered the market in the period 2009-2014, as per the PMPRB Meds Entry Watch Report, were selected for this part of the analysis. The actual sales reported to the PMPRB for all of medicines from this time period was retrieved from the PMPRB's database of patentee submitted information. Reported sales data was then forecasted for up to 12 years (assumed length of market exclusivity) to map the growth curve in sales for all new medicines introduced each year from 2009-2014.

The sales for all new patented medicines were aggregated by year of introduction, and total annual data was collected for each group of medicines post introduction. All available data was used as the basis for which to forecast expected future expenditure per aggregated group. Table 8 below demonstrates the annual sales data for each group of medicines from year of introduction up until the end of 2015. It also provides the 12-year forecast in medicine expenditure for groups of medicines that were used as the basis for projecting new medicine spending.

Table 8: Total New Medicine Spending Per Year of Introduction

Year of sales	2009[4]	2010	2011	2012	2013	2014
1st	9M	4M	4M	2M	6M	23M

[4] It is important to note that no erosion curve was applied to the 2009 group of medicines despite the 12-year projection extending beyond the 11-year assumption of small molecules.

2nd	102M	24M	101M	33M	252M	688M
3rd	143M	83M	222M	149M	421M	1,227M
4th	257M	148M	283M	330M	641M	1,465M
5th	369M	223M	366M	468M	848M	1,679M
6th	472M	286M	467M	617M	1,055M	1,902M
7th	575M	335M	558M	766M	1,262M	2,128M
8th	656M	395M	648M	915M	1,469M	2,352M
9th	751M	454M	739M	1,064M	1,676M	2,576M
10th	846M	513M	830M	1,212M	1,883M	2,800M
11th	941M	572M	920M	1,361M	2,090M	3,024M
12th	1,036M	632M	1,011M	1,510M	2,297M	3,248M

Reported sales data Forecasted sales

As evident in Table 8, the growth curves in new medicine expenditure for the years 2013-2014 are decidedly different from the growth in all previous years. 2013 saw the introduction of the first direct-acting antiviral (DAA) medicines to treat Hepatitis C. These were very expensive, but cost-effective medicines meant to treat a large patient population in Canada. Most of the new medicine spending in 2013-2014 can be attributed to DAAs, and the introduction of these medicines in 2013-2014 offered an exceptional “one-time event” for new expenditure growth, as seen in Table 9.

Table 9: Impact of DAAs on New Medicine Spending

Year of Sale	Average new medicine spending in years without DAAs (2009-2012)	Average new medicine spending in years with DAAs (2013-2014)	Average new medicine spending over all years (2009-2014)
1	5M	15M	8M
2	65M	470M	200M
3	149M	824M	374M
4	255M	1,053M	521M
5	356M	1,263M	659M
6	461M	1,478M	800M
7	559M	1,695M	937M
8	653M	1,910M	1,072M
9	752M	2,126M	1,210M
10	850M	2,341M	1,347M
11	949M	2,557M	1,485M
12	1,047M	2,772M	1,622M

Unusually high growth in new medicine spending due to a one-off event like the introduction of a particularly expensive, but cost-effective new medicine for a large population is uncommon, but likely in any future pipeline. As such, a sensitivity analysis was performed to isolate and control the impact of DAAs to account for the likelihood that a similar class of expensive breakthrough medicines will be launched within the forecasted 10 years. The main baseline assumes that another such event will occur during the study period, and uses the average new medicine spending for all years (2009-2014) to capture this impact. The two alternative scenarios in the sensitivity analysis either predicts that the effect of the DAAs was singular in nature and will not repeat again during the study period (used the average for the years 2009-2012 only), or predicts that these types of events will become more commonplace (doubled the weight of the 2013-2014 data).

A compounded growth rate was also introduced to account for inflation and population growth in future medicine expenditures. Inflation was forecasted using 2010-2015 data and assuming a return to 2% by 2025, while the population growth assumption was taken from Statistics Canada predictions. Table 10 below outlines the calculated growth rate used for each year of the study period.

Table 10: Adjusted Growth Rates

Year	Inflation	Population	Compounded Growth Rate (Inflation + Pop)
2011	2.91%	0.99%	1.039
2012	1.52%	1.19%	1.067
2013	0.94%	1.17%	1.090
2014	1.91%	1.11%	1.123
2015	1.13%	0.86%	1.102
2016	1.42%	1.22%	1.175
2017	1.17%	0.79%	1.198
2018	1.27%	0.71%	1.222
2019	1.38%	0.68%	1.247
2020	1.48%	0.67%	1.274
2021	1.59%	0.66%	1.303
2022	1.69%	0.64%	1.333
2023	1.79%	0.63%	1.365
2024	1.90%	0.61%	1.399
2025	2.00%	0.59%	1.436
2026	2.00%	0.57%	1.473

2027	2.00%	0.56%	1.510
2028	2.00%	0.55%	1.549

The main baseline estimate for new medicine expenditure was then calculated by taking the average new medicine spending over all years (2009-2014) in Table 9 and multiplying it by the compounded growth rate in Table 19. The new medicine expenditure associated for each year of study in the main baseline scenario is thus the sum of all new expenditure for each medicine cohort categorized by year of introduction.

Table 11: Sum of New Medicine Revenues by Year of Introduction

Year of Study in the Baseline	Year of introduction for new molecules											
	2018	2019	2020	20201	2022	2023	2024	2025	2026	2027	2028	Sum
0	10											10
1	235	10										245
2	440	240	10									689
3	612	448	244	10								1,315
4	774	624	457	249	10							2,115
5	940	789	636	467	255	11						3,098
6	1,101	958	805	649	477	261	11					4,262
7	1,260	1,123	977	822	663	487	267	11				5,611
8	1,422	1,285	1,145	998	839	678	499	273	11			7,150
9	1,583	1,450	1,310	1,169	1,019	858	694	511	280	12		8,886
10	1,745	1,614	1,478	1,337	1,194	1,042	878	711	524	287	12	10,823

Finally, to construct the baseline, it was assumed that 49.7% of all new medicine expenditure as calculated for years 1 to 10 above would be for high-priority medicines, while the rest would be for low-priority medicines. This is consistent with trends observed between during the study period.

To form the baseline that is first outlined in Table 2 (reproduced below), the existing medicine sales, as calculated above, is simply added to the estimated new medicines sales, for both high and low priority medicines.

Table 2: Baseline Summary (Billion CAD)

	Year 1	***Year 2***	***Year 3***	***Year 4***	***Year 5***	***Year 6***	***Year 7***	***Year 8***	***Year 9***	***Year 10***
New High-Priority Medicines	0.1	0.2	0.5	0.7	1.0	1.4	1.9	2.4	3.0	3.6

Existing High-Priority Medicines	2.2	2.5	2.8	3.0	3.2	3.2	2.6	2.2	2.3	2.5
New Low-Priority Medicines	0.2	0.5	0.9	1.4	2.1	2.8	3.7	4.7	5.9	7.1
Existing Low-Priority Medicines	16.9	16.8	17.1	17.0	16.9	16.4	16.3	15.6	14.1	12.6
Total Medicine Spending	19.3	20.0	21.2	22.2	23.2	23.9	24.4	25.0	25.3	25.7

6.0 Literature Review

The high price of medicines is a major concern for governments, policy-makers, insurers, employers and patients. High prices can make medicines unaffordable, compromising equitable access to them, and threaten the financial sustainability of public health systems. This applies especially to new high priced medicines that are protected by exclusive market rights, such as patents and data protection.

Starting in the early 1970's, most industrialized countries began creating mechanisms aimed at containing medicine costs in the face of rising prices and limited health care budgets. While the goal was similar, each country designed and implemented its own cost-containment mechanisms to reflect its domestic market. In Canada, this led to the creation of the PMPRB and the heavy reliance on external public list price referencing with the PMPRB7 as the core measure of price excessiveness.

For a number of years, patented medicine prices in Canada have consistently been among the highest in the world. Among all 35 OECD member countries, which represent the world's wealthiest industrial nations, only the United States and Switzerland currently have higher patented prices than Canada. Prices in Canada exceed the OECD median by 28%.

7.0 Assessment and Underlying Assumptions

The baseline represents the health care costs to Canadians as measured by total patented medicine expenditure, which reached $15.2 billion in 2015. It is assumed that excessively priced patented medicines lead to undue rationing of health care resources at the system level and higher rates of cost-related non-adherence of prescription medicines at the individual level. Both of these outcomes result in worse health for Canadians.

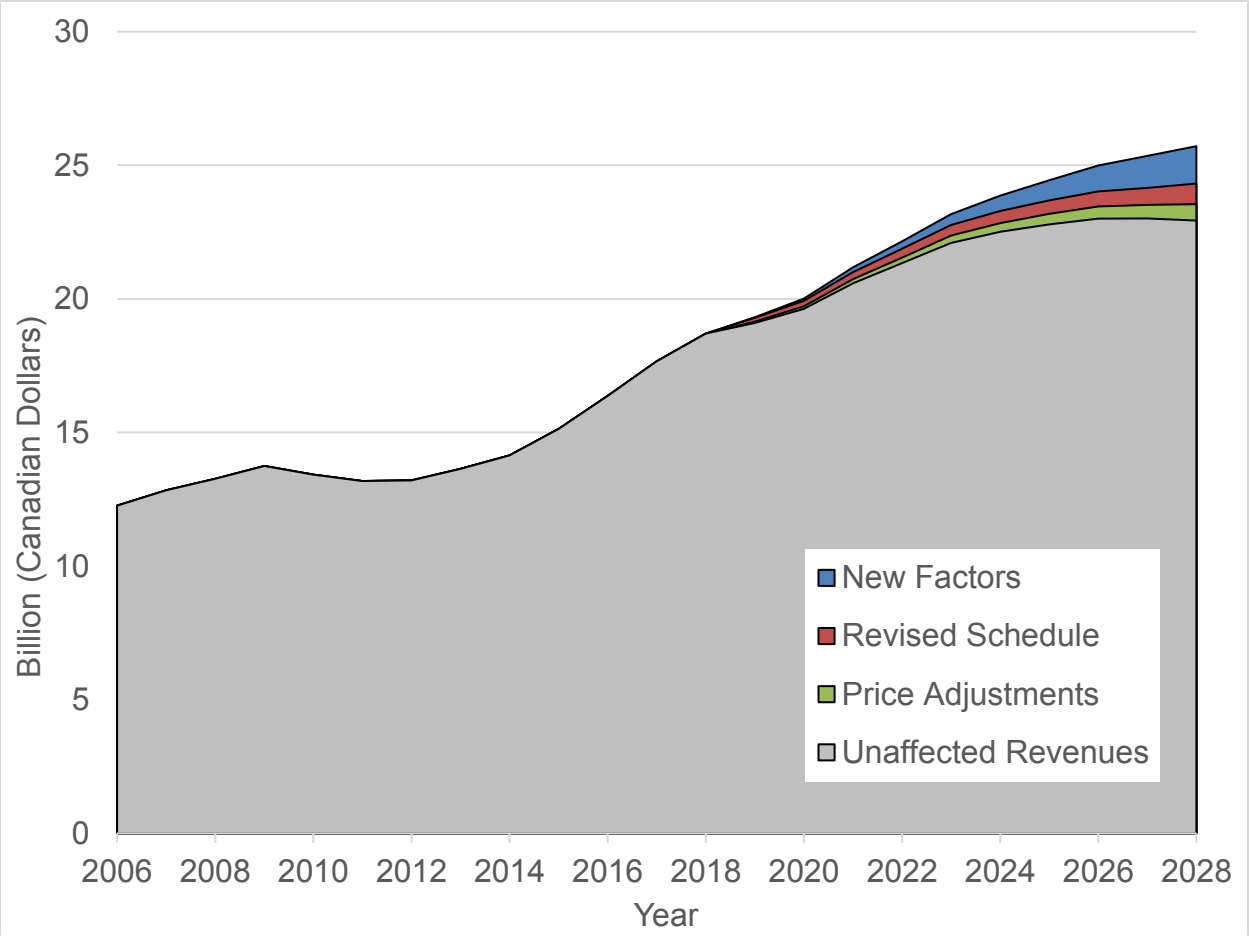
Not all medicines will see a reduction in prices, as most existing products are still expected to be priced below the non-excessive price ceilings, even after the coming into force of these amendments. The CBA assumes that the PMPRB will take a risk-based approach to price regulation, whereby it will place a higher degree of regulatory scrutiny on medicines with a higher potential to exert market power ("high-priority medicines"), such as those medicines that have few or no therapeutic alternatives or provide a substantial health benefit over existing treatments. It is assumed that medicines with a lower risk of excessive prices ("low-priority" medicines) will receive less oversight, for example, medicines that will not be required to report on the new pharmacoeconomic value factor. The new price regulatory factors do not apply to medicines that obtained a Drug Identification Number (DIN) in Canada prior to the publication of the amendments in the *Canada Gazette, Part II.*

8.0 Benefits

8.1 Benefit Summary

Total benefits were calculated based on reduced overall patented medicine expenditure because of lower medicine prices. The projected baseline of future medicine expenditure (2017-2028) was calculated using medicine trends and expected launches from the current pipeline. This baseline also includes the expected loss of market exclusivity and patent protection of current medicines under the PMPRB's jurisdiction. The total benefits arising from the regulatory amendments are estimated to be $8.8 billion dollars (PV) over 10 years. The introduction of the new price regulatory factors will be expected to have the biggest impact on patented medicine expenditure ($3.8 billion), followed by the updated Schedule ($2.8 billion) and the reporting of price and revenue net of all price adjustments ($2.0 billion).

Graph 3: Estimated Impact of the Regulatory Amendments on Total Patented Medicine Expenditure



In calculating the quantitative benefits, assumptions surrounding the PMPRB's Guidelines were made. As with the current regulatory regime, the regulations provide the factors and information to be provided to the Board, while the Guidelines describe the price tests and target ceilings for new and existing products. Consistent with the intended risk-based approach, each aspect of the regulatory amendments applies differently depending on the characteristics of individual medicines, something that the PMPRB intends to reflect in its updated Guidelines that will follow the amendments. The new factors are intended to have the most impact on high-priority medicines, which are a subset of medicines with higher potential to exert market power due to greater demand, fewer (if any) substitutes, or very small patient populations. In contrast, the effects of third party price adjustments on expected expenditure is mostly concentrated on low priority medicines as the disclosure of adjustments primarily affects the price levels of subsequent entrants to an established therapeutic class. Updates to the Schedule of international comparators are expected to affect all medicines.

8.2 Description of the Elements of the Regulatory Amendments

There are five elements included in the amendments:

- introduce new, economics-based price regulatory factors that will enable the PMPRB to ensure non-excessive prices reflect value-for-money and Canada's willingness and ability to pay for patented medicines;
- update the Schedule of countries used by the PMPRB for international price comparisons to better align with the PMPRB's consumer protection mandate;
- provide reduced reporting obligations for patented veterinary, over-the-counter and 'generic' medicines;
- set out the patentee price information reporting requirements to enable the PMPRB to operationalize the new price regulatory factors; and,
- require patentees to report on all price adjustments (such as direct or indirect third party discounts or rebates).

Of these, three in particular are expected to affect the projected patented medicine expenditure in Canada: 1) introducing new price regulatory factors, 2) updating the Schedule of comparator countries, and 3) requiring patentees to report on all price adjustments. A more detailed description of each of these three amendments follows.

8.2.1 Introduce new, economics-based price regulatory factors that will ensure prices reflect value-for-money and Canada's willingness and ability to pay for patented medicines

These amendments will introduce the new price regulatory factors of pharmacoeconomic value, market size, and GDP and GDP per capita in Canada. These new factors will enable the PMPRB to consider complementary and highly relevant aspects of price excessiveness, such as the value for money of the medicine, and the willingness and ability of Canadian consumers to pay for it. They will equip the PMPRB to evaluate the price excessiveness of high cost specialty medicines.

Pharmacoeconomic value is a measure of a medicine's therapeutic benefit, or the value the medicine brings in relation to patients' health and impact on the health care system. It identifies, measures, and compares the costs and benefits of a medicine to patients and the healthcare system. The economic analysis of medicines is an increasingly common approach being adopted by health systems around the world. The inclusion of this factor will permit the PMPRB to consider whether a medicine's price is commensurate with the benefits it provides to patients.

Specifically, these regulatory amendments provide the PMPRB with Cost Utility Analyses (CUAs) to measure the pharmacoeconomic value of medicines sold in Canada. A CUA is a type of pharmacoeconomic evaluation that uses a common unit of measurement to enable comparisons across different types of medicines and health interventions. It uses the quality-adjusted life year (QALY) - a generic measure of disease burden, including both the quality and the quantity of life lived. The QALY is the established benchmark for quantifying benefits used in economic evaluation to assess the value for money of medical interventions. One QALY equals one year in perfect health. The cost per QALY measure allows for a comparison between medicines to provide an assessment of opportunity cost, i.e., what one must give up to pay for the medicine in question. Other developed countries rely to some degree on cost per QALY in determining whether and how much to pay for a new medicine.

The introduction of market size as a price regulatory factor will allow the Board to consider the price of the medicine against its projected sales volume and cost to insurers. This will allow the PMPRB to consider price excessiveness in relation to the total projected financial impact of the medicine in Canada, and in terms of the size of the market for the medicine in Canada.

Market size as a factor enables the PMPRB to evaluate the price-volume relation of medicines sold in Canada at introduction, and to reassess that relationship over time as the market size for that medicine expands. Patentees are assumed to set their introductory prices at a profitable level to recoup initial investment. A subsequent exponential growth in the market size of a medicine should ideally align and correct the price of the medicine downwards to a comparable level. Failure to do so could suggest that the original price of the medicine in the expanded market is excessive. Since monopolies are protected from new entrants, prices tend to remain unaffected from subsequent fluctuations in market size.

The introduction of GDP in Canada and GDP per capita in Canada as a price regulatory factor will provide the PMPRB with measures of ability to pay for medicines at the national and individual level. GDP is a measure of a country's economic output. GDP growth measures how much the inflation-adjusted market value of the goods and services produced by an economy increases over time. Per capita GDP measures how much a country is producing relative to its population. Growth in Canadian GDP can be taken as an indicator of the country's ability to pay year-over-year, whereas per capita GDP is a proxy for buying power at the level of the individual.

Impact of introducing the new price regulatory factors:

As Table 3 below summarizes, the addition of these new factors is expected to yield an overall benefit of $3.8 billion (PV) over 10 years.

Table 12: Total Benefits of Adding the New Factors (Million CAD/year)

Year	1	2	3	4	5	6	7	8	9	10
Benefits	33	90	184	285	417	574	755	962	1195	1399
Benefits (NPV)	33	84	160	233	318	409	503	599	696	761

The new price regulatory factors were applied in accordance with a risk-based approach to price regulation as mentioned in Section 2.0, such that new high-priority medicines are assessed against all three of the new price regulatory factors, while no other categories of medicines are impacted.

As a whole, the three new factors are expected to lower the price of new high-priority medicines by 40% on average. The price of other medicines (existing high-priority, new and existing low-priority) is not affected by the introduction of the new factors.

The 40% price reduction was calculated by applying specific price tests to the 70 high-priority medicines outlined in Table 7 to their 2015 revenues. The combined price reduction witnessed in 2015 for those 70 medicines was then extended for each year of the new high-priority expenditure as outlined in the baseline calculation in Section 5.4.

Table 13: Anticipated Reductions of Applying the New Factors (2015 Revenues)

		Expensive Drugs for Rare Diseases (EDRD)	High-Priority Medicines	High Prevalence Medicines	Total[5]
Number of Molecules		20	45	5	70
Total expenditures		$210.7M	$184.6M	$499.7M	$895.1M
Pharmacoeconomic Value	Threshold	150K/QALY	50K/QALY	35K/QALY	
	Savings	$62.2M	$74.4M	$162.8M	$299.4M
	% savings	29.5%	40.3%	32.6%	33.4%
Market Size & GDP	Budget Model	Hollis	ICER	ICER	
	Thresholds	$4.9M	$20.0M	$20.0M	
	Savings	$42.6M	$1.5M	$214.1M	$258.2M
	% Savings	20.2%	0.8%	42.9%	28.8%

[5] All 70 high-priority medicines listed Table 7 were used to for the basis of this analysis. EDRDs and high-priority medicine treating a disease with a large patient population were further isolated from the remaining high-priority medicines in order to apply different thresholds for each of the three categories.

Combined Factors	Savings	$70.4M	$74.4M	$214.1M	$358.9M
	% Savings	33.4%	40.3%	42.9%	40.1%

Finally, for all elements of the regulatory amendments, a 50% reduction cap was applied so that the price for a medicine cannot be reduced by more than 50%, even if that is required to meet the specific Guidelines' test. This was done for several reasons. First, the PMPRB Guidelines are non-binding and the PMPRB has indicated the desire to introduce a "reverse onus" process where, if a price appears to be excessive during an investigation, patentees will be able to provide the PMPRB with a rationale as to why their medicine does not meet the Guideline tests. This gives the PMPRB the flexibility to consider mitigating factors that will likely result in a lower price than will be the case with a stricter application of the Guidelines tests.

Second, the methodology in this CBA assumes a 1-to-1 ratio between price and revenue reductions. If prices go down 10%, then revenues are lowered by 10%. Given the prevalence of substantial confidential rebates to public medicine insurance plans in Canada, this ratio is known to be incorrect. That said, third party rebate information is not currently being provided to the PMPRB, which makes modeling lower than expected revenues from a reduction of known inflated prices challenging. To counter this, the 1-to-1 ratio between price and revenues was maintained, but a 50% cap was applied knowing that a revenue reduction greater than 50% for any single medicine will not be likely, even if the price reduction itself appears to be greater.

Impact of Pharmacoeconomic value factor

The impact of the pharmacoeconomic value factor was calculated by reducing the price of each high-priority medicine to the cost-effective threshold as published in the publically available CADTH CUAs. For each medicine, the submitted price in the analysis was reduced to one of the three cost-effective threshold prices that were assumed to be part of the new PMPRB Guidelines. The thresholds differ based on a medicine's characteristic and are as follow:

- $50k/QALY for most high-priority medicines;
- $150k/QALY for high-priority EDRDs
- $35k/QALY for high-priority medicine for a high prevalence disease

In all, 46 of the 70 high-priority medicines had publically available CUAs published by CADTH. No CUAs were available for the remaining 24 medicines, meaning there was no publically available incremental cost-effectiveness ratio (ICER) to test against the thresholds mentioned above. In cases where no CUAs are available, the new

pharmacoeconomic value factor was not applied. Below is a list of all high-priority medicines that had a publically available ICER.

Table 14: High-Priority Medicines with Publically Available CUAs

High-Priority		EDRD	High Prevalence
AFATINIB	POMALIDOMIDE	BRENTUXIMAB VEDOTIN	ABIRATERONE ACETATE
BELIMUMAB	PONATINIB	CANAKINUMAB	DIMETHYL FUMARATE
BOCEPREVIR	REGORAFENIB	ELTROMBOPAG	LIRAGLUTIDE
BOCEPREVIR/RIBAVIRIN PLUS/PEGINTERFERON ALPHA	RIFAXIMIN	IBRUTINIB	SOFOSBUVIR
BOSUTINIB	ROMIDEPSIN	IPILIMUMAB	USTEKINUMAB
CABAZITAXEL	RUXOLITINIB	IVACAFTOR	
CERITINIB	TEDUGLUTIDE	NINTEDANIB	
CRIZOTINIB	TELAPREVIR	OCRIPLASMIN	
DABRAFENIB	TEMOZOLOMIDE	PIRFENIDONE	
ENZALUTAMIDE	TERIFLUNOMIDE	PLERIXAFOR	
FAMPRIDINE	TRABECTEDIN	RIOCIGUAT	
LEVODOPA	VALSARTAN	RUFINAMIDE	
OBINUTUZUMAB	VEMURAFENIB	SAPROPTERIN	
PEMBROLIZUMAB	VISMODEGIB	TOCILIZUMAB	
PERTUZUMAB			

On average, high-priority medicines will need to reduce their prices by 33% to meet their respective cost-effective thresholds. This figure includes both instanceswhere a price reduction occurred (maximum 50% impact) and where no CUA was available (0% impact). The specific price reductions associated for each of these 46 medicines are listed in Tables 15, 16, and 18 below.

Impact of GDP and Market Size Factors

High-Priority and High-Prevalence Medicines (ICER Model)

In calculating the benefits of this factor, it was assumed that the PMPRB will develop market impact tests for medicines likely to pose affordability challenges for insurers due to their market size. It was also assumed that the Board will revisit an initial price in circumstances where there are significant differences between actual and projected

market size for a medicine, such as when an existing medicine is approved for a new indication that substantially expands its market size. Both the Board's decision to develop market impact tests and revisit an initial price upon market expansion will have to be introduced in the PMPRB's Guidelines. High-priority medicines (e.g. lifesaving medicines with no direct therapeutic alternatives) will be most impacted by the market size factor as non-excessive prices for other types of medicines are addressed through the PMPRB's current Guidelines and pricing mechanisms (i.e. therapeutic class comparisons and external price referencing).

Two models were used to calculate the impact of market size and GDP as new factors. The model developed by the Institute for Clinical and Economic Review (ICER model)[6] was used for high-priority and high prevalence medicines, while the Hollis model was used to calculate the impact on EDRDs.

The ICER model takes into account a country's annual GDP growth to determine the affordability of new medicine launches in any given year. Growth in GDP is used to set a maximum revenue threshold of new medicines to be introduced in that year, and any medicines with total revenues exceeding that threshold will see their prices reduced. This is to ensure that the introduction of any single medicine into the Canadian market at any given year does not threaten the overall ability-to-pay of consumers in the overall healthcare system.

The thresholds that were used to calculate the impact of this model for new medicines introduced after the coming into force of these amendments was $20 million. This threshold was calculated using the ICER model, which predicted a maximum threshold between $12.5M and $24.6M for the years 2012-2016, based on Canada's GDP growth and the number of new medicines that entered the market in those years.

Table 15: Calculating the Market Size Threshold

Item	Parameter	2012	2013	2014	2015	2016	Source
1	Growth in GDP (+1)	2.75%	3.48%	3.57%	1.94%	2.47%	OECD
2	Total Healthcare Spending ($B)	$205.4B	$209.7B	$216.2B	$225.5B	$232.9B	CIHI
3	Contribution of patented medicines %	6.43%	6.39%	6.38%	6.70%	6.70%	Calculation (Row 4 / Row 2)
4	Annual threshold for net healthcare cost	$13.20B	$13.4B	$13.8B	$15.1B	$15.6B	PMPRB

[6] Not to be mistaken with the incremental cost-effectiveness ratio (ICER) acronym used in the section above.

	growth for all new patented medicines ($M)						
5	Annual threshold for net healthcare cost growth for all new patented medicines ($M)	$363.0M	$466.3M	$492.7M	$292.9M	$385.3M	Calculation (Row 1 X Row4)
6	Average number of patented medicines per year	35	44	40	47	33	PMPRB
7	Annual threshold of average cost growth per new patented medicine ($M)	*$10.4M*	*$10.6M*	*$12.3M*	*$6.2M*	*$11.7M*	*Calculation (Row 5 / Row 6)*
8	*Annual threshold for estimated budget impact for each new patented medicine ($M) Multiplied by 2*	*$20.7M*	*$21.2M*	*$24.6M*	*$12.5M*	*$23.4M*	*Calculation (Doubling of Row 7)*

In calculating the price reduction, the price for each medicine was reduced by the same percentage needed to bring the total revenues of a medicine in line with the maximum threshold of $20M for the first year of sale. The price reduction of each medicine was restricted to a maximum of 50%.

Table 16: Anticipated Revenue Reductions of Select High-Priority Medicines

High-Priority			
Molecule	% Reduction from Pharmacoeconomic Value factor	% Reduction from GDP & Market Size[7] Factors	% Reduction for Combined New Factors
AFATINIB	45%	NA	45%
ALANYL-GLUTAMINE	0%	NA	0%
ANIDULAFUNGIN	0%	NA	0%
AXITINIB	0%	NA	0%

[7] Reduction for GDP and Market size is not provide as a single medicine is affected. This impact, combined with Table 13, could disclose the revenues for that medicine that was reported in 2015.

BELIMUMAB	50%	NA	50%
BIMATOPROST	0%	NA	0%
BOCEPREVIR	50%	NA	50%
BOCEPREVIR	50%	NA	50%
BOSUTINIB	50%	NA	50%
CABAZITAXEL	35%	NA	35%
CERITINIB	50%	NA	50%
COLLAGENASE CLOSTRIDIUM HISTOLYTICUM	0%	NA	0%
CRIZOTINIB	50%	NA	50%
DABRAFENIB	50%	NA	50%
ENZALUTAMIDE	50%	NA	50%
EPOPROSTENOL	0%	NA	0%
FAMPRIDINE	50%	NA	50%
FENTANYL	0%	NA	0%
FLUOCINOLONE ACETONIDE	0%	NA	0%
FUMAGILLIN	0%	NA	0%
HEXAMINOLEVULINIC ACID	0%	NA	0%
IDELALISIB	0%	NA	0%
INTERFERON GAMMA-1B	0%	NA	0%
LEVODOPA	50%	NA	50%
OBINUTUZUMAB	0%	NA	0%
PALIFERMIN	0%	NA	0%
PEMBROLIZUMAB	50%	NA	50%
PERTUZUMAB	50%	NA	50%
POMALIDOMIDE	50%	NA	50%
PONATINIB	41%	NA	41%
POSACONAZOLE	0%	NA	0%
REGORAFENIB	50%	NA	50%
RIFAXIMIN	0%	NA	0%
ROMIDEPSIN	50%	NA	50%
RUXOLITINIB	50%	NA	50%
TEDUGLUTIDE	50%	NA	50%
TELAPREVIR	0%	NA	0%
TEMOZOLOMIDE	0%	NA	0%
TERIFLUNOMIDE	50%	NA	50%
TRABECTEDIN	50%	NA	50%
VACCINE, NEISSERIA MENINGITIDIS GROUP B	0%	NA	0%

VALSARTAN	0%	NA	0%
VANDETANIB	0%	NA	0%
VEMURAFENIB	50%	NA	50%
VISMODEGIB	50%	NA	50%
Total	40%	1%	40%

Table 17: Anticipated Revenue Reductions of Select High Prevalence Medicines

High Prevalence			
Molecule	Savings from Pharmacoeconomic Value factor	Savings from Market Size factor	Combined New Factors
SOFOSBUVIR	23.9%		50.0%
DIMETHYL FUMARATE	46.2%	50.0%	50.0%
LIRAGLUTIDE	50.0%	50.0%	50.0%
USTEKINUMAB	0.0%	0.0%	0.0%
ABIRATERONE ACETATE	50.0%	50.0%	50.0%
Total	32.6%	42.9%	42.9%

Expensive Drugs for Rare Diseases (Hollis Model)

Unlike the ICER model, which uses the market size and GDP factors to align new medicine spending with Canada's economic growth, the "Hollis model" calculates the R&D contribution of a new medicine based on the size of a country's economy and its ability to pay. PMPRB suggested this model as one possibility to operationalize the market size factor in its new Guidelines, especially for EDRDs. These medicines have a very small target population, meaning their total revenues are unlikely to exceed the total revenue thresholds following the ICER model.

The Hollis' model estimates a country's share of a medicine's development costs. The share is calculated using the estimated total cost of development relative to a country's share of GDP in the OECD. In the Hollis model, the maximum annual cost per patient threshold is calculated using the county's predicted global medicine development contribution given its economic output relative to the OECD.

Table 18: Example of the Hollis Model (Canada vs. UK)

	Cost of development	Country's Share of OECD GDP	Country's Share of Cost of Development	Annual Earnings (Given 10yrs Market Exclusivity)	Annual Cost per Patient (Assuming 200 Patients)
UK	$1,000M	5%	$50M	$5M	$25,000
Canada	$1,000M	3%	$30M	$3M	$15,000

In calculating the price reduction, the price for each medicine was reduced by the same percentage needed to bring the total revenues in line with the threshold. A $4.9 million market size threshold was applied to all EDRDs that were part of the 70 high-priority basket. The price reduction of each medicine was restricted to a maximum of 50%, as was the case for the other factors.

Table 19: Anticipated Revenue Reductions of Select EDRDs

EDRD			
Molecule	Savings from Pharmacoeconomic Value factor	Savings from Market Size Factor	Combined New Factors
BRENTUXIMAB VEDOTIN	0.0%	0.0%	0.0%
CANAKINUMAB	50.0%	0.0%	50.0%
ELTROMBOPAG	0.0%	0.0%	0.0%
EVEROLIMUS	41.1%	50.0%	50.0%
IBRUTINIB	25.3%	50.0%	50.0%
IPILIMUMAB	35.7%	0.0%	35.7%
IVACAFTOR	50.0%	50.0%	50.0%
LOMITAPIDE	41.1%	0.0%	41.1%
MACITENTAN	41.1%	21.9%	41.1%
NINTEDANIB	50.0%	0.0%	50.0%
OCRIPLASMIN	0.0%	0.0%	0.0%
PASIREOTIDE	41.1%	0.0%	41.1%
PIRFENIDONE	50.0%	0.0%	50.0%
PLERIXAFOR	0.0%	15.3%	7.7%
RIOCIGUAT	50.0%	0.0%	50.0%
RUFINAMIDE	8.7%	0.0%	8.7%
SAPROPTERIN	50.0%	50.0%	50.0%
TALIGLUCERACE ALPHA	0.0%	0.0%	0.0%

TOCILIZUMAB	0.0%	0.0%	0.0%
VELAGLUCERASE ALFA	41.1%	0.0%	41.1%
Total	29.5%	20.2%	33.4%

Combined Impact of the New Factors

Once combined, the basket of 70 high-priority medicines that were first introduced in Canada between 2010-2014 will have required a 40.1% price reduction in 2015 to meet the new PMPRB price ceilings. Given the assumed 1-to-1 ratio between price and revenues, it was estimated that revenues for these 70 medicines will also be reduced by 40.1%. In 2015, this means that total expenditure for these 70 medicines would have fallen from $895.1M to $536.2M, representing a total savings of $358.9M.

The 40% revenue reduction was then projected throughout the length of the study period to calculate the expected impact of the new factors on new high-priority spending. It is important to highlight that the new factors will only apply to new medicines. The new factors will not affect the price ceilings of existing medicines.

		EDRD	High-Priority Medicines	High Prevalence Medicines	Total
Number of Molecules		20	45	5	70
Total expenditures		$210.7M	$184.6M	$499.7M	$895.1M
Pharmacoeconomic Value factor	Threshold	150K/QALY	50K/QALY	35K/QALY	
	Savings	$62.2M	$74.4M	$162.8M	$299.4M
	% savings	29.5%	40.3%	32.6%	33.4%
Market Size & GDP Factors	Budget Model	Hollis	ICER	ICER	
	Thresholds	$4.9M	$20.0M	$20.0M	
	Savings	$42.6M	$1.5M	$214.1M	$258.2M
	% Savings	20.2%	0.8%	42.9%	28.8%
Combined Factors	Savings	$70.4M	$74.4M	$214.1M	$358.9M
	% Savings	33.4%	40.3%	42.9%	40.1%

Finally, two changes were introduced since the regulatory package was pre-published in the *Canada Gazette,* Part 1 to clarify when the new factors will be used to regulate price ceilings in Canada. First, the amendments specify that all medicines that received a DIN prior to the publication of the amendments in the *Canada Gazette, Part II* will be exempt from the new factors. The new price regulatory factors will only be used to

regulate the price ceilings of new medicines. Consequently, all associated reporting information for the new factors have also been removed for existing medicines.

Second, an amendment was introduced to limit the reporting requirement for the pharmacoeconomic value factor to high-cost medicines.[8] The modernized regulatory framework was always envisioned to place greater regulatory scrutiny on medicines most at risk of abusing their monopolies and charging Canadians excessive prices, while reducing regulatory burden on all other patented medicines. As such, only medicines with a treatment cost exceeding ½ of Canada's GDP per capita will now need to provide published CUAs, if any, to the PMPRB.

Finally, it is important to stress that both the thresholds and the tests themselves are not part of these regulatory amendments. These need to be further developed by the PMPRB's through a separate Guidelines consultation process.

8.2.2 Update to the Schedule of countries used by the PMPRB for international price comparisons to be better aligned with the PMPRB's consumer protection mandate and median OECD prices

The PMPRB uses the public list prices of patented medicines sold in the PMPRB7 to set maximum prices for the same patented medicines in Canada at introduction and in subsequent years. The selection of countries can have a significant impact on the maximum prices for patented medicines in Canada.

This amendment reconsiders the PMPRB7 in an effort to update the Schedule to be better aligned with the PMPRB's consumer protection mandate, and Canada's wealth and status as a major market for medicines.

The scope of countries considered for the revised Schedule was the 35 OECD countries as they share the same economic and social policies as Canada. Requiring patentees to report on prices in all 35 member countries was deemed unnecessary as 1) this will present a significant administrative reporting burden; 2) some OECD countries are better aligned with Canada's domestic policy priorities and economic standing; and, 3) it may be difficult to obtain price and sales information from some countries.

Three criteria were used to select a sub-set of OECD countries to form the update Schedule:

1. the countries must have medicine pricing policies that are well-aligned with the consumer protection mandate of the PMPRB, such as whether the country has

[8] The amendments interpret high-cost medicines as one with a treatment cost exceeding ½ of Canada's GDP per Capita.

national pricing containment measures (e.g. price regulatory bodies, statutory pricing schemes, national level price reimbursement frameworks and negotiation) to protect consumers from high medicine prices. For example, the United States does not satisfy this criterion.

2. the countries must possess reasonably comparable economic wealth as Canada, such as whether the country has a similar economic standing to Canada, as measured by GDP per capita. This is to ensure that prices correspond to Canada's ability to pay for medicines. For example, Canada's GDP per capita ranks eleventh among OECD countries, but prices for patented medicines are the third highest. The updated Schedule includes countries that have reasonably higher, similar and lower GDP per capita as Canada.
3. the countries were required to have a similar pharmaceutical market size as Canada, such as population, consumption, revenues and market entry of new products. This is to ensure that the resulting Schedule produces a price level that is commensurate with Canada's share of global medicine sales.

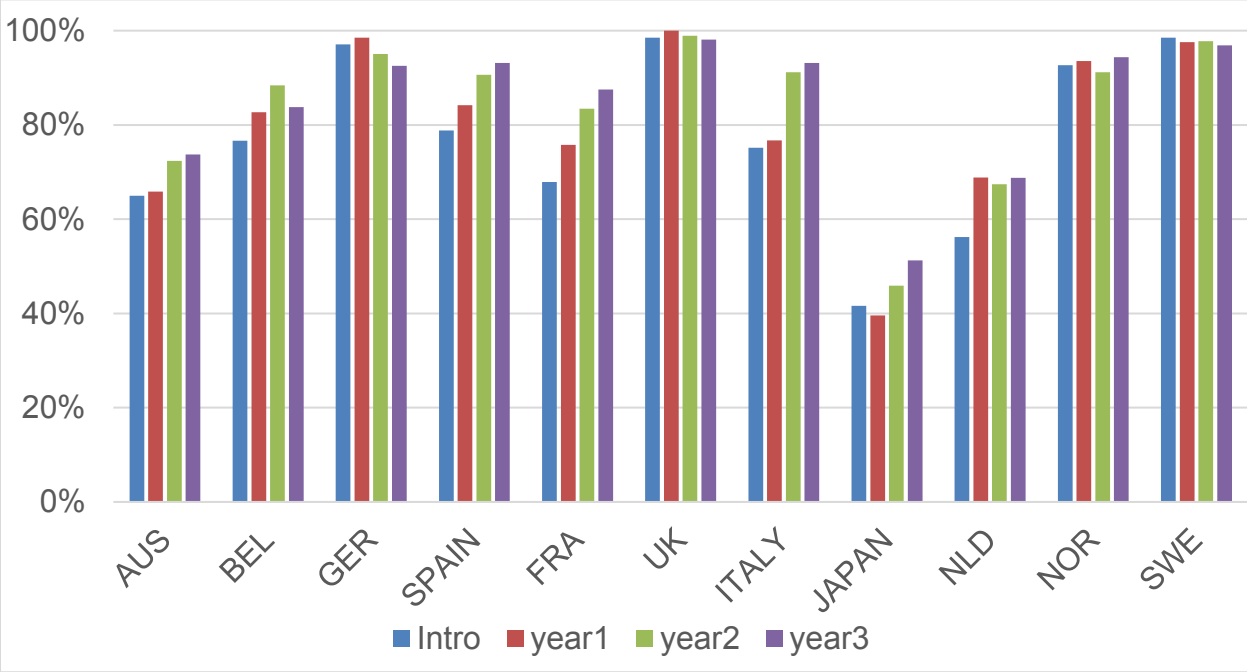
Using these criteria, the new Schedule is: Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden and the United Kingdom (PMPRB11). This will increase the number of countries listed in the Schedule from seven to 11. A larger number will make price tests less sensitive to the influence of countries with outlier prices and reduce instances where price and sales information is delayed or not available. For example, with only seven reference countries, delayed or missing price information from just two of the reference countries could impact the sample median by as much as 10%. Increasing the Schedule to include 11 countries will reduce this impact to just 4%. A slightly larger list will provide the PMPRB with a more balanced perspective of prevailing market prices and greater stability of the sample median without imposing significantly greater reporting requirements on patentees or administrative burden on the PMPRB.

In calculating the benefits, it was assumed that the introductory non-excessive price maximum for all medicines that will come onto the market will be set at the median price of the PMPRB11 instead of the median of the PMPRB7. To adjust for the availability of pricing information from other jurisdictions, it was assumed that the median price test will set a price ceiling as soon patentees report pricing information for 7 of the 11 countries, or if 3 years has passed since the medicine was first sold in Canada, whichever comes first.[9] As Graph 4 demonstrates, not all medicines launched in

[9] This is similar to current guidelines, where the PMPRB sets the introductory international price ceiling after prices in five countries of the PMPRB7 are reported, or after 3 years has passed since the medicine was first sold in Canada.

Canada are also available in comparator countries at the time of introduction, and some are still not available 3 years after their launch in Canada.

Graph 4: PMPRB11 Medicines Availability by Year



Under the current Guidelines, prices for older medicines are deemed excessive if they breach the highest international price in the Schedule. This means that any existing medicines sold in Canada that currently cost less than medicines sold in the US or Switzerland (two countries being removed from the Schedule) but more than any other countryin the list, might see their price ceilings affected by this amendment, since they would become the highest priced in the updated Schedule.

As Table 20 demonstrates, the average ratio between Canada and the PMPRB11 during the study period (2010-2017) was 0.94 at introduction, 0.97 after year 1, 0.94 after year 2, and 0.91 after year 3. These price ratios were calculated for all 200 molecules using the PMPRB's CIMS data for domestic prices and IQVIA data for international prices.

Table 20: Canada vs PMPRB11 price ratios (2010-2017)

	2010	2011	2012	2013	2014	2015	2016	2017
Intro	0.94	0.81	0.97	0.96	1.05	0.77	0.81	1.2
Year 1	1	0.82	1	1.07	0.97	0.9	1.01	
Year 2	1	0.84	0.94	1	0.96	0.91		
Year 3	0.97	0.81	0.93	0.91	0.95			

Updating the current Schedule of seven comparator countries (PMPRB7) to the new Schedule of 11 countries (PMPRB11) is expected to yield a benefit of $2.8 billion (PV) over 10 years.

Table 21: Total Benefits of Updating the Schedule of Countries (Million CAD/year)

Year	1	2	3	4	5	6	7	8	9	10
Benefits	138	198	263	329	397	459	506	563	633	770
Benefits (PV)	138	185	230	269	303	328	337	351	368	419

All new medicines will be tested against the median of the updated Schedule of price comparator countries (PMPRB11) at introduction. Existing high and low-priority medicines are also expected to be tested against the highest priced country in the PMPRB11 – currently Germany, which has an average price level similar to Canada.

Updating the Schedule of comparator countries is expected to reduce the revenues of high-priority medicines by 4.5%, while low-priority medicines are expected to be reduced by 3.49%. The weights are based on the share of sales of each medicine in the high-priority medicine market in Canada. The price reductions were applied to all high-priority medicines and all low-priority medicines in the baseline calculations.

The estimated impact of 4.5% is the weighted average of the average transaction price (ATP) to median international price (MIP) for the 70 high-priority medicines as listed in Section 5.3.

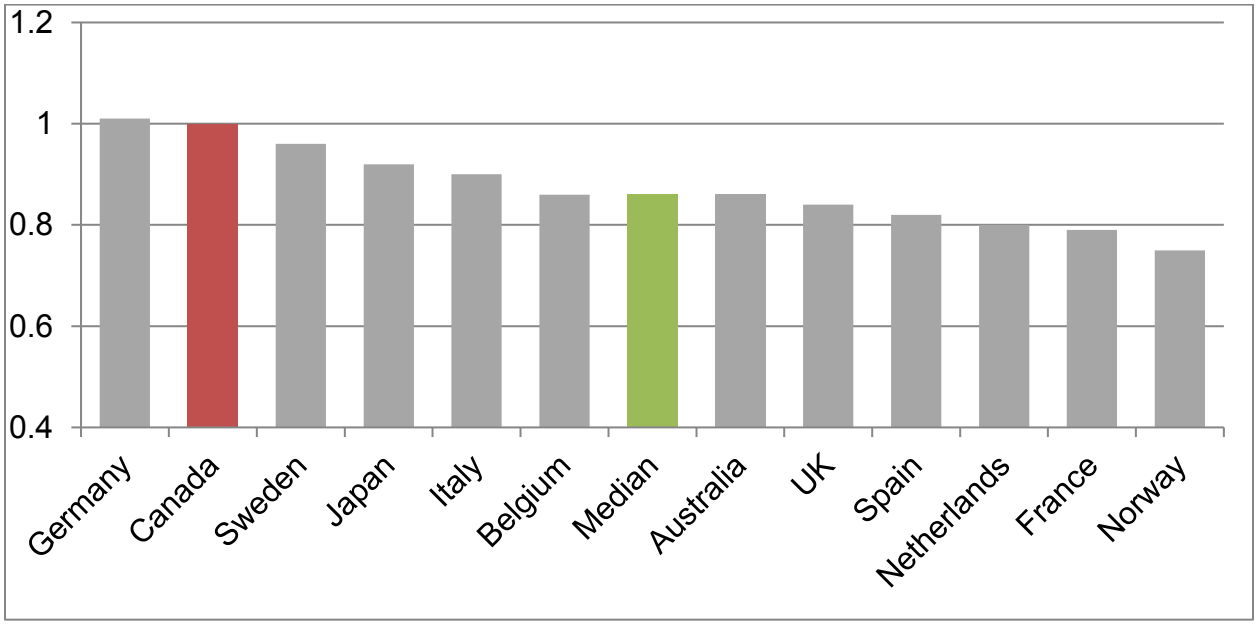
Table 22: Canadian to Median PMPRB11 Price Reductions for High-Priority Medicines

High-Priority Medicines				EDRDs		High Prevalence Medicines[10]	
AFATINIB	0%	LEVODOPA	8%	BRENTUXIMAB VEDOTIN	8%	ABIRATERONE ACETATE	-
ALANYL-GLUTAMINE	22%	OBINUTUZUMAB	0%	CANAKINUMAB	3%	DIMETHYL FUMARATE	-
ANIDULAFUNGIN	0%	PALIFERMIN	18%	ELTROMBOPAG	12%	LIRAGLUTIDE	-
AXITINIB	1%	PEMBROLIZUMAB	0%	EVEROLIMUS	6%	SOFOSBUVIR	-
BELIMUMAB	28%	PERTUZUMAB	0%	IBRUTINIB	0%	USTEKINUMAB	-
BIMATOPROST	0%	POMALIDOMIDE	0%	IPILIMUMAB	2%		
BOCEPREVIR	0%	PONATINIB	5%	IVACAFTOR	0%		
BOCEPREVIR	10%	POSACONAZOLE	0%	LOMITAPIDE	6%		
BOSUTINIB	0%	REGORAFENIB	16%	MACITENTAN	0%		
CABAZITAXEL	0%	RIFAXIMIN	0%	NINTEDANIB	0%		
CERITINIB	22%	ROMIDEPSIN	0%	OCRIPLASMIN	0%		
COLLAGENASE CLOSTRIDIUM HISTOLYTICUM	12%	RUXOLITINIB	45%	PASIREOTIDE	6%		
CRIZOTINIB	16%	TEDUGLUTIDE	1%	PIRFENIDONE	0%		
DABRAFENIB	0%	TELAPREVIR	0%	PLERIXAFOR	0%		
ENZALUTAMIDE	0%	TEMOZOLOMIDE	0%	RIOCIGUAT	1%		
EPOPROSTENOL	0%	TERIFLUNOMIDE	16%	RUFINAMIDE	11%		
FAMPRIDINE	16%	TRABECTEDIN	13%	SAPROPTERIN	1%		
FENTANYL	24%	VACCINE, NEISSERIA MENINGITIDIS GROUP B	11%	TALIGLUCERACE ALPHA	0%		
FLUOCINOLONE ACETONIDE	0%	VALSARTAN	25%	TOCILIZUMAB	0%		
FUMAGILLIN	0%	VANDETANIB	4%	VELAGLUCERASE ALFA	0%		
HEXAMINOLEVULINIC ACID	9%	VEMURAFENIB	1%				
IDELALISIB	0%	VISMODEGIB	0%				
INTERFERON GAMMA-1B	47%						

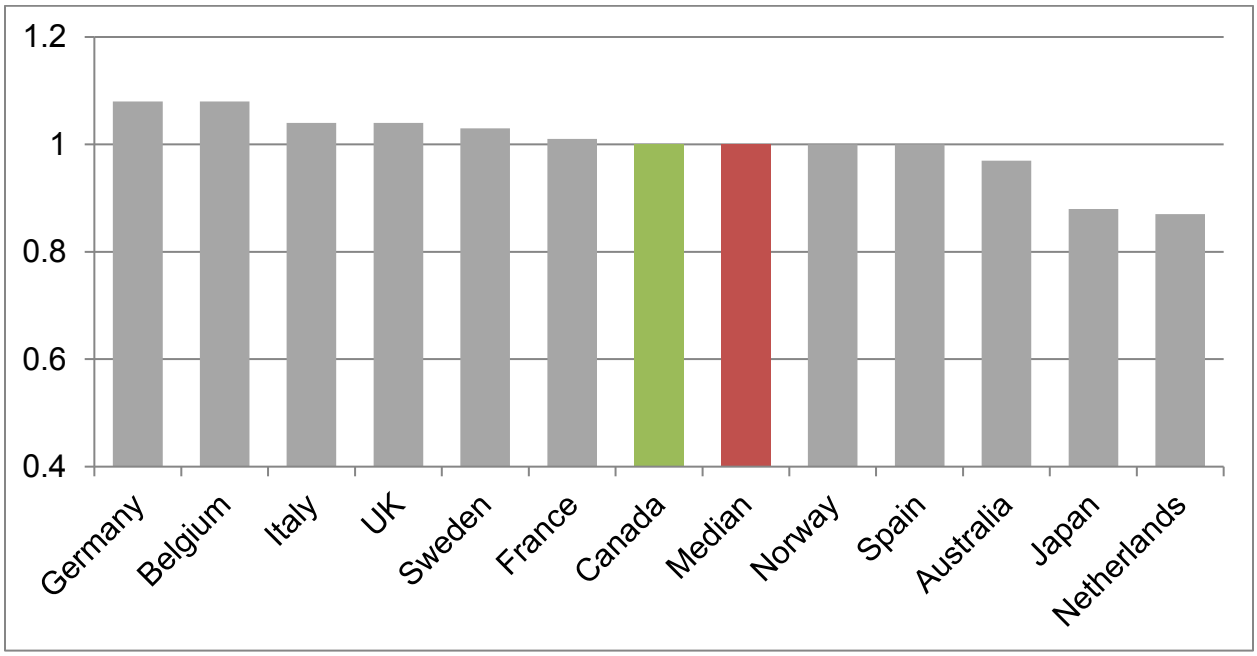
[10] Only one high-prevalence medicine would have been affected (price reduction of 4%). This instance is excluded from the table since combining this value with the values in Table 13 could result in the derivation of confidential information reported to the PMPRB by the patentee.

Canadian list prices for patented medicines are not expected to fall to current OECD median prices. This is because list prices for new patented medicines have 'flattened' over time. Since 2010, international medicine pricing has largely shifted from a model where price differences across jurisdictions occurred transparently, to a model where confidential pricing became the dominant form of price discrimination. Patentees still price their products at different price levels across jurisdictions, but now do so confidentially so as not to show other countries the actual price around the world. As the two graphs below demonstrate, average list prices of the PMPRB11 were 14% lower for all patented medicines launched in Canada between 2006-2010, when product listing agreements (PLAs) were less common; while Canadian prices and international median prices were identical for medicines launched between 2011-2015, when PLA use had become more widespread.

Graph 5: Foreign Price Comparison (2006-2010)



Graph 6: Foreign Price Comparison (2006-2010)



These graphs also demonstrate that median international price tests are now significantly less informative and effective than they were just a decade ago. The growing use of confidential rebates and the flattening of international pricing is a driver for why the PMPRB's regulatory framework needs to be modernized and move beyond the use of simple list price comparison tests.

8.3.3 Require patentees to report on all price adjustments

The Regulations currently require patentees to report information on price adjustments for the first point of sale only. Patentees are not required to report the significant price adjustments that may be given to third party payers, such as provincial insurers that reimburse patients for the price of the medicine. Provincial insurers are some of the biggest payers of patented medicines in Canada and patentees routinely negotiate significant confidential price adjustments with them to ensure that their medicines are covered by public plans. Without this information, the PMPRB sets the maximum price of a medicine based on price information that only includes some price adjustments (i.e. rebates given directly to wholesalers, pharmacies, or patients) but does not include the price adjustments given to third party payers..

This amendment will require patentees to report price information that is net of **any** price adjustments to **any** party in Canada that pays for, or reimburses, the medicine. This information will be considered privileged as per section 87 of the *Patent Act* and will be considered by the PMPRB when determining price excessiveness.

In calculating the benefits, it was assumed that the PMPRB will use the ex-factory price that is net of any price adjustments to calculate the non-excessive price ceiling under its therapeutic class comparison tests. The PMPRB currently regulates the non-excessive price of a medicine based on the prices of other medicines in the same therapeutic class for sale in Canada. Since that price information does not include third party price adjustments, the prices of comparator products are often inflated (as it does not reflect the actual price paid in Canada). As a result, the therapeutic class comparison tests yield non-excessive price maximums that are higher than they would otherwise be if the actual price paid were available to the PMPRB. Compelling actual price information, inclusive of all price adjustments, will help to ensure that a medicine that enters an established therapeutic class will be priced similarly to its comparator products, irrespective of third party price adjustments. This element is expected to impact low-priority medicines (i.e. medicines that already have many comparator products).

As summarized in Table 23, requiring patentees to report all price adjustments is expected to yield a benefit of $2.0 billion (PV) in over 10 years.

Table 23: Total Benefits of Requiring Patentees to Report All Price Adjustments (Million CAD/year)

Year	1	2	3	4	5	6	7	8	9	10
Benefits	48	98	153	209	268	327	396	462	510	613
Benefits (PV)	48	92	133	170	205	233	264	288	297	334

Under this amendment, new low-priority medicines will be tested against the price of the therapeutic class, net of all third party price adjustments. Existing medicines will need to report third party price adjustments, but this information will only be used to set the average therapeutic class ceiling for new entrants. Prices of existing medicines are not expected to be affected by this reporting requirement, as it is not anticipated that the PMPRB will use this information to regulate prices of existing medicines.

Average rebates across all low-priority medicines are currently estimated to be 10% below what is currently reported to the PMPRB. This is a weighted average based on current medicine expenditure, where newer medicines are estimated to have larger discounts than older medicines.

It is important to note that this element of the regulatory amendments affects separate classes of medicines differently. High-priority medicines are anticipated to benefit since information on third party price adjustments will allow patentees to demonstrate compliance with the price ceiling that will result from the new price regulatory factors. This means that high-priority medicines could benefit from list prices that are higher than what will otherwise be possible without this element of the amendments.

Low-priority medicines are anticipated to face lower price ceilings that reflect the actual market prices, since the therapeutic class ceilings will now include the effects of third party price adjustments for all medicines in that therapeutic class.

9.0 Costs

A reporting framework already exists under the PMPRB's current regime. For the most part, the types of information to be filed and the filing frequencies will remain unchanged. Due to the new price regulatory factors, there is an increased administrative burden on patentees. The amendments remove existing reporting requirements on some types of medicines (some patented OTC, veterinary, and generic medicines) but this reduction in administrative burden is not sufficient to offset the addition of the new price regulatory factors and new reporting requirements.

9.1 Costs to Industry

9.1.1 Industry's Lost Revenues

It is estimated that the amendments will result in reduced industry revenues of approximately $8.8 billion (PV) over 10 years, due to reduced thresholds for maximum non-excessive prices in Canada. This reduction in revenues is exactly proportional to the benefit of lower patented medicines expenditure, as calculated in Section 8.

The PMPRB only regulates excessive patented medicine prices in Canada. Any price reduction and repayment of excess revenues will be pursuant to a VCU or Board Order. Price reductions will not occur without voluntary compliance or a ruling by the Board. This means that lost revenues arising from these amendments will only occur due to voluntary compliance by patentees or because of prices being deemed "excessive" for the purposes of the *Act*.

For the purpose of this CBA, national treatment of revenue was given to all patented medicine manufacturers in Canada, despite the fact that 90% of the companies that report to the PMPRB are multinational enterprises (MNEs). While this deviates from TBS Guidance, which only requires consideration of impact on domestic firms, it was decided to acknowledge the full impact on industry given its economic footprint in Canada. Doing so resulted in the lost revenue calculations being several times higher than it will have normally been for a CBA whose purpose is to ensure the greatest overall benefit to current and future generations of Canadians.

9.1.2 New Reporting Costs

Patentee price information reporting requirements already exist under the current regulatory framework. For the most part, the types of information to be reported and the reporting frequencies remain unchanged. The increased administrative burden on patentees is to report on the pharmacoeconomic value and market size factors. The amendments also include the benefit of reduced administrative burden for certain types of medicines (some patented OTC, veterinary, and generic medicines) but this reduction does not fully offset the new reporting requirements.

New industry costs include both new administrative and new compliance costs.

New administrative costs for reporting on the new price regulatory factors obligate patentees to report to the PMPRB:

1. every CUA that is 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 analysis; and
2. the estimated maximum use of the medicine in Canada, by total quantity of the medicine in final dosage form that is expected to be sold.

There is an ongoing administrative cost to provide CUAs every time a new medicine with an annual treatment cost exceeding 50% of Canada's GDP per capita enters the market. There is also a requirement to provide market estimates for all new medicines. It was estimated that 90 DINs will enter the market each year post coming into force of the amendments. Of these 90 DINs, 100% will have to provide market size information, while 20% will have to report CUAs.

These amendments also require patentees to provide the PMPRB with any subsequently published CUAs in the event the medicine is approved for a new or modified therapeutic indications Again, this will only pertain to medicines with an annual treatment cost exceeding 50% of Canada's GDP per capita. Patentees are also expected to provide update market size information each time their medicine is approved for a new or modified therapeutic use. It was assumed that this ongoing requirement will affect 5% of DINs introduced after the coming into force of the amendments that are under the PMPRB's jurisdiction.

Total administrative costs to report on the new price regulatory factors are estimated to be $6,175 annually or $43,373 (PV–2012 reference year) over 10 years. In calculating this burden, it was estimated that each reporting obligation event will take 0.5h to fulfill (per DIN) with a clerical labour cost of 25.24/hr ($2012 CAD) plus 25% for added overhead costs.

New compliance costs are for the changes in patentee reporting of:

- foreign prices (updating from the PMPRB7 to the PMPRB11); and
- domestic prices and revenues (updating from reporting some rebates to reporting all price adjustments)

Patentees already have reporting systems in place for domestic and international prices – these amendments only modify the type of information to be reported. This includes updating the Schedule of comparator countries (from the “PMPRB7” to the “PMPRB11”) for which patentees will report international pricing information every six months, and updates of their domestic prices and net revenues to ensure that this information now includes all price adjustments.

Patentees already have reporting systems in place for domestic and international prices; the regulatory amendments only alter the content that is to be reported. The change from 7 to 11 countries in the Schedule will have a net increase in the cost of filing international price information. Under the current regulatory framework, patentees must file pricing information for each of the seven countries where an exact comparator to the Canadian product is being sold. Enlarging the Schedule to 11 countries will increase the number of foreign jurisdictions for which patentees have to file pricing information. At the same time, 20% of Canadian patented medicines are only found in the United-States, which will be removed from the Schedule of countries, meaning that the patent holders of these products will no longer have to file foreign pricing information. While there is likely to be a net overall increase in the filing of international price information due to the larger number of countries, this burden will not be evenly applied and some patentees may experience reduced filing costs since they no longer have to file international price information at all.

For domestic filing requirements, the amendments require patentees to file price information net of all third party price adjustments. This reporting requirement does not entail patentees filing any of the adjustments themselves, but rather filing the revenues and prices associated with their medicines net of all rebates, rather than net of some rebates, as is currently the case.

It was estimated that each patentee will dedicate 10 hours of labour per reporting obligation to modify their systems. Total compliance costs are estimated to be $4,144 annually or $29,106 (PV–2012 reference year) over 10 years.

9.1.3 Regulatory Burden Reduction

The amendments remove the need for some OTC, veterinary and generic patented medicines to file identity and price information to the PMPRB, unless that information is requested by the PMPRB. 96 medicine products (out of the PMPRB's 1359) fall under these categories and currently file information to the PMPRB. Given that the Federal Court of Appeal only recently clarified and upheld the PMPRB's jurisdiction over these medicines. Assuming full compliance (estimated at 240 DINs by 2019), the administrative burden reduction is expected to be $8,656 (PV) over 10 years.

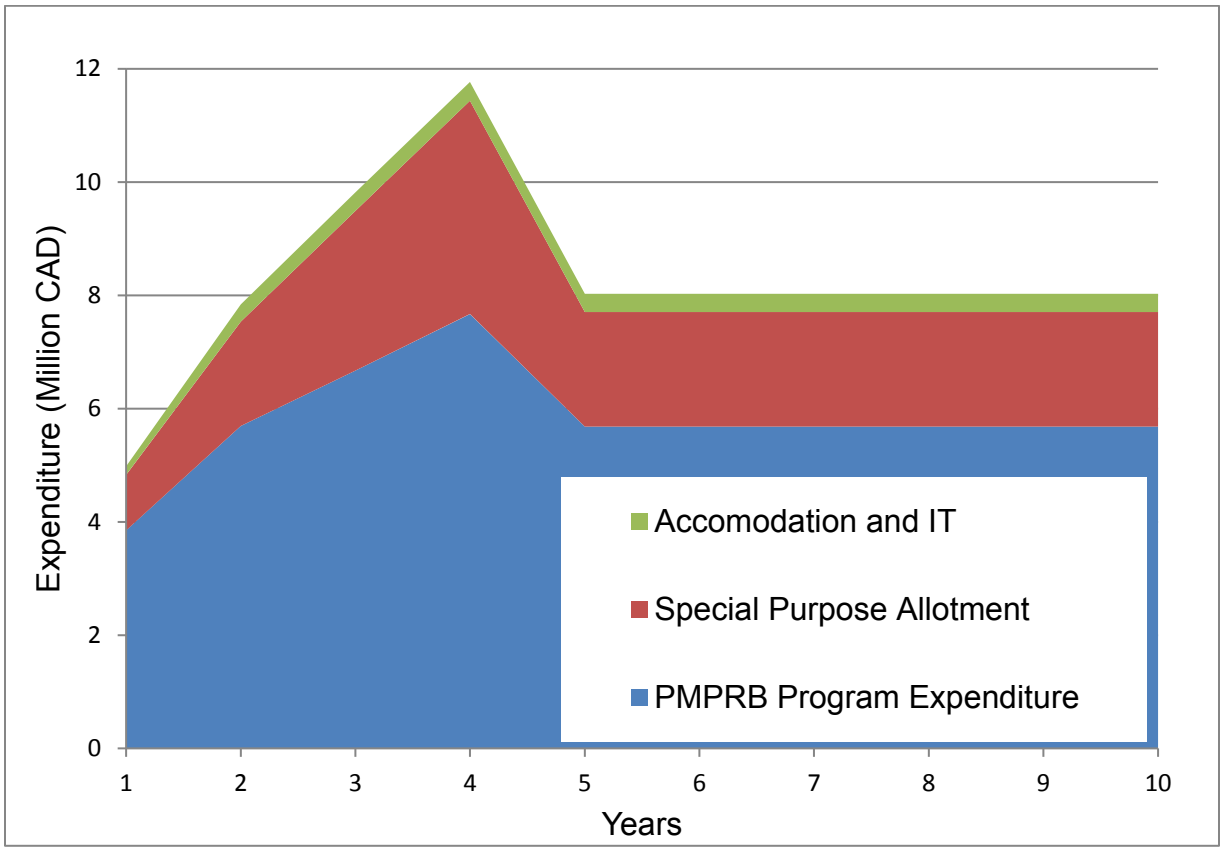
9.2 Cost to the Government of Canada

It is anticipated that the Government of Canada will face increased enforcement costs, particularly in the years immediately following the coming into force of these amendments. The total costs to the Government of Canada are anticipated to be $61.7 million (PV) over 10 years. These costs are to increase the PMPRB's capacity and legal resources. These are the costs specifically allocated for these purposes as outlined in Budget 2017.

These costs will likely arise from a greater number of PMPRB hearings and Federal Court proceedings as patentees seek to clarify the revised authorities. The costs can be broken down into three streams:

- increasing the PMPRB's capacity (PMPRB Program Expenditure);
- increasing Special Purpose Allotment (SPA) Funding (additional legal counsel and expert witnesses as the number of litigation increases); and
- offsetting Public Services and Procurement Canada and Shared Services Canada (Accommodation and IT Support for new PMPRB staff).

Graph 7: Projected Annual Cost to the Government of Canada



Increasing the PMPRB's Capacity

The PMRPB will hire additional staff to support the expected increase in enforcement-related activities. Staff with expertise in cost-effectiveness analysis will also be required to administer the new price regulatory factors. The base (2018–19), second (2019–20), third (2020-21), and fourth years (2021-22) are anticipated to cost $3.8 million, $5.7 million, $6.7 million, and $7.7 million respectively. From the fifth year onwards, it is anticipated that the costs to Government will be $5.7 million per year to maintain the PMPRB's increased capacity.

Increasing Special Purpose Allotment (SPA) Funding

With the amendments in place, patentees may be less willing to accept a VCU, and may instead press for formal and potentially prolonged public hearings. Patentees may also challenge in Federal Court the PMPRB's constitutional authority to regulate based on the new price regulatory factors as well as conceptual and methodological aspects of their implementation. The PMPRB will require additional funding for its SPA to cover the costs of outside legal counsel and expert witnesses. The base (2018–19), second (2019–20), third (2020-21), and fourth years (2021-22) are anticipated to cost $1.0

million, $1.8 million, $2.8 million, and $3.8 million respectively. From the fifth year onwards, it is anticipated that costs to the Government will be $2.0 million per year to maintain the PMPRB's increased SPA funding.

Offsetting Public Services and Procurement Canada and Shared Services Canada (Accommodation and IT Support for new PMPRB staff)

Increasing the PMPRB's staffing levels increases the costs of accommodation and IT services. Combined, the base (2018–19), second (2019–20), third (2020-21), and fourth years (2021-22) are anticipated to cost $151,000, $305,000, $328,000, and $331,000 respectively. From the fifth year onwards, it is anticipated that costs to Government will be $319,000 per year to offset Public Services and Procurement Canada's accommodation costs and Shared Services Canada's IT services.

The total cost to the Government of Canada is anticipated to be $61.7 million (PV over 10 years).

9.3 Other Possible Costs

A possible concern could be that a reduction in industry revenues through lower patented medicine prices could lead to a reduction in domestic employment and overall R&D spending by industry. It is unlikely that these amendments will generate an adverse impact on employment or overall R&D spending. The amendments will align patented medicine prices in Canada with prices found in comparator countries. Despite having lower prices than Canada, these countries enjoy a significantly higher industry presence than Canada. As Table 24 below demonstrates, Canada has the highest price level but lowest R&D investment as a share of sales than all of the countries in the PMPRB11. Cross-sectional analysis finds no evidence that countries with the highest prices enjoy the most R&D investments. The highest priced country in the world, the United States, fails to attract very high levels of R&D-to-sales ratio, while some of the low priced countries in the OECD, such as Belgium, attracts some of the highest levels in the world. Other factors, rather than domestic prices, tend to influence R&D investments, such as headquarter location, tax incentives, and the presence of strong academic and research infrastructure. Cross-sectional analysis finds no evidence that countries with the highest prices enjoy the most R&D investments.

Historical experience in Canada also does not corroborate the association between price level and domestic investment in the pharmaceutical sector. The PMPRB's first Annual Report in 1987 reveals that the R&D-to-sales investment in 1987, when Canada's prices were relatively low and the country began strengthening its patent protection, stood at nearly 7%. Thirty years later, despite Canada being the third most

expensive country in the world for patented medicines, R&D-to-sales investment stands at just 4%.

Table 24: Price and R&D International Comparison

Country	Foreign Prices Relative to Canadian Prices	R&D as a Share of Sales
Canada	1	4%
Germany	0.99	22%
Japan	0.91	17%
Sweden	0.89	22%
UK	0.82	29%
Italy	0.81	6%
Australia	0.79	20%
Belgium	0.78	56%
France	0.78	18%
Spain	0.78	7%
Netherlands	0.75	14%
Norway	0.73	8%
Median	0.78	17%

Impacts on employment in the patented medicine sector

Likewise, no observable links were found between domestic price levels and sector employment. Cross-sectional analysis finds little evidence that countries with the highest prices enjoy higher rates of employment. For instance, Ireland enjoys the highest employment rates in the OECD despite enjoying patented medicine prices that are, on average, 19% less than Switzerland that has the second highest employment rate. Likewise, Canada and Norway enjoy near identical employment rates in the patented pharmaceutical sector, despite Norway's domestic price levels being 25% lower than Canada's.

Canada's historical experience also does not corroborate the link between prices and sector employment. Employment rates in the sector have been falling in recent years, despite evidence showing that price levels in Canada have been increasing.

Finally, while there is no evidence of any link, these amendments are not expected to reduce employment in Canada due to their gradual anticipated impact. Revenue reductions for year 1 are only anticipated to be 1.1%, growing to 10.8% by year 10.

Impacts on access to medicines in Canada

There is no evidence to suggest that these amendments will limit access to medicines in Canada. For one, the availability of a medicine in another country does not affect the availability of medicines in Canada. More importantly, the size of the market and utilization rates of prescription medicines in Canada makes it an appealing market for new medicine launches. This will remain so even after the amendments and estimated price reductions.

Canada's prices are 22% higher than the PMPRB11, yet it only has access to 2% more molecules than the PMPRB11 median. This means that many comparator countries have similar, or better, access while enjoying significantly lower prices (see Graph 4 in Section 8).

10.0 Sensitivity Analysis

Two variables could greatly affect the estimates provided in the CBA:

1. the PMPRB Guidelines Reforms; and
2. the Growth in Patented Medicine Spending.

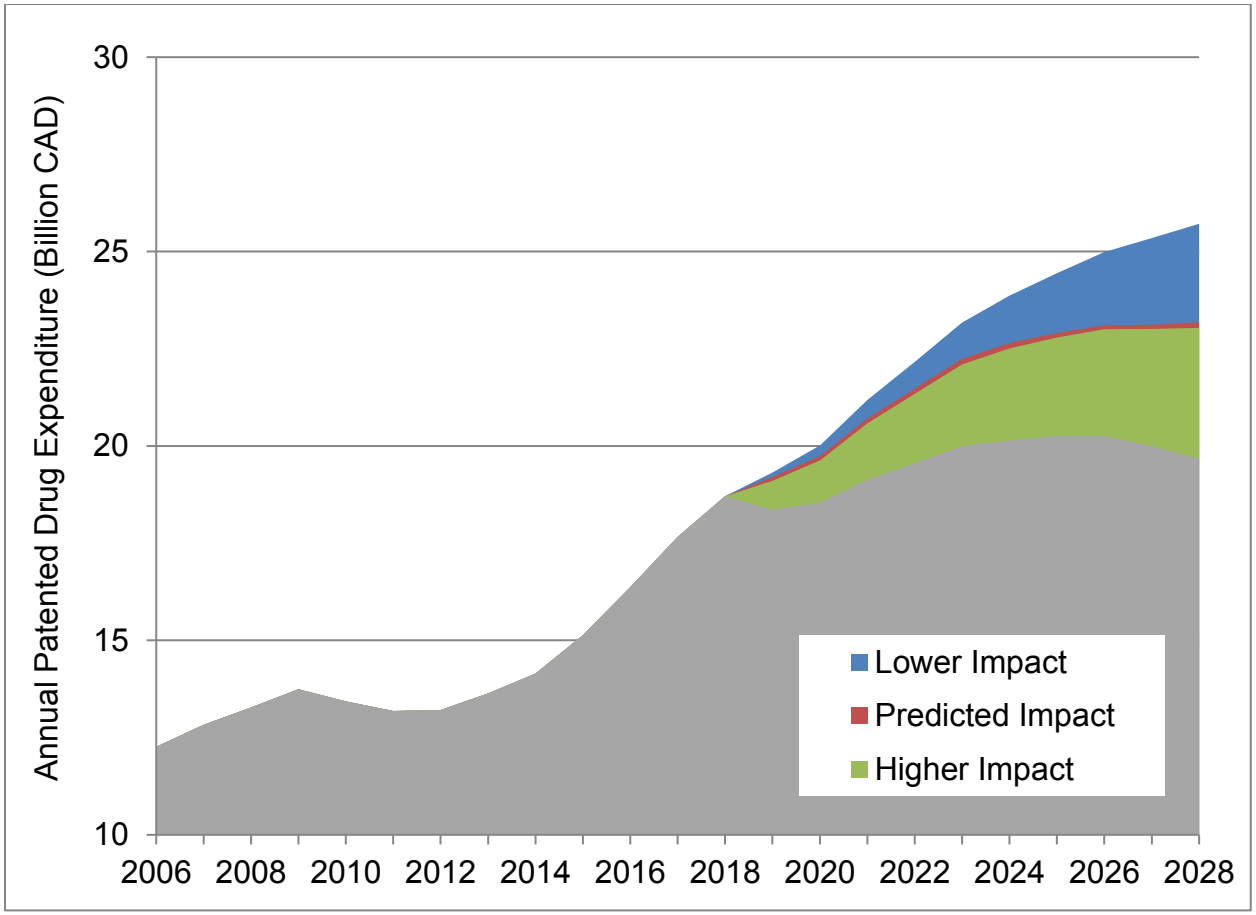
PMPRB Guidelines Reforms

Many of the core regulatory concepts in the *Patent Act* and *Patented Medicine Regulations* have been further developed in the PMPRB's *Compendium of Policies, Guidelines and Procedures* ("Guidelines"). The PMPRB is authorized to create and amend its Guidelines under section 96 of the *Act*, subject to consultation with relevant stakeholders. Operationally, the *Act* and Regulations provide the factors and reporting requirements, while the Guidelines provide the assessments that the Board Staff employs to determine whether the price appears to be compliant with the PMPRB's non-excessive price ceiling for that medicine. The purpose of the Guidelines is to establish, and ensure that patentees are aware of, the policies and procedures undertaken in determining whether a price is believed to be excessive.

The Board will operationalize the new factors and reporting requirements through its Guidelines. Changes to the Guidelines with respect to how the PMPRB calculates the maximum non-excessive price ceiling for any medicine will be required as a result of these amendments. How the PMPRB decides to translate the amendments into its Guidelines can have a significant impact on lowering projected medicine expenditure in Canada. The amendments only specify the new price regulatory factors and their

associated information reporting requirements. The Guidelines will determine how this new information will be used in assessing whether a medicine is priced excessively. Extensive consultation with the PMPRB produced various scenarios based on the new price regulatory factors and information reporting requirements. Any changes to the current Guidelines will follow the finalization of a PMPRB-led stakeholder consultation. Graph 8 provides a lower and higher range of impact based on the multiple scenarios that the r amendments could generate.

Graph 8: Possible Impact based on PMPRB Provided Scenarios

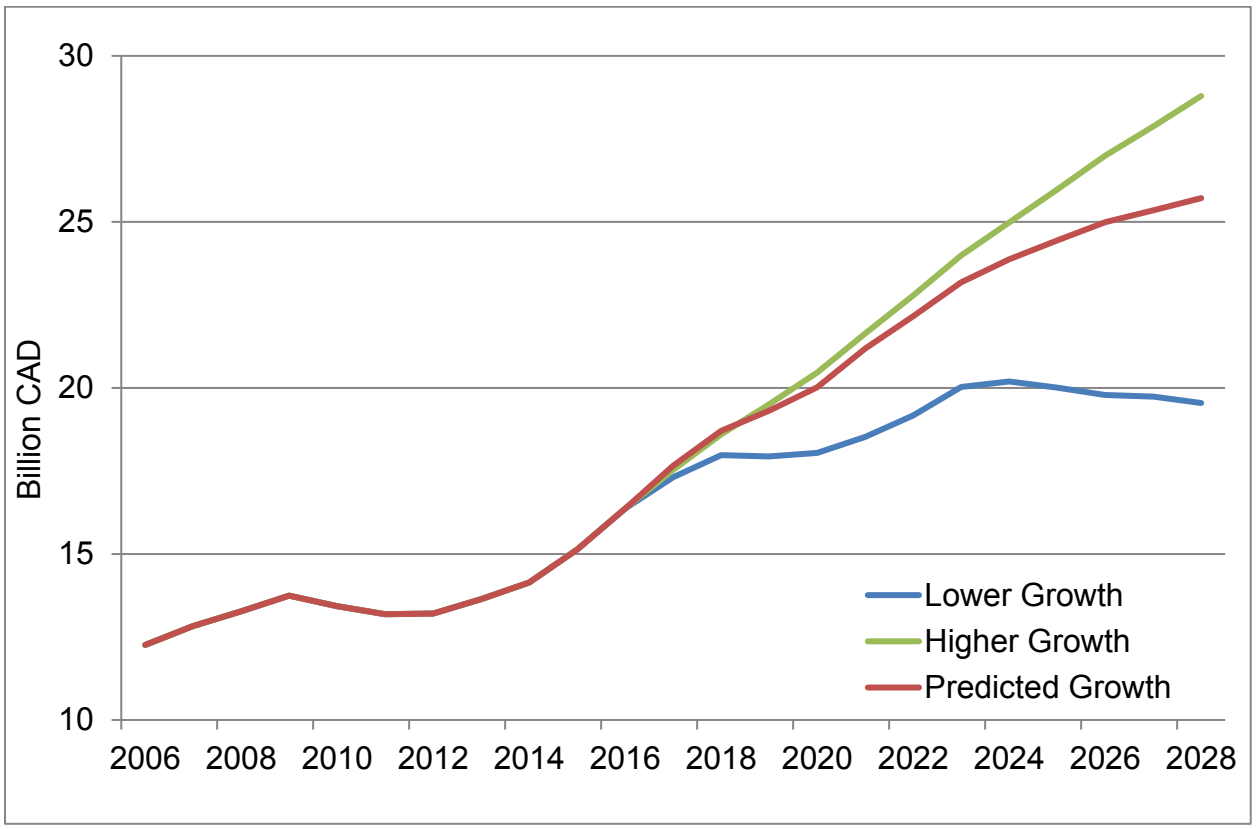


Growth in Patented Medicine Spending

The impact of the amendments is highly dependent on the projected growth in patented medicine expenditure. If growth in patented medicine expenditure is higher than anticipated, the benefit measured in dollars, calculated from a percent reduction due to lower patented medicine prices, will be higher than anticipated. Likewise, if growth in expenditure is lower than anticipated, then the overall benefit will also be lower.

Graph 9 provides a sensitivity analysis on different growth projections for patented medicine expenditure. The calculation of each of these baselines is explained above in Section 5.

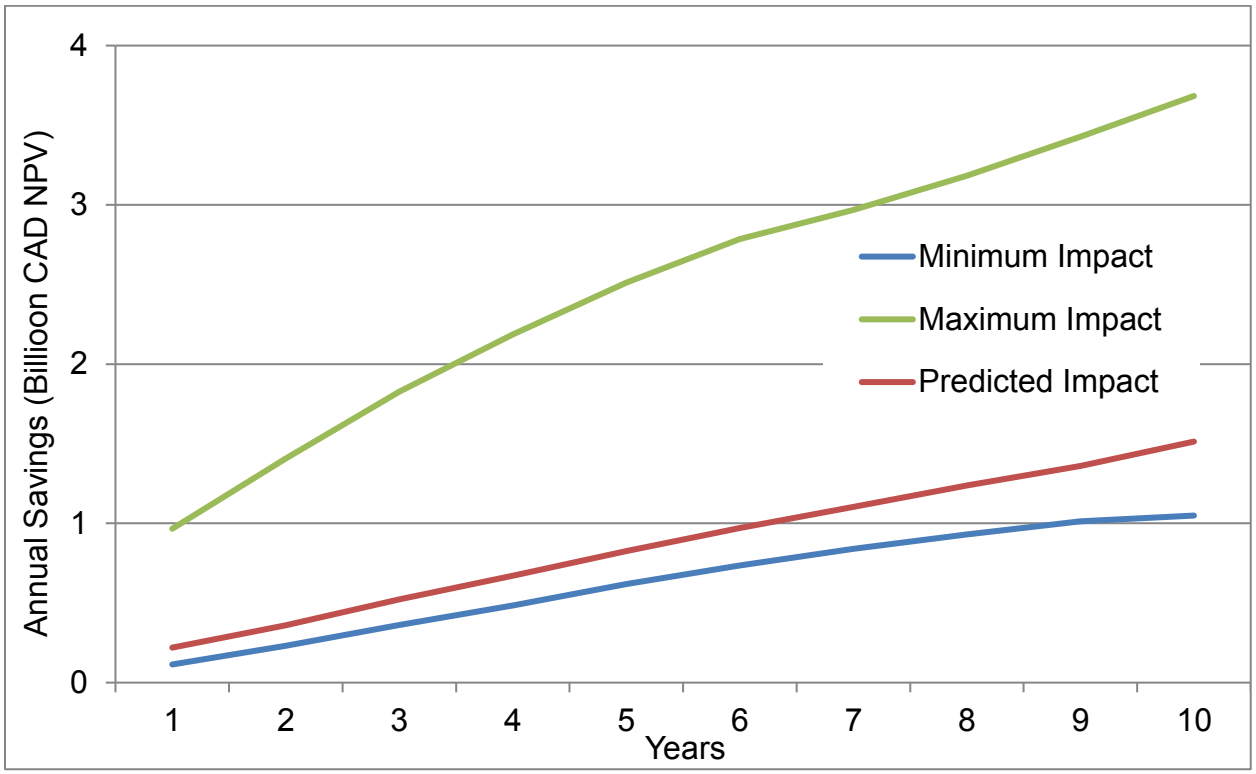
Graph 9: Projected Baseline Analysis



Sensitivity Analysis Summary

Graph 10 summarizes the maximum and minimum impact that the amendments might have using the lowest and highest parameters. The minimum impact represents the lowest projected patented medicine sales coupled with the least aggressive reforms to the Guidelines. The maximum impact represents the highest projected patented medicine sales coupled with the most aggressive reforms to the Guidelines. The sensitivity analysis demonstrates that total patented medicine expenditure could be lowered from a minimum of $6.4 billion dollars (PV) after 10 years to a maximum of $24.9 billion dollars (PV) after 10 years. The current CBA estimates the baseline cumulative expenditure after 10 years to be $8.8 billion dollars (PV).

Graph 10: Sensitivity Analysis Summary – Impact of the Regulatory Amendments



Discount Rate

Finally, additional analysis has been conducted surrounding the applied discount rate. TBS Guidance suggests that a 7% discount rate be applied to all Government of Canada regulatory proposals to keep PV assessment consistent across all departments. However, in order to provide more context to these regulatory amendments, the sensitivity analysis was also conducted using different possible discount rates. Below is the total 10-year impact of the main estimates of lower patented medicine spending at four different discount rates.

Table 25: Estimated Impact Using Different Discount Rates

Lower Expenditure (10-Year Total Billion CAD)		Discount Rates			
		7%	3%	1.5%	None
	Low	6.4	7.9	8.7	9.6
	Expected	8.8	10.8	11.8	13.2
	High	24.9	29.9	32.6	36.7

11.0 Distributional Analysis

The vast majority of patented medicine manufacturers are located in Ontario, Quebec, British Columbia, and Alberta. These four provinces constitute 98% of all companies that will be affected by the amendments.

All - public, private, and out-of-pocket - payers of patented medicines from across the country will benefit from lower prices.

Usage by Age and Gender:

According to Statistics Canada's report "Prescription medication use by Canadians aged 6 to 79", prescription medicine use rose with age from 12% among 6- to 14-year-olds to 83% among 65- to 79-year-olds. Prescription medicine use was also associated with the presence of physical and mental health conditions. The percentage of Canadians taking prescription medicines did not differ by household income. Females were generally more likely than males to report taking prescription medications (47% versus 34%). However, at ages 6 to 14, a higher percentage of boys than girls used prescription medications, and at ages 65 to 79, the prevalence of prescription medicine use was similar for men and women. Prescription medicine use intensity—the number of different medications taken—was strongly associated with age. The percentage taking more than one medication rose from 3% at ages 6 to 14 to 70% at ages 65 to 79.

Disbursement of Monies Collected through Board Orders and Voluntary Compliance Undertakings (VCU):

The *Patent Act* gives the authority to the Minister of Health to enter into agreements with any province or territory to distribute any amounts collected by the PMPRB through either VCUs or Board Orders. There currently are no provisions for the Minister of Health to enter into agreement with private payers to disburse any excess revenues collected by the PMPRB because of medicines being sold at excessive prices. While patentees are expected to consider the *Patented Medicines Regulations* when pricing their products in Canada, these amendments may lead to an increase in VCUs and Board Orders. This could result in the PMPRB collecting more excess revenues, which, once disbursed, will mean a net transfer of expenditure by private payers (private insurance and individuals) into public revenues for provincial/territorial medicine plans.

12.0 "One-for-One" Rule

The amendments will create new price regulatory factors within existing sections of the Regulations. These new factors will be supported by new information reporting

requirements that create a new incremental administrative burden on the patented medicine industry in Canada.

The PMPRB currently has jurisdiction over 1359 patented medicines, with an estimated 90 new medicines entering the market each year. The 77 patented medicine manufacturers in Canada will have to ensure that the required information, as described in Section 8, is provided for all new and existing medicines.

The estimated added regulatory burden to patentees was calculated to be approximately $43,373, with an estimated reduction in regulatory burden of $8,656, for a total of $34,717 (PV) over 10 years. This calculation includes the added regulatory burden of providing new information, as well as the regulatory burden reduction for patented veterinary, over-the-counter medicines, and adding generic medicines to those same reduced reporting obligations. These regulatory amendments are considered an "IN" for the One-for-One Rule with an estimated impact of $3,062.

The cost estimates associated with the "One-for-One" Rule are reported in constant 2012 dollars.

Table 26: One-for –One Rule

Current initiative is an:	*"IN" (One-for-One Rule)*		
	Values to report in Regulatory Impact Analysis Statement:	**Rounding:**	**Unit of Measure**
Annualized administrative costs (constant 2012 $)	$3,062	0 digit	Constant 2012 dollars,PV Base Year 2012
Annualized Administrative Costs Per Business ($2012)	$40	0 digit	Constant 2012 dollars, PV Base Year 2012

13.0 Small business lens

Only patented medicine manufacturers that have a product for sale in Canada will be affected by the amendments. Due to their revenue generation and capital-intense characteristics, few of these businesses, if any, will meet the small business definition. Many Canadian small and medium enterprises within the medicine industry are typically in the development phase of research and often lack the capital necessary to bring their

research to market (i.e. costs for the regulatory expertise to bring a product through the extensive clinical trial process, obtain medicine approvals and establish manufacturing infrastructure); therefore, they often partner with, or sell their intellectual property to, multinational enterprises (MNEs). As these MNEs are responsible for the manufacturing and distribution of the medicine, it will be the MNEs that will fall under the PMPRB's jurisdiction once the medicine enters the Canadian marketplace.

The small business lens does not apply to these regulations.

14.0 Conclusion

Table 1: Cost-Benefit Statement

	Base Year (Year 1 PV)	Final Year (Year PV)	Total (PV)	Annualized Average
		Benefits		
Lower Medicine Expenditure	$219,993,857	$1,513,601,539	$8,786,998,457	$1,251,067,609
New Factors	$33,443,984	$761,063,624	$3,796,634,596	$535,792,273
Updated Schedule	$138,187,980	$418,977,091	$2,926,192,236	$396,948,040
3rd-Party price adjustments	$48,361,892	$333,560,824	$2,064,171,625	$287,005,201
Total Benefits	$219,993,857	$1,513,601,539	$8,786,998,457	$1,251,067,609
		Costs		
Industry	$219,993,857	$1,513,601,539	$8,787,062,280	$1,251,076,677
Loss in profits	$219,993,857	$1,513,601,539	$8,786,998,457	$1,251,067,609
Administrative Cost			$34,717	$4,924
Compliance Cost			$29,106	$4,144
Government	$4,981,481	$8,025,361	$61,716,822	$8,787,064
PMPRB Program Expenditure	$3,849,215	$5,680,633	$43,361,629	$6,173,704

Special Purpose Allotment	$981,481	$2,025,361	$16,119,394	$2,295,033
Accommodation Requirements	$143,085	$304,667	$2,131,142	$303,425
IT Services	$7,700	$14,700	$104,657	$14,900
Total costs (PV)	$224,975,338	$1,521,626,900	$8,848,779,102	$1,259,863,741
Net benefits (NPV)			-$61,780,645	-$8,796,132

Qualitative impacts

Other Benefits

- Greater population health and increased savings to the health care system due to fewer acute care incidents. Lower prices could result in lower patient cost-related non-adherence to needed medicines (for example, not filling prescriptions or skipping doses).
- Opportunity to improve access to medicines and reallocate resources to other important areas of the healthcare system.
- Reduction in the burden placed on price negotiating bodies (e.g. the pan-Canadian Pharmaceutical Alliance) to ensure system affordability.

Other Costs

- Potential impact on wholesalers, distributors, pharmacies, and generic medicine manufacturers whose markups and prices are often expressed as a percentage of patented medicines prices.

These amendments are intended to ensure that patented medicine prices in Canada are not excessive. The total quantified benefit of lower patented medicine prices is estimated at $8.8 billion (PV) over 10 years. The total quantified cost of these amendments, including all of the industry's lost profit, is also estimated at $8.8 billion (PV) over 10 years.

Once compliance and administrative costs to industry and implementation costs to the Government are factored in, the total net benefits of these amendments are estimated to be negative $62 million (NPV) over 10 years. However, a number of benefits have not been monetized and are not reflected in this equation. In addition to the qualitative impacts listed above, the amendments are likely to reduce welfare losses attributable to the monopolistic nature of the industry.