Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements) Statutory authority

Patent Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Executive summary

Issues: The Patented Medicine Prices Review Board (PMPRB) was established in 1987 to protect all Canadian consumers from excessive prices for patented medicines. The PMPRB's regulatory framework has not been substantively updated since, despite changes in the market that have diminished the PMPRB's ability to fulfill its mandate. The PMPRB relies on outdated regulatory tools and information that foreign medicine pricing authorities updated years ago. As a result, list prices for patented medicines in Canada are now among the highest in the world.

Description: The *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)* (the Amendments) update the PMPRB's regulatory framework to a risk-based approach that includes new price regulatory factors and patentee information reporting requirements to protect Canadian consumers from excessive prices.

There are three elements to the Amendments:

1. *Additional price regulatory factors*

    - Supplementing the factors that the PMPRB must consider when determining whether the price of a patented medicine is excessive under section 85 of the *Patent Act* to include its value to, and financial impact on, consumers in the health system.

2. *An updated schedule of comparator countries*

    - Updating the schedule to the *Patented Medicines Regulations* that sets out the countries (now the PMPRB7) on which patentees report pricing information so

that it includes countries with similar consumer protection priorities, economic wealth and marketed medicines as Canada.

3. Changes in reporting requirements

- Reducing patentee reporting obligations for medicines at the lowest risk of excessive pricing, including all veterinary medicines, an expanded subset of medicines that do not require a prescription and certain "generic"[1] medicines, so that the PMPRB can focus its attention and resources on medicines at greater risk of excessive pricing.

- Requiring patentees to report information related to the new price regulatory factors so that the PMPRB can administer them effectively.

- Requiring patentees to report price and revenue information that is net of all price adjustments such as direct or indirect third party discounts or rebates. This will ensure that the PMPRB is informed of the actual prices for patented medicines in Canada and enhance the relevance and impact of domestic price tests.

The new section 85 factors and information reporting obligations associated with those new 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. All other features of the Amendments apply to all patented medicines upon their coming-into-force.

Costs and benefits: 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) as a result 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 an equivalent amount of lost profits, as well as administrative and compliance costs as described below.

It is not anticipated that these Amendments will significantly impact medicine industry employment or investment in Canada. There is no indication that high prices have been a meaningful determinant of the location of industry investments. Other considerations, such as the availability of skilled labour and high quality scientific and research infrastructure appear to hold much greater influence, and Canada's competitive advantages in those areas will remain.

[1] I.e. medicines approved by means of an abbreviated new drug submission, or ANDS.

"One-for-One" Rule and Small Business Lens: The "One-for-One" Rule applies and the anticipated administrative burden is estimated to be $3,062 (2012 dollars) annually. The Small Business Lens does not apply.

Domestic and international coordination and cooperation: The regulation of pharmaceutical prices is a common international practice, although there is a significant variation in approach. These differences often arise from a need to tailor policy instruments to work within each country's unique legal and health care system. While Canada closely monitors regulatory developments in other countries to keep abreast of international best practices, perfect alignment with any one particular country's model is neither practical nor desirable. The regulation of prices for patented medicines is not subject to trade provisions.

Background

Patented medicines are an important part of Canada's health care system

Innovative medicines, including those that are subject to patent protection, help prevent and cure disease as well as save lives. But Canadians are not getting the value for money they deserve relative to total medicine spending, which has increased from 8.5% of the total health care expenditures in 1977 to about 16% today. Medicines are now the second-largest category of spending in health care, more than physician services but less than hospital care (which includes medicines used in hospital). Only the United States, Switzerland, and Japan spend more per capita on medicines than Canada. Excessive spending can limit access to innovative medicines by straining the budget envelope of public and private insurers, place a financial burden on those who pay out of pocket for their medicines, and mean fewer resources for other critical areas of the health care system.

In January 2016, federal, provincial and territorial health ministers agreed to work together to improve the accessibility, affordability, and appropriate use of medicines to better meet health care system needs. The Government of Canada is committed to this work and is taking action to lower the cost of medicines, provide faster access to new medicines that are safe and effective, and support the development of tools for more appropriate prescribing. To support these actions, Budget 2017 outlined an investment of $140.3 million over five years, starting in 2017–2018, and $18.2 million for ongoing years. These Amendments contribute to the Government's commitment by lowering the prices of patented medicines in Canada.

The Patented Medicine Prices Review Board ("PMPRB")

The PMPRB was created in 1987 as the consumer protection "pillar" of a major set of reforms to the *Patent Act* ("Act"), which were designed to encourage greater investment in pharmaceutical research and development (R&D) in Canada through stronger patent protection. The PMPRB is a quasi-judicial body with a regulatory mandate to ensure that patentees do not charge consumers excessive prices during the statutory monopoly period. Its creation arose out of concern that stronger patent protection for medicines might cause prices to rise unacceptably so as to become unaffordable to consumers.

Canadians obtain medicines either out of pocket or through public or private insurers whose funding comes from premiums or taxes. Consequently, in the Canadian context, consumer protection from excessively priced patented medicines necessarily includes the protection of both individual and institutional purchasers.

The Act and the *Patented Medicines Regulations* ("Regulations") together form the legal framework that is administered by the PMPRB through its Guidelines and quasi-judicial function. While the Regulations are made pursuant to the Minister's recommendation, the PMPRB carries out its regulatory mandate at arm's length from the Minister.

The Patent Act and Patented Medicines Regulations

Although the Act doesn't expressly articulate Parliament's understanding of what constitutes an excessive price to charge consumers in this context, it does specify the factors and information that the PMPRB must consider in determining whether the price of a patented medicine has become "excessive". Subsection 85(1) of the Act sets out the following such factors:

- 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.

The Regulations specify the information that patentees must report to the PMPRB to allow it to regulate patented medicine prices and report on trends. This includes identity and price information for patented medicines sold in Canada and their prices in seven other countries. These countries are the United States, the United Kingdom, France, Germany, Switzerland, Italy and Sweden (the "PMPRB7"). The Act allows for further

section 85 price regulatory factors to be prescribed in the Regulations, though none have been promulgated until now.

The PMPRB's Compendium of Policies, Guidelines and Procedures

Many of the core regulatory concepts in the Act and the Regulations are further developed in, and operationalized by, Guidelines. The PMPRB is authorized to make non-binding Guidelines under section 96 of the Act, subject to consultation with relevant stakeholders. The purpose of the Guidelines is to ensure that patentees are aware of the general policies and procedures undertaken by PMPRB staff to identify patented medicines that appear to be priced excessively.

How the current regulatory framework works

Under the PMPRB's current practices, new patented medicines are assessed for the degree of therapeutic benefit they provide relative to existing medicines on the market. Depending on the outcome of that process, patentees are expected to set their prices with regard to a price ceiling for new patented medicines that is based either on the price of that same medicine in the PMPRB7 countries, the price of medicines in Canada in the same therapeutic class, or some combination of the two. Once a patentee sets a medicine's introductory price in relation to that ceiling and it enters the market, the patentee may increase its price but subject to limitations based on changes in the Consumer Price Index.

The PMPRB's regulatory framework is operationalized by PMPRB staff, civil servants who monitor and investigate patented medicines that appear to be priced excessively. Staff applies the tests and thresholds specified in the Guidelines in order to identify instances of potential excessive pricing. If prices appear to be excessive, patentees are encouraged to submit a voluntary compliance undertaking (VCU) based on the Guidelines. The VCU may include a written commitment by a patentee to lower the price of the patented medicine in question and to offset any potential excess revenues related to past sales of the patented medicine at a higher price in Canada.

In the absence of an acceptable VCU, an investigation may proceed to a public hearing before a panel composed of Governor-in Council appointed members of the Board. During a hearing, the Board panel acts as a neutral arbiter between the parties (staff and the patentee). The Board panel must consider every factor under subsection 85(1), to the extent that information on the factors is available, in determining whether the price of the medicine is excessive. If the Board panel determines that the patented medicine was sold at an excessive price, it may issue an order requiring the patentee to reduce its price to a non-excessive level and/or to repay any excess revenue that

resulted from selling the patented medicine at an excessive price. An order of the Board can be enforced in the same manner as an order of the Federal Court.

Canada's changing market and rising medicine costs

Since the establishment of the PMPRB three decades ago, the pharmaceutical industry has changed significantly. R&D is increasingly focused on high-cost medicines, such as biologics, genetic therapies targeted to smaller patient populations and medicines for rare diseases. The risk of excessive pricing is often greater for these products since they have few, if any, competitive substitutes and demand for new and better treatments among the more severely affected population is very high. This is especially true for medicines that are first of their kind, or for which alternatives are less effective or have less tolerable side effects.

The current market dynamic has led to affordability challenges for consumers that, if left unaddressed, pose a very real threat to the sustainability of the pharmaceutical system in Canada. Between 2007 and 2017, the average annual cost of treatment for the top 10 selling patented medicines in Canada increased by 800% and the number of medicines in Canada with annual per-patient treatment costs of at least $10,000 swelled from 20 to 135. These high cost medicines now account for 40% of new patented medicines coming under the PMPRB's jurisdiction every year. Fully 30% of public and private insurer spending is allocated to these medicines, which cover less than 2% of beneficiaries.

Canadian patented medicine prices are among the highest in the world. Of the 35 member countries of the Organisation for Economic Co-operation and Development (OECD), only the United States and Switzerland have higher prices than Canada. In 2017, median OECD prices for patented medicines were on average 19% below those in Canada.

Confidential price adjustments

In Canada and other developed countries, it is common practice for medicine manufacturers to negotiate confidential rebates and discounts off public list prices in exchange for having their products reimbursed by public and private insurers. This empowers manufacturers to price-discriminate between buyers based on their perceived countervailing power and ability to pay. It also results in a growing discrepancy between the list prices (i.e. gross "ex factory" prices) that are reported to the PMPRB and the actual prices that are paid in the market.

Limitations of current price regulation

Over the past several decades, many developed countries have relied on international price comparisons as a method to contain medicine costs. As price authorities in these countries grapple to contain costs in the face of confidential pricing and a sudden influx in very high cost medicines, they are adopting newer methods of evaluating medicine prices that look at the cost of the medicine relative to its health benefits and the impact reimbursement would have on overall health system expenditure. Although public list prices in other countries are still commonly referenced, it is increasingly as a starting point to a more probing and substantive analysis of a medicine's intrinsic value to and financial impact on the health system.

Excessive Price factors under subsection 85(1)

As mentioned, subsection 85(1) of the Act sets out the factors that the PMPRB must consider, to the extent that information is available, in determining whether a patented medicine is being or has been sold at an excessive price in Canada. These include the prices at which a medicine or other medicines in the same therapeutic class have been sold in Canada and in other countries. In making these comparisons, the PMPRB is forced to rely on public list prices that are increasingly divorced from true market prices because of the aforementioned confidential discounts and rebates negotiated between manufacturers and insurers. Additional factors are thus needed if the PMPRB is to undertake a truly meaningful assessment of whether the price of a patented medicine should be considered excessive from a consumer standpoint in today's regulatory environment.

The schedule of comparator countries

The Regulations include a schedule of countries the PMPRB must look to when comparing prices in Canada with prices in other countries as required under subsection 85(1). At the time the original schedule was composed, it was believed that patent protection and price were key determinants of the locus of pharmaceutical R&D investment globally. The choice was made to offer a comparable level of patent protection and pricing for patented medicines in Canada as existed in countries with a strong pharmaceutical industry presence on the assumption that Canada would come to enjoy comparable levels of R&D. However, that policy presumption has proven flawed and is no longer considered to be the most appropriate basis for the composition of the countries listed in the schedule.

Issues

The PMPRB determines whether the price of a patented medicine is excessive based on the factors in section 85 of the Act, using information required of patentees under the Regulations and related data. An evolution in pharmaceutical market dynamics has made apparent two important limitations to the PMPRB's current regulatory framework: (1) the insufficiency of the existing statutory factors; and (2) the inadequacy of information provided by patentees in relation to these factors.

Objectives

The purpose of these Amendments is to equip the PMPRB with the regulatory tools and information reporting authorities it needs to effectively protect Canadian consumers from excessively priced patented medicines in today's regulatory environment. Given its mandate and status as a federal regulator, the intention is for the PMPRB to use these tools in order to identify a national ceiling price above which it would be unreasonable for any consumer in Canada to pay, as opposed to an ideal price for different types of consumers having regard to their individual ability and willingness to pay. The desired result of these changes is for the gross and net ceiling prices of patented medicines in Canada to be more closely aligned with prices in like-minded countries, more reflective of their value to Canadian consumers and more informed by the affordability constraints of the Canadian economy.

Description

The Amendments are composed of three elements, described in more detail below.

1. Additional price regulatory factors

The Amendments add three new price regulatory factors that, in addition to those already specified in subsection 85(1) of the *Patent Act*, are to be considered by the PMPRB. The new factors include: pharmacoeconomic value; market size; and, gross domestic product (GDP) and GDP per capita in Canada. The need for these new factors arises from the limitations to evaluating whether a price is excessive on the basis of unit price information alone. Unit price divorced from overall cost to consumers does not capture key inputs in determining whether a medicine represents reasonable value for money or the ability of constrained health budgets to absorb new costs without rationing access or displacing other needed treatments. These are critical considerations in an era marked by an aging population and a burgeoning number of medicines with annual average treatment costs in the tens of thousands and hundreds of thousands of dollars.

The pharmacoeconomic value in Canada of the medicine

Pharmacoeconomic value is a measure of how much a medicine costs for the health benefit it provides, which can be compared to other medicines or treatments (e.g., surgery, dialysis, assisted living) by using a standard measure of benefit. The standard measure preferred by health technology assessment agencies worldwide is the Quality Adjusted Life Year (QALY). Evidence of the expected costs and health effects of making a new medicine available to specific populations in a particular setting and health care system are often summarised as incremental cost-effectiveness ratios (ICERs) and expressed as the cost per QALY gained. ICERs provide a useful metric for quantifying the additional resources required to achieve a measured improvement in health (i.e., the additional cost required to gain one QALY).

In a public health care system, a new medicine will only improve health outcomes overall if its additional health benefits exceed the opportunity costs associated with the additional resources required to pay for it. Opportunity cost is measured by reference to the estimated health foregone by other patients within the health care system when fixed and fully allocated resources are used to adopt a new medicine. Such an assessment of health opportunity cost reflects the maximum a health care system can pay for the health benefits that a new medicine offers without reducing total population health. This is referred to as a supply-side threshold and requires knowledge of the marginal cost of a QALY within that health system (i.e., the point at which spending on a new medicine for one set of patients in the public system will result in the loss of one QALY for another set of patients in the system).

It is often noted that Canada is the only country with a publicly funded health care system that does not include universal pharmaceutical coverage. The result is a patchwork of public and private payers who lack the national buying power to counter the monopoly position of patentees. That monopoly position is bolstered by an increasing proportion of public and private spending that is taken up by high cost medicines with few or no therapeutic alternatives. Requiring the PMPRB to consider the pharmacoeconomic value of these medicines will ensure that the concept of opportunity cost is taken into account in determining whether their price is excessive. Given that the private market for pharmaceuticals in Canada is an offshoot of the public system and cannot function without it, the policy intent is for the PMPRB to adopt the perspective of the public health care system and favour a supply-side cost effectiveness threshold in estimating opportunity cost.

The PMPRB’s approach to giving effect to this new factor must align with its role as a price regulator, not a price setter.

The size of the market for the sale of the medicine in Canada

The size of the market relates to the economic impact of a particular medicine on consumers, which is a function of both price and volume. Where public and private insurers are called on to cover the cost of a medicine for a significant number of patients (i.e. a large market size), its price could render it unaffordable to consumers. This can be true even of medicines with favorable pharmacoeconomic profiles because their large market size can result in the displacement of more cost effective technologies. The converse is also true of medicines with a very small market size in that they do not tend to raise affordability constraints on a one-off basis even when they have a very high opportunity cost. Requiring the PMPRB to consider the size of the market for a medicine will ensure that the impact of paying for the medicine for everyone who needs it is taken into account in determining if its price is excessive. It will also allow the PMPRB to reassess the prices of patented medicines over time as their market size expands or contracts.

GDP in Canada and GDP per capita in Canada

The GDP is a measure of a country's economic output. GDP growth measures how much the inflation-adjusted market value of goods and services produced by an economy is increasing over time. Per capita GDP measures how much a country is producing relative to its population. The former is looked at as an indicator of overall societal wealth while the latter is looked at as indicator of individual wealth within that society.

While it is recognized that the financial circumstances of different institutional purchasers in Canada will vary, year over year growth in GDP serves as a rough proxy for what the entirety of the Canadian population can afford to pay for the new patented medicines that come to market on an annual basis. Per capita GDP can serve a similar purpose as a proxy for what would be considered affordable to individual consumers if they were required to pay the entirety of the price of a new medicine out-of-pocket.

Taken together, the addition of the three new section 85 factors enable the PMPRB to assess the economic impact of a patented medicine's price on both insurers and individual consumers and enable it to develop screening criteria and market size tests for medicines that are likely to pose affordability challenges for the Canadian health care system.

Treatment of existing medicines

Those medicines that obtained a DIN in Canada prior to the publication of the Amendments in the Canada Gazette, Part II are exempt from the new section 85 price regulatory factors and all information reporting obligations that are associated with those factors. This provides a degree of continuity for existing medicines. Medicines sold in Canada prior to the publication of the Amendments in the Canada Gazette, Part II that did not have a DIN, are not exempt from the new section 85 factors or their associated information reporting obligations.

2. Updating the schedule of comparator countries

The Amendments update the schedule of countries that is to be reported in relation to the existing section 85 price regulatory factor that requires the PMPRB to consider the prices of the medicine in other countries. This update is needed to better align the schedule of countries with the PMPRB's consumer protection mandate and the Government's commitment to improve the affordability of prescription medicines in Canada. Three criteria were used to select the countries which makeup the new schedule. **First,** countries needed to have policy measures in place to constrain free market pricing for medicines. The United States is a primary example of a country that does not satisfy this criterion, and was therefore removed from consideration. **Second**, countries must have a similar economic standing to Canada, as measured by GDP per capita. This is to ensure that reference countries have a similar wealth and ability-to-pay for medicines as Canada. **Third,** countries must have similar market characteristics to Canada, such as population, consumption and access to medicines containing new active substances. This is to ensure that prices are compared against those in countries that are of comparable significance to global patented medicine sales.

The combined application of these criteria resulted in an updated schedule that is composed of Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden and the United Kingdom (the "PMPRB11"). Upon the coming-into-force of these Amendments, all patentees are to report according to the updated schedule of comparator countries.

3. Reduce reporting obligations for patented veterinary, "over-the-counter" and "generic" medicines

The Regulations currently only require patented veterinary and certain medicines that do not require a prescription (i.e., those that do not contain a controlled substance or are not a radiopharmaceutical or biologic listed on Schedules C and D of the *Food and*

Drugs Act and the *Food and Drug Regulations*) to report price and sales information to the PMPRB on a complaints basis.

The Amendments further reduce reporting obligations for these medicines so that patentees are only required to report price, sales, identity information and information on the new price regulatory factors when that information is requested by the PMPRB. The scope of medicines that do not require a prescription that are eligible for reduced reporting is also expanded to include those that appear on Schedule C of the *Food and Drugs Act* (i.e., radiopharmaceuticals) and those containing controlled substances.

The Amendments also extend the same reduced reporting obligations to patented generic medicines (i.e. medicines approved by means of an abbreviated new drug submission, or ANDS, but that are subject to patent protection). Patentees of generic medicines typically face greater competition, and the risk of excessive pricing due to market power is generally not cause for concern.

These Amendments will spare patentees unnecessary reporting burden for medicines that pose a lower risk of excessive pricing. It will also allow the PMPRB to focus its resources on medicines that pose a more substantive risk of excessive pricing. These reduced reporting obligations will apply to all qualifying patented medicines upon the coming-into-force of these Amendments

The reduced reporting obligation is not extended to patented medicines that are biologics (i.e., those listed on Schedule D to the *Food and Drugs Act*, such as vaccines and insulins) but that are available without a prescription due to the significance of these medicines to patient and population health as well as recent examples of PMPRB investigations and compliance actions that have involved these categories of products. Patentees of Schedule D medicines not requiring a prescription will continue to actively report all information to the PMPRB.

4. Information to be reported by patentees to allow PMPRB to operationalize the new section 85(1) factors

The Amendments specify information that patentees are required to report to the PMPRB that is relevant to the new section 85 factors of pharmacoeconomic value and market size, and the circumstances that prompt the obligation to report that information. Patentees are not required to report on information related to GDP and GDP per capita, as this information can be obtained from Statistics Canada.

As explained above, the new price regulatory factors do not apply to medicines that obtained a DIN prior to the publication of the Amendments in the Canada Gazette, Part II. Therefore, the information reporting requirements associated with those new factors also do not apply to those medicines.

Information related to the pharmacoeconomic value factor

Patentees are required to provide the PMPRB with cost-utility analyses that express the medicine's value in terms of the cost per quality-adjusted life year (QALY). Patentees are only required to provide the PMPRB with published cost-utility analyses, if communicated to the patentee, from a publicly funded Canadian organization, such as the Canadian Agency for Drugs and Technologies in Health (CADTH) or the Institut national d'excellence en santé et services sociaux (INESSS). Both CADTH and INESSS are Canadian centres of expertise in the clinical and economic evaluation of medicines. Their published cost-utility analyses are principally used to inform public drug plans of value considerations associated with coverage and reimbursement decisions, and their reports are always communicated to the patentee. Additional Canadian organizations may also publish qualifying cost-utility analyses, and if those are communicated to the patentee, would also need to be provided to the PMPRB.

Any redacted portions of the published analysis that pertain to the patentee's medicine must also be provided, since that information may be necessary to understand the underlying assumptions and data that supported the findings of the analysis. In the case of CADTH and INESSS reports, the redacted information is in the patentee's possession.

Recognizing that not all medicines will be subject to a cost-utility analysis, patentees are not obligated to prepare a cost-utility analysis if one does not exist.

Any other cost-utility analyses that are subsequently published and satisfy the above criteria must also be reported by patentees to the PMPRB. Cost-utility analyses are typically performed infrequently, and are often triggered by relevant developments in the lifecycle of medicine such as its initial launch, the approval of a new indication or new scientific data related to the therapeutic benefit of the medicine. Such developments are relevant to updating the PMPRB's assessment of the price of the medicine against the pharmacoeconomic value factor.

A risk-based approach has been taken so that only high-cost medicines, which pose the greatest risk of excessive pricing, are required to report cost-utility analysis information. Specifically, only those medicines with costs that may occur within a 12-month period that would exceed a threshold of 50% of Canada's GDP per capita are subject to this reporting obligation. Some medicines are taken on an ongoing basis, and the costs associated with those medicines can be expressed in 'annual' terms. Other medicines are not taken "annually", such as those taken for a fixed duration or a number of cycles.

In those cases, the cost of the medicine that could reasonably occur within a 12-month period is to be considered. To illustrate, in the case of a medicine that costs $25,000 for a 4-month course of treatment, those costs would be prorated to occur over a 12-month period, so that the cost of this medicine that would occur within 12-months is $25,000.

The information needed to determine whether the medicine meets this cost threshold can be found in the qualifying cost-utility analysis, and may include statements of annual cost of treatment, or provide information on the cost of each cycle or round of treatment, supplemented by additional information on the number of cycles or treatment rounds that may occur. This information reporting obligation is triggered if any scenario of the medicine's use, as identified in a qualifying cost-utility analysis could result in a 12-month cost of the medicine reaching or exceeding the 50% of Canada's GDP per capita threshold.

Information related to the market size factor

Patentees are required to provide the PMPRB with information on the estimated maximum use of the medicine in Canada, based on the prevalence of the approved therapeutic use of the medicine in Canada. This information must identify the quantity of the medicine that is estimated to be sold in final dosage form and the period of time that was used to produce that estimate. Patentees already compile this information in the development of internal business plans, sales forecasts, and for CADTH and INESSS reviews, and therefore the reporting obligation does not compel patentees to create documents that don't otherwise exist. Patentees are also required to provide the PMPRB with market size estimates when a medicine receives approval from Health Canada for a new or modified therapeutic use. This is because such approvals could lead to important changes in the estimated maximum use of the medicine.

5. Require patentees to report price and revenues, net of all price adjustments

The Regulations currently require patentees to report information on price adjustments for the first point of sale ("ex-factory") only. Patentees are not required to report the significant rebates and discounts they may provide to third party insurers, such as public drug plans, that reimburse consumers for the cost of a medicine. Public drug plans are some of the biggest payers of patented medicines in Canada, collectively accounting for over 40% of total pharmaceutical spending.

To ensure that the PMPRB is informed of the actual prices for patented medicines in Canada, patentees will be required to report price and revenue information that is net of any price or other adjustments, including discounts, rebates and free goods and services, to any party that pays for, or reimburses, the patented medicine. Requiring patentees to provide this information will facilitate compliance with the new, lower price

ceilings that are expected to result from the PMPRB's application of the new subsection 85(1) factors. More generally, it will also allow the PMPRB to factor third party rebates into its calculation of average transaction prices to inform existing factors. However, this information would be considered privileged as per section 87 of the *Patent Act*.

Upon the coming-into-force of these Amendments, all patentees are to report price and revenue information that is net of all adjustments.

Regulatory and non-regulatory options considered

Status quo

Taking no action was considered and rejected on the grounds that the PMPRB's current regulatory framework lacks effective price regulatory factors and sufficient patentee price information reporting requirements for the new categories of medicines and industry pricing behaviours that have emerged since the creation of the PMPRB. The PMPRB's current patentee price information reporting requirements produce incomplete domestic pricing information and provide international price information from a number of countries with high patented medicine prices that are poorly aligned with the Canadian market.

Non-regulatory modernization (updates to the PMPRB's Compendium of Policies, Guidelines and Procedures)

This option would be primarily limited to revised price tests that continue to rely on domestic and international price referencing methods. This option was fully explored, and included in a stakeholder consultation by the PMPRB in 2016, but was rejected as simply updating the Guidelines does not address the underlying limitations of the existing Regulations. Regulatory reform is needed to provide the PMPRB with the regulatory tools and information it needs to effectively protect Canadian consumers from excessively priced patented medicines in today's environment. Under a modernized regulatory framework, the PMPRB will have a stronger basis from which to modernize its Guidelines.

Benefits and costs

The impacts of the Amendments have been assessed in accordance with the Treasury Board Secretariat (TBS) Canadian Cost-Benefit Analysis Guide. Regulatory impacts have been identified, quantified and monetized where possible, and compared incrementally to a non-regulatory scenario. The analysis estimated these impacts over a sufficient time period to demonstrate whether there is likely to be a net benefit.

Benefit: 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 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. In accordance with TBS guidance, a discount rate of 7% was used in all PV calculations. The complete cost-benefit analysis is available upon request.

Cost-benefit statement

	Base Year (Year 1 PV)	Final Year (Year PV)	Total (PV)	Annualized Average
		Benefits		
Lower Drug 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 (includes reg burden reduction)			$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).
- Providing the 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 benefits of these Amendments are 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 above, 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 on the basis of 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.

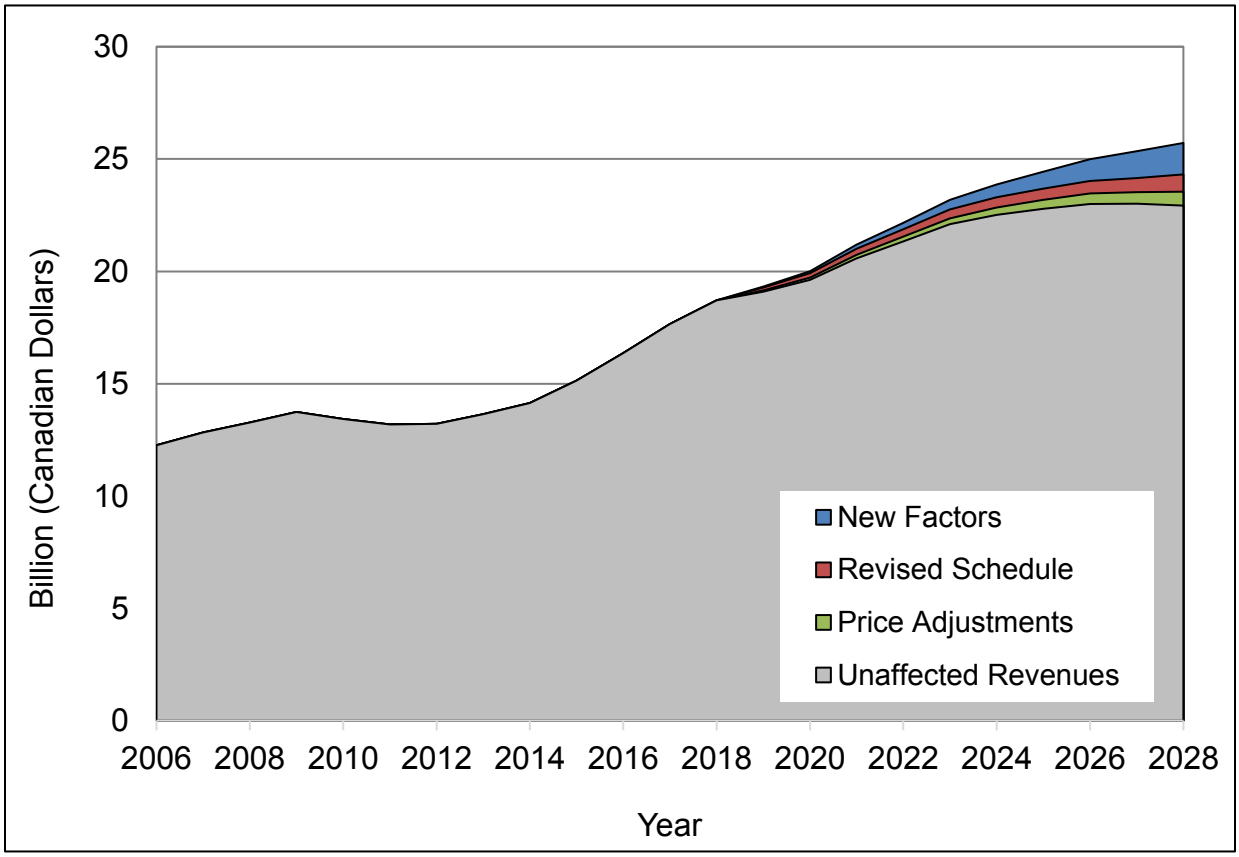
The total quantitative benefits of the Amendments are estimated at $8.8 billion dollars (PV) over 10 years and consist exclusively of the direct benefits of lower prices for patented medicines. The impact on patented medicine prices in Canada are limited to the three elements of the Amendments, namely:

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).

Figure 1: Estimated Impact of the Amendments on Total Patented Medicine Expenditure



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 cost-benefit analysis assumes that the PMPRB will take a risk-based approach to price regulation, whereby it would 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) would receive less oversight, for example, medicines that would not be required to report on the new pharmacoeconomic value factor. The new price regulatory factors do not apply to medicines that obtained a DIN in Canada prior to the publication of the Amendments in the Canada Gazette, Part II.

Below is a brief description on how the impacts of each element of the Amendments were calculated. For the full methodology, please consult the standalone cost-benefit analysis that accompanies these Amendments and which is available upon request.

Introduction of New Price Regulatory Factors

The new price regulatory factors are expected to lower patented medicine spending by $3.8 billion (PV) over 10 years.

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	1,195	1,399
Benefits (PV)	33	84	160	233	318	409	503	599	696	761

In calculating these benefits, only new high-priority medicines were assessed against the new price regulatory factors. The application of the new factors meant that the price of new high-priority medicines was reduced by 40% on average relative to the baseline forecasts. This would lead to a 5.4% reduction in projected patented medicine revenues by year 10.

The 40% average reduction in price for high-priority medicines assumes that the PMPRB would apply a $50k cost-per-QALY threshold for medicines for standard diseases (including cancer), a $150k threshold for medicines for rare diseases, and a $35k threshold for medicines with a high-prevalence population. The 40% impact was calculated following the application of anticipatory Guidelines' tests on a basket of 70 medicines that were launched in Canada between 2010-2015 and were used as a proxy for high-priority medicines. The 40% reduction represents an average across all 70 medicines, which was then projected forward as the necessary reduction for all new

high-priority medicines that are expected to be sold in Canada for the first 10 years after the Amendments come-into-force.

For the full list of Guidelines tests that were applied to all 70 medicines, as well as the price reduction impact for each of the 70 medicines, please consult the standalone cost-benefit analysis that accompanies these Amendments.

Updating the schedule of comparator countries used by the PMPRB

Updating the schedule of comparator countries is expected to lower patented medicine spending by $2.8 billion (PV) over 10 years.

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

The cost-benefit analysis assumes that new medicines first sold in Canada following the coming-into-force date of these Amendments will be tested against the median of the updated schedule of comparator countries (PMPRB11) at introduction. Prices of new high-priority medicines are estimated to be reduced by 4.5%, while prices of other medicines are expected to be reduced by 3.49%.

Since the PMPRB uses a Highest International Price Comparison (HIPC) test, updating the schedule, especially removing the typically highest price (e.g. US), could have impacts on existing drug revenue if the Canadian price becomes the highest price among all comparators in the updated schedule. The cost-benefit analysis calculates that Canadians will pay $788.5 million (PV) less for existing medicines over the next 10-years as a result of updating the schedule of comparator countries. This is the only instance in the cost-benefit analysis where prices of existing medicines are anticipated to be affected as a result of these Amendments.

For the calculation of impacts on new and existing high-priority medicines, as well as for the calculation of impacts on low-priority medicines, please consult the standalone cost-benefit analysis that accompanies these Amendments.

Requiring patentees to report price and revenues net of all price adjustments

Requiring patentees to report price and revenues net of all price adjustments is expected to lower patented medicine spending by $2.0B (PV) over 10 years.

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

Manufacturers of high-priority medicines are anticipated to benefit from this element since information on third party price adjustments would allow demonstration of compliance with the potentially lower ceiling that would result from the new price regulatory factors.

However, low-priority medicines are anticipated to face lower price ceilings that reflect actual market prices of their competitors. New medicines introduced in a therapeutic class with existing comparator products will be tested against the price of all medicines in that class, net of all discounts. Prices net of third-party adjustments will be collected for existing low-priority medicines, since that information is needed to inform existing section 85 factors that will be used to set the ceilings for new medicines. However, it is not anticipated that the prices of existing low-priority medicines would be affected by this element.

Assuming that actual prices paid are, on average for all medicines and across all payers, 10% lower than what is currently being reported to the PMPRB, requiring this information is estimated to result in a 7.68% reduction in projected patented medicine expenditures in the long run. However, since the therapeutic class comparison test compares the price of new entrants to the price of existing drugs that might not have any confidential rebates, the full-effect of this change is not expected to be felt immediately after the coming-into-force of these Amendments. As such, the impact on the 10-years under study is expected be a 4.54% reduction in medicine expenditure.

For the calculations of impacts on new and existing high-priority medicines, as well as for the calculation of impacts on low-priority medicines, please consult the standalone cost-benefit analysis that accompanies these Amendments.

Administrative Burden Reduction

The Amendments remove the need for medicines that pose the lowest risk of excessive pricing to file identity and price information to the PMPRB, unless that information is requested by the PMPRB. These include patented veterinary medicines, an expanded

subset of medicines that do not require a prescription and certain "generic"[2] medicines. A total of 96 medicines (out of PMPRB's 1359) were found to fall under these categories. Since the PMPRB's jurisdiction over patented generics was only recently clarified and upheld by the Federal Court of Appeal, it is anticipated that these medicines have not been fully compliant in their existing reporting obligations. Assuming full compliance at 250 DINs, the administrative burden reduction is expected to be $8,656 (PV) over 10 years. In calculating this burden, it was estimated that each report would take 0.5 hours to complete (per DIN) with a clerical labour cost of 25.24/hr ($2012 CAD) plus 25% for added overhead costs, and that the obligation to report identity information occurs once (affects all 250 DINs), while the obligation to report price information occurs every 6 months (affects 100 DINs).

Costs

Lower Industry Revenue

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.

The PMPRB only regulates excessive patented medicine prices in Canada. Any price reduction and repayment of excess revenues would 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. Price reduction would not occur without voluntary compliance or a ruling by the Board. This means that loss revenues arising as a result of these Amendments would only occur due to voluntary compliance by patentees or as a result of prices being deemed "excessive" for the purposes of the *Patent Act.*

For the purpose of this cost-benefit analysis, 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 would have normally been for a cost-benefit analysis whose purpose is to ensure the greatest overall benefit to current and future generations of Canadians.

[2] I.e. medicines approved by means of an abbreviated new drug submission, or ANDS.

Administrative and Compliance 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 medicines (including all patented veterinary medicines, an expanded subset of medicines that do not require a prescription and medicines approved by means of an ANDS) 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 industry to report to the PMPRB:

1. every cost-utility analysis 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.

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 cost-utility analyses 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 drug products (as identified by the unique DIN issued by Health Canada before products are marketed in Canada) would enter the market each year following the coming-into-force of the Amendments. Of these 90 drug products, 100% would have to provide market size information, while 20% would have to provide cost-utility analyses.

The Amendments also require patentees to provide the PMPRB with any subsequently published cost-utility analyses in the event the medicine is approved for a new or modified therapeutic use. Again, this would only pertain to medicines with an annual treatment cost exceeding 50% of Canada's GDP. Medicines are also expected to provide updated market size information each time the medicine is approved for a new or modified therapeutic use. It was assumed that this ongoing requirement would affect 5% of DINs introduced after the coming-into-force that are under PMPRB 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 would take 0.5h to complete (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)
- 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. It was estimated that each patentee would 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.

Government of Canada

The total costs to the Government of Canada are anticipated to be $61.7 million in present value 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.* Specific cost components are described in the sections that follow.

Increasing the PMPRB's capacity

Costs to Government include hiring additional staff to support the expected increase in enforcement-related activities, and administering 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 costs to Government are $5.7 million/year to maintain the PMPRB's increased capacity.

Increasing special purpose allotment funding

Patentees might be less willing to offer VCU and instead press for formal and potentially prolonged hearings. The PMPRB requires additional funding for its special purpose allotment (SPA) to cover the costs of outside legal counsel and expert witnesses. Patentees might also more frequently challenge decisions made under the new regime in the Federal Court. The base (2018–19), second (2019–20), third (2020–21), and

fourth years (2021–22) would be 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 Government would be $2.0 million/year to maintain the PMPRB's increased SPA funding.

Offsetting costs to Public Service and Procurement Canada and Shared Services Canada

Increasing the PMPRB's staffing levels also increases accommodation and information technology (IT) costs. 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 be $319,000/year to offset Public Service and Procurement Canada's accommodation costs and Shared Services Canada's IT services costs.

Sensitivity analysis summary

A sensitivity analysis was performed on two variables that could greatly affect the estimated impact of these Amendments. The first variable relates to possible approaches that could be taken by the PMPRB to implement the Amendments, while the other relates to the projected growth rate in patented medicine expenditure.

The baseline analysis was conducted on an assumption that the PMPRB continues to apply price test methods that are similar to those currently in place. This assumption is necessary since any changes to the Guidelines are within the control of the PMPRB. For example, the PMPRB currently uses the median PMPRB7 price to test new medicines against prices in other countries. The baseline assumes that the median price test would also be applied to the new PMPRB11. The sensitivity analysis of this variable examined possible alternate approaches to the use of existing price regulatory factors and possible approaches to implementation of the new factors in the Guidelines.

The second variable relates to the growth of expenditures in patented medicines. If growth in patented medicine expenditures is higher than anticipated, the benefit measured in dollars, calculated from a percent reduction due to lower patented medicine prices, will be higher than estimated. Likewise, if growth in expenditure is lower than estimated then the overall benefit will also be lower. Growth in the patented medicine industry is difficult to predict, and the emergence of new types of patented medicines, such as biologics, introduces new uncertainties into modelling efforts.

The sensitivity analysis found that the estimated impact of the Amendments on total patented medicine expenditure could range 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 minimum sensitivity analysis impact represents the lowest projected patented medicine sales

growth coupled with the least aggressive reforms to the PMPRB Guidelines. The maximum sensitivity analysis impact represents the highest projected patented medicine sales coupled with the most aggressive reforms to the PMPRB Guidelines. The cost-benefit analysis estimates the baseline cumulative expenditure reduction after 10 years to be $8.6 billion dollars (PV).

Since the cost-benefit analysis largely assumed the retention of current Guideline tests and procedures where possible, the resulting impact assessment is closer to the lower end of the scale than the upper end. This was done to isolate, as much as possible, the impact of the calculation to the Amendments, rather than any broader Guideline changes that could be made by the PMPRB independently from the Amendments.

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 submissions to keep present value assessment consistent across all departments. However, in order to provide more context to these Amendments, the sensitivity analysis was also conducted using different possible discount rates.

Lower Expenditure (10-Year Total Billion CAD)		Discount Rates			
		7%	3%	2%	None
	Low	6.4	7.9	8.7	9.6
	Expected	8.6	10.8	11.8	13.2
	High	24.9	29.9	32.6	36.7

Distributional analysis summary

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 would be affected by these 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: Patented medicines account for more than 60% of total spending on prescription medicines in Canada. According to the Statistics Canada 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, rather 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 either through VCUs or Board Orders. There are currently no provisions for the Minister of Health to enter into an agreement with private payers to disburse any excess revenues collected by the PMPRB as a result of medicines being sold at excessive prices. While patentees are expected to consider the *Patented Medicines Regulations* when pricing their products in Canada, modernizing these regulations may lead to an increase in VCUs and Board Orders. This could result in the PMPRB collecting more excess revenues, which, once disbursed, would mean a net transfer of expenditure by private payers (private insurance and individuals) into public revenues for provincial/territorial public drug plans.

“One-for-One” Rule

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 three elements: (1) the upfront cost of providing the PMPRB with cost-utility and market size analyses for new medicines, (2) the ongoing costs of updating this information in the event of that the medicine gets approved for a new or modified therapeutic use, (3) the reduction in reporting requirements for patented veterinary medicines, an expanded subset of medicines that do not require a prescription and medicines approved by means of an ANDS. These Amendments are considered an “IN” under the “One-for-One” Rule and have an estimated impact of $3,062.

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, Present Value Base Year 2012
Annualized Administrative Costs Per Business (constant 2012 $)	$40	0 digit	Constant 2012 dollars, Present Value Base Year 2012

Small Business Lens

The Small Business Lens does not apply to these Amendments, as only medicine manufacturers that have a patented medicine for sale in Canada will be affected by these Amendments. Among the 77 companies reporting to the PMPRB, none were identified as satisfying the small business definition. In general, patented medicines are sold by multinational enterprises or their subsidiaries.

Consultation

Three major consultations, including pre-publication in the Canada Gazette, Part I, informed the development of these Amendments. In view of subsection 101(2) of the *Patent Act* and normal processes often followed in making amendments to regulations, the following stakeholders were invited to participate in these consultation processes: Canadians, provincial and territorial ministries of health, patient associations, the pharmaceutical industry, private health insurance organizations, health and pharmaceutical policy academics and policy think tanks.

As an additional feature and in response to considerations raised by stakeholders through consultation activities, in June 2018, Health Canada commissioned David Dodge and Ake Blomqvist to perform an independent assessment of the features of the regulatory proposal and its accompanying cost-benefit analysis.

An overview of each consultation is provided in the sections that follow. At the end of each section, a summary of main points is provided that also identifies aspects of the

proposal that were modified in response to stakeholder feedback.

Consultation 1: PMPRB Guidelines Consultation (June – October 2016)

Initial consultations began in June 2016, when the PMPRB initiated a review of its Guidelines. That process included the issuance of a public consultation document, targeted discussion questions and a series of meetings with stakeholder groups from across Canada. This phase of consultation ended on October 31, 2016, and received a total of 66 stakeholder submissions. Based on feedback received, it was determined that advancement of issues raised during the consultation, such as the limitations of existing price regulatory factors and the disparity between the price information patentees are obligated to report to the PMPRB and the actual market prices occurring in Canada, could not be resolved through updated Guidelines and would require regulatory amendments.

Consultation 2: Health Canada Pre-Consultation on Proposed Regulatory Amendments (May 16 – June 28, 2017)

On May 16, 2017, the Minister of Health announced the launch of a Health Canada-led **pre-consultation** on proposed Amendments to the Regulations. A consultation document entitled "Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations" was posted on Health Canada's website as well as the Government of Canada's Consulting with Canadians website. The consultation was promoted through a news release and an e-mail notification that was distributed widely to stakeholders. The Minister also wrote to her counterparts in the provinces and territories, inviting them to comment on the proposed Amendments. During the consultation period, Health Canada hosted nine engagement sessions with external stakeholders, including representatives from public and private health insurance providers, patient organizations, the pharmaceutical industry, the health professions and academia. Submissions were received from a diverse and representative range of stakeholder groups that provided a range of views:

The ***new price regulatory factors*** were generally supported by public and private insurers, health practitioners and academics as relevant considerations of price 'excessiveness'. Some academics suggested that GDP per capita would provide a more relevant consumer-level perspective of 'excessiveness' than GDP. Representatives of the innovative medicines industry expressed concerns that the new factors could add complexity to regulatory and reimbursement processes in Canada and may duplicate considerations that are already built into existing processes such as the Common Drug Review, and price listing agreements with public payers. Industry representatives were

also concerned that the new factors could be associated with a potentially significant increase in existing reporting obligations. Patient groups acknowledged high prices as a concern, but expressed continued timely access to new medicines as an overarching priority that should not be compromised by overly-aggressive price regulation. Patient groups and health practitioners encouraged flexibility in the new factors so that PMPRB would not be bound to a rigid cost per QALY metric.

The ***revised schedule of countries*** was generally supported by public and private insurers, health practitioners and academics as achieving better alignment with a more representative sample of international price levels rather than the high-priced countries currently referenced by the PMPRB. Representatives from the innovative medicines industry expressed concern about the added regulatory burden associated with the obligation to report on prices in (then) 12 rather than 7 countries. Industry representatives also encouraged the retention of the United States as a highly relevant reference country due to geographic proximity and similarity of pharmaceutical product markets and coverage models.

The proposed obligation for patentees to report on ***price information net of all rebates*** and discounts to third parties was met with concern from several stakeholders. Academics encouraged the reporting obligation to also include circumstances that could allow price increases, such as medicines that deliver better than anticipated outcomes though pay-for-performance agreements. Public and private insurers, health practitioners, patients and the innovative medicine industry expressed concerns that the reporting price information net of rebates and discounts should not compromise the confidentiality of this information or the willingness of companies to continue their participation in price negotiations with public and private payers.

The proposed extension of existing ***reduced reporting obligations*** to include low-risk patented generic medicines received a mixed reaction. Public and private insurers and health practitioners suggested that generics in Canada are high-priced relative to international norms and should therefore continue reporting actively to the PMPRB. Representatives from the generic and innovative medicines industry suggested that reduced reporting could reasonably be extended to a broader set of ‘low-risk’ products, such as biosimilars and the brand version of a medicine that faces generic competition.

In response to stakeholder feedback, several features of the proposal were refined for pre-publication in the Canada Gazette, Part I. These refinements included:

- The new price regulatory factors remained broad so that the PMPRB could consider measures other than cost per QALY, and develop appropriate measures using market size and GDP.

- GDP per capita was added to the GDP factor.
- To minimize new regulatory reporting burden, patentees would only be required to report Canadian cost-utility analyses, and not analysis from other countries.
- Reduced patentee information reporting requirements were further extended to include all patented medicines that do not require a prescription, including radiopharmaceuticals, biologics and those containing controlled substances. Consideration was given to also including other products such as biosimilars, other patented generic medicines that are not authorized for sale by way of an ANDS and brand versions of patented generics, but there was insufficient evidence to determine whether these products pose a sufficiently low risk of excessive pricing.
- Patentee price information reporting requirements were modified to capture all price adjustments that either would lower (e.g. discounts, rebates, free goods, free services) or raise (e.g. payment for performance) the price of a medicine.

Consultation 3: Pre-publication in Canada Gazette, Part I

The proposed *Regulations Amending the Patented Medicines Regulations* were pre-published in the Canada Gazette, Part I, on December 2, 2017. The proposed Regulations were open for comment for 75 days, ending on February 14, 2018. To support stakeholders in the development of feedback, Health Canada hosted three engagement sessions, and a separate discussion on the cost-benefit analysis with representatives from public and private insurers, patient organizations, the medicine industry and their associations, and the general public. These stakeholder sessions provided further detail and discussion on the regulatory proposal and gave stakeholders an opportunity to explore issues of concern or that required clarification.

The focus of the Canada Gazette, Part I, consultation was the proposed regulatory amendments. However, at the request of Health Canada, the PMPRB prepared a draft Guidelines Scoping Document to provide stakeholders with a preliminary sense of how the amended Regulations could be operationalized by the PMPRB into specific price tests. Health Canada issued this request to accommodate comments received from a number of innovative medicines industry representatives that such a document would enhance their ability to participate in the consultation. The scoping document was published on the PMPRB's website and a direct link to the document was included on the consultation page for this regulatory proposal. As noted, the scoping document is preliminary, since amendments to PMPRB's *Compendium of Policies, Guidelines and Procedures* are subject to separate consultation requirements. The PMPRB is leading the consultations on the new Guidelines.

Approximately 100 stakeholders provided input during the Canada Gazette, Part I, consultation. Input was received from representatives of provincial ministries of health, public and private health insurance providers, the innovative medicines industry, the generic medicines industry, patient organizations, health professional associations, academics and policy think-tanks. Consideration was also given to correspondence, reports and articles that were submitted or published during, or in close proximity to, the consultation period. The significant majority of feedback was from representatives of the innovative medicines industry, as the principal party that would be subject to these Amendments.

Overview of Stakeholder Feedback to Canada Gazette, Part I

Overall, provincial ministries of health, public and private health insurance providers, health professional associations and academics continued to express general support for the proposal and its features, including the three new price regulatory factors, the revised schedule of international price comparator countries and the importance of patentees reporting prices that are net of all adjustments. For the pharmacoeconomic factor, some of these stakeholders asked for the Regulations to prescribe a strict value threshold while others expressed support for greater flexibility in value determinations. These stakeholders also expressed the importance of the PMPRB's ability to protect the confidentiality of reported price information.

The innovative medicines industry and policy think-tanks were generally opposed to all features of the proposal, with particular emphasis on the proposed new price regulatory factors and the obligation to report price information net of all adjustments to third parties. Feedback from these stakeholders questioned whether the rationale for the proposal had been sufficiently demonstrated, including whether sufficient evidence had been provided to conclude that the prices of patented medicines in Canada are high by international standards. These stakeholders were opposed to the proposed new price regulatory factor of pharmacoeconomic value, noting that this was a tool for reimbursement bodies and that associated methodologies are complex and not appropriate to inform the establishment of a firm national price ceiling. These stakeholders were also concerned with the proposed patentee obligation to report price information that is net of all third party adjustments on the primary argument that such agreements occur below the PMPRB price ceiling. These stakeholders were concerned with the assumptions and findings of Health Canada's cost-benefit analysis, and provided the results of their own analysis which estimated the negative impact on industry revenues in Canada would be much closer to the upper bound of Health Canada's sensitivity analysis. Finally, these stakeholders expressed concerns that the uncertain business climate created by the Amendments would result in reduced industry

investment and employment in Canada and delay Canadians' access to new innovative medicines.

The generic medicines industry expressed support for the proposed extension of reduced reporting obligations to generic medicines approved by means of an ANDS, but re-iterated their comments to the pre-consultation that these reduced reporting obligations should be extended to all generic and biosimilar medicines, regardless of the regulatory approval process that was used to obtain market authorization.

Patient organizations generally expressed the dual concern of high prices and access to new medicines. While these stakeholders acknowledged the importance of addressing high medicine prices and the management of finite health care system resources, they were likewise concerned that lower prices could result in companies deciding to delay or refrain from introducing new medicines in Canada.

The sections that follow provide more detail on specific comments that were received from stakeholders. A number of refinements to the Amendments were made based on the stakeholder feedback. These refinements are identified in the responses to specific stakeholder feedback. A summary of refinements to the regulatory proposal is provided at the end of this section.

Comment #1: Mandate of the PMPRB

Representatives of the innovative medicines industry questioned whether the features of the proposal are consistent with the mandate and statutory authorities of the PMPRB.

Response #1: The regulatory framework of the PMPRB has not been substantively updated in decades despite significant changes in both the products that are on the market and the tools that are now available to pricing authorities. These Amendments exercise a Governor-in-Council authority to modify patentee information reporting obligations and to specify additional price regulatory factors that are to be taken into account by the PMPRB in its consideration of whether the price of a patented medicine in Canada is 'excessive'.

Comment #2: Lack of Meaningful Consultation

Representatives of the innovative medicines industry expressed concerns that Health Canada's consultation process to develop these Amendments did not include meaningful opportunities for stakeholders to provide feedback.

Response #2: There have been three phases to this consultation process over a period of nearly three years. All stakeholders were invited to participate in each stage of consultation. In addition, Health Canada provided a number of venues at each stage to ensure that stakeholders were informed of the features of the proposal and the rationale for their inclusion in order to support full stakeholder engagement and participation in consultation processes. Several modifications, as listed in the comments and responses below, have been made to the proposal based on feedback that was received from various stakeholder groups.

Comment #3: New Factors:

Provincial ministries of health, the pan-Canadian Pharmaceutical Alliance (pCPA), patient groups, professional associations, and private insurers all agreed that the current subsection 85(1) factors are necessary, but not sufficient price regulatory tools. Industry stakeholders commented that there are no medicine pricing pressures in Canada and that new price regulatory factors are not warranted. They also argued that introducing new factors leads to considerable price predictability concerns that could impact medicines currently on the market.

Response #3: Canada's patented medicine price levels relative to international peers demonstrate that the current system is not sufficient in protecting Canadians from excessive prices. However, to provide greater regulatory certainty for existing medicines, Health Canada amended the proposed Regulations so that the new price regulatory factors, and reporting of information related to those factors do not apply to any medicine that obtained a DIN in Canada prior to the publication of the Amendments in the Canada Gazette Part II. This change aligns with the policy intent of the proposal and codifies the assumptions found in the cost-benefit analysis.

Comment #4: Pharmacoeconomic Value

Provincial ministries of health, the pCPA, and private insurers all agreed that pharmacoeconomic value was important in regulating medicine prices in Canada, so long as the obligation to report cost-utility analyses does not delay or negatively impact access to new medicines. Industry stakeholders questioned the use of the pharmacoeconomic value factor and indicated that it is not an appropriate instrument in a price regulatory context.

Response #4: Pharmacoeconomic value assessment is an increasingly important tool to support informed health care decisions. It does so by evaluating whether the price of a medicine is commensurate to the value is produces. This type of assessment is

particularly important for high-cost medicines, to ensure that there is a rational basis for the price. For high cost-medicines, pharmacoeconomic value is a necessary consideration for PMPRB, since these medicines typically treat vulnerable patient populations, and the market power of the patentee in those circumstances may preclude a negotiated outcome, even at prices that exceed any proximity to the recommendations of CADTH and INESSS. In these instances, regulatory levers are warranted to ensure consumer protection.

Comment #5: Strict cost/QALY thresholds prescribed in the Regulations

Stakeholder feedback from the industry, patient organizations, academics, and provincial ministries of health suggested predictability could be improved by setting thresholds in the regulations that would constrain the circumstances that the pharmacoeconomic value factor is to be used.

Response #5: The particular importance of the pharmacoeconomic value factor is for high-cost medicines, since these are typically for vulnerable patient populations and patentee market power to dictate high prices has been repeatedly demonstrated. To align the use of this new factor with those circumstances, Health Canada has amended the proposed Regulations so that patentees only report information related to the pharmacoeconomic value factor for high-cost medicines – namely, those medicines with costs that represent a significant share of the annual income of a typical Canadian. This constraint on information reporting is intended to provide patentees with improved certainty regarding the medicines that could reasonably be subject to the pharmacoeconomic value factor. The pharmacoeconomic value factor and information reporting requirements associated with that factor do not apply to medicines that obtained a DIN in Canada prior to the publication of the Amendments in the Canada Gazette, Part II.

Comment #6: Market Size

Industry stakeholders expressed concerns over using market size as a regulatory factor, arguing that using projections of expected units sold to regulate actual prices is highly problematic. Due to the complex nature and unpredictability of market projections, it was recommended that market size should not be used as a price regulatory factor, or if it must be used, that it should be confined to a secondary factor.

Response #6: Market size provides the PMPRB with a relevant consideration both when a medicine is introduced in Canada, and as a means to revisit introductory prices based on changes to the market for the medicine. Prices of medicines should reflect the

demand for that medicine, and any considerable change in demand should likewise affect its assessment of price excessiveness. The market size factor and information reporting requirements associated with that factor do not apply to medicines that obtained a DIN in Canada prior to the publication of the Amendments in the Canada Gazette, Part II.

Comment #7: GDP and GDP per capita

Stakeholders noted that the proposed Regulations do not fully explain how GDP and GDP per capita were going to be used to regulate medicine prices in Canada. Industry stakeholders suggested that GDP per capita as a factor is too volatile and that GDP does not have a place in a price regulation framework.

Response #7: GDP and GDP per capita are relevant considerations of what is affordable by the Canadian health system. Medicines with prices that would impose financial hardship on a typical Canadian, or total costs that would represent financial burden on Canada's health care system require enhanced scrutiny. The GDP and GDP per capita factor will not apply to medicines that obtained a DIN in Canada prior to the publication of the Amendments in the Canada Gazette, Part II.

Comment #8: Schedule of Countries

Provincial ministries of health, the pCPA, private insurers, health experts and patient groups were all supportive of the new schedule of comparator countries, so long as the new schedule does not impact access to new medicines. Concern was raised about the exclusion of the United States (US) - as some medicines are only sold there and in Canada, they would no longer have an international comparator. Although insurers supported the revised schedule of comparator countries, they suggested consideration should be given to medicines that are sold in the US. Industry stakeholders were clear in arguing that the new schedule should include the US and not include countries with markedly fewer new medicine launches than Canada, such as South Korea.

Response #8: The revised schedule of countries will provide the PMPRB with a more balanced perspective of prices in other countries. Selection for the new schedule was carefully done using a criteria-based approach, with the OECD as a starting point to ensure that the new schedule broadly reflects Canada's current medicine market and is comprised of countries with similar pharmaceutical pricing policies. Health Canada amended the proposed regulations to remove South Korea given concerns surrounding lower market access and outlier prices that are well below the OECD median. Similarly, the US has not been reinstated and is not considered to be a relevant price comparator

due to the absence of consumer protection policies, and list prices that are dramatically higher than those in any other country. Prices in the US are considered to be an inappropriate data point, including in scenarios where the US is the only other market for a patented medicine.

Comment #9: Price Information Net of Third Party Adjustments

Industry stakeholders expressed concerns that reporting price information net of third party adjustments would place patentees at odds with provincial statutes that protect the confidentiality of that information. There were also concerns that the disclosure of confidential rebate information to the PMPRB could inhibit public drug plans' ability to negotiate medicine prices, which could limit patient access to new medicines. This is because a potential loss of confidentiality may impact manufacturers' choice to enter the Canadian market.

Response #9: Protecting the confidentiality of patentee pricing was a central consideration in the decision to require patentees to report this information. The amended regulations require patentees to report prices net of all price adjustments, whether to third parties or not. The terms and conditions of any particular third party rebate, if any, will therefore not be apparent to the PMPRB. As they currently do, patentees will only need to report the total net revenues for the medicine, the number of units sold for the medicine, and the average transaction price for any market in Canada, without providing any information on the size or existence of third party rebates.

Comment #10: Reduced Reporting Obligations

All stakeholders were supportive of moving towards a risk-based approach, where the PMPRB would focus its resources on medicines with a greater risk of being priced excessively, and low-risk products would have their current reporting obligations reduced. Provincial ministries of health and health experts cautioned that the reporting exemption advanced in the Canada Gazette, Part I, was too broad, and included certain products that are particularly important to population health and have demonstrated a higher risk of excessive prices, with particular concerns about biologics.

Response #10: The reduced reporting obligation for veterinary and generic medicines remains unchanged from Canada Gazette, Part I. However, based on feedback received, some medicines that do not require a prescription have been returned to active reporting status. Specifically, patented medicines that appear on *Schedule D* of the *Food and Drugs Act*, such as insulins and vaccines, that do not require a prescription, will continue to actively report to the PMPRB.

Comment # 11: Added Patentee Regulatory Reporting Burden

Several representatives of the innovative medicines industry expressed concerns that the proposal would result in a significantly increased administrative reporting burden. Particular concerns related to: 1. Increasing the schedule of international price reference countries from seven to (then) twelve; 2. The obligation to provide the PMPRB with information related to the size of the market factor each time that information is 'updated' (some representatives indicated that this information is often updated quarterly or even monthly); and, 3. Ambiguity regarding the information to be reported in relation to the pharmacoeconomic value factor, as patentees may not be aware of all 'published' cost-utility analysis reports.

Response #11: For most patentees, the amended Regulations will impose only modest, incremental reporting obligations. This includes reporting public list prices from a slightly larger schedule of comparison countries, but only if the medicine is sold in those countries. The majority of the regulatory burden will be in the first reporting period after the amended regulations come-into-force as patentees adapt to the new forms and information sources. Only incremental effort will be required for each subsequent reporting period, which would continue to occur twice annually. This reporting obligation continues to be significantly less than that of most European countries, which typically require patentees to report on prices in 20 - 30 comparator countries.

For the information reporting obligations related to the market size factor, Health Canada agreed with industry feedback that the Canada Gazette, Part I, proposal would result in an unnecessary reporting burden on patentees. This reporting requirement was modified so that updated information associated with the market size factor is only required when the medicine is approved for a new or modified therapeutic use.

For information reporting obligations related to the pharmacoeconomic value factor, Health Canada agreed with industry feedback that the Canada Gazette, Part I, proposal did not provide enough specificity regarding patentee reporting obligations. This reporting requirement was modified to be clear that only those cost-utility analyses that are both published and communicated to the patentee are to be reported to the PMPRB. For example, all cost-utility analyses that are published by CADTH and INESSS would satisfy this requirement.

Comment #12: Cost-Benefit Analysis (Assumptions and Findings)

Industry stakeholders expressed concerns that the cost-benefit analysis severely underestimated the impact of the Amendments. Based on a publically available analysis published by the consultant firm PDCI Market Access, many patentees argued that the impact would be $26.1B NPV instead of the predicted $8.6B NPV.

Response #12: Health Canada commissioned an Independent Assessment of the cost-benefit analysis, which compared both Health Canada's cost-benefit analysis and the industry funded PDCI report. This assessmentwas undertaken with input and participation from both Health Canada and industry stakeholders. [3]

With respect to Health Canada's cost-benefit analysis, the Independent Assessment concluded that "[t]he impact of proposed regulatory changes has been carefully done and was done based on empirical analysis that made judicious use of recent data." The Independent Assessment did note a concern with respect to the use of a fiscal multiplier to calculate the social benefit of lower medicine prices in Canada. The multiplier has been removed, with the social benefit of the proposal being described qualitatively instead.

Also, the Independent Assessment asked for greater transparency, including elaboration of cost impact modelling assumptions and calculations. This information was provided to industry stakeholders and the authors of the Independent Assessment. The Independent Assessment strongly recommended that the new cost-benefit analysis for Canada Gazette, Part II, include all working assumptions and calculations, and make clear its precise assumptions about the PMPRB's future implementation of the new regulations. The new cost-benefit analysis has been updated to address these recommendations, and both it and the Independent Assessment are available upon request.

Comment #13: Treatment of Existing Patented Medicines

Industry stakeholders recommended the new regulations should not apply to existing medicines and additional consideration be given to transitional measures for products introduced soon after implementation. This would lower uncertainty generated by the reforms and prevent unintended delays in new product launches.

Response #13: The purpose and principal focus of these Amendments is to ensure that Canadian consumers are adequately protected from excessive prices for patented medicines, in a context where prices in Canada are currently among the highest in the

[3] David Dodge and Ake Blomqvist: independent assessment of Health Canada's cost-benefit analysis of the impact of the proposed of the proposed Amendments to the patented medicine regulations (August 23, 2018). Available upon request.

world. To respond to industry concerns and provide greater stability for existing medicines, changes have been made such that the new section 85 factors and information reporting obligations associated with those new factors do not apply to medicines that obtained a DIN in Canada prior to the publication of the Amendments in the Canada Gazette, Part II. However, all patentees will be required to report on the updated schedule of countries to ensure that, going forward, Canadian prices are not significantly higher than international norms. All patentees will also be required to report prices net of third party rebates because this information is needed to ensure that the PMPRB is informed of the actual prices for patented medicines that occur in Canada. For all medicines, patentees will also have a lenghty period of time between the publication of the Amendments in Canada Gazette, Part II, and their coming-into-force to make any necessary adjustments to their business plans in order to comply with the amended regulatory framework.

Comment #14: Access to New Medicines

Patient organizations, although against rising prices for medicines, expressed concern that there could be delayed introduction or reduced availability of new medicines due to these Amendments. Many commented that CADTH assessments were too restrictive and that it determines the value to public payers but not to patients. Industry stakeholders argued that the reforms could lead to companies ignoring the Canadian market due to pricing barriers and that companies will be reluctant to invest in Canada. Insurers argued that the high price of medicines are a principal barrier to accessing new and innovative medicines and threaten the sustainability of Canada's health care system.

Response# 14: Even with reduced prices, Canada would continue to be a significant consumer of medicines and an important market for patentees. The suggestion that these Amendments could cause patentees to delay introducing medicines in Canada is not supported by available international evidence, which shows that new medicines are introduced to important markets, such as Canada, in comparable timeframes. By comparison, list prices do not appear to be an important determinant of medicine launch sequencing.

Comment #15: Industry Investment and Employment

Industry stakeholders argued that the reforms would lower pharmaceutical investment and employment in Canada. Provincial business networks and Chambers of Commerce also expressed concerns that fewer clinical trials will occur in Canada, threatening clinical trial competitiveness, and damaging Canada's reputation as a place for research collaboration, clinical trials and investments to drive the commercialization of innovative health products.

Response #15: Historical data using a consistent metric clearly demonstrates that pharmaceutical investment in Canada has been falling since 1995, despite rising prices of patented medicines and increasing industry revenues from the Canadian market. For many years, Canada has paid among the highest prices for patented medicines on the assumption that this would incent industry to locate and invest in Canada. That assumption has not materialized, and industry employment and investment in Canada is currently among the lowest in the OECD. The link between high domestic prices and industry investment has not been demonstrated. There is no empirical data to suggest that, among highly industrialized countries, high domestic prices are necessary to attract and/or maintain a high employment rate in the manufacturing of medicines for domestic use or to export abroad. The Government has instruments in place to encourage innovation, including the Strategic Innovation Fund and the Superclusters Initiative. The Government also established the Health and Biosciences Economic Strategy Table to advise on growth opportunities for the sector. Other initiatives under the Innovation and Skills Plan such as the Global Skills Strategy can also serve to enhance Canada's attractiveness for R&D spending.

Comment #16: Consistency with Canada's Trade Obligations

Industry stakeholders expressed concerns that these Amendments might not be in compliance with international trade treaties. Specifically, arguing that the reforms would devalue patent rights, and suggesting that all patentable innovations must be given equal rights under the law such that a patent cannot be used as a tool to devalue the product of innovation. They also suggested that these Amendments undermine the objective of creating a modern Intellectual Property (IP) regime.

Response #16: While the Amendments will result in lowering the price ceiling for patented medicines sold in Canada and enable the PMPRB to consider additional factors in its price review, the changes brought to the regulations are not an unreasonable alteration of the existing legal regime.

Summary of modifications based on the Canada Gazette, Part I, consultation

Aspects of the Amendments that were modified:

Coming-into-force

1. The coming-into-force date is July 1, 2020. This postpones the coming-into-force date that was identified in pre-publication by eighteen months, so that the PMPRB

has additional time to complete its Guidelines consultation, and patentees have time to make any necessary adjustments to comply with the new regulatory regime.

Treatment of Existing Medicines

2. The new section 85 factors and information reporting obligations associated with those new factors do not apply to medicines that obtained a DIN in Canada prior to the publication of the Amendments in the Canada Gazette, Part II. This adjustment provides a degree of continuity for existing medicines. Medicines sold in Canada prior to the publication of the Amendments in the Canada Gazette, Part II that did not have a DIN, are not exempt from the new section 85 factors or their associated information reporting obligations. Also, this exemption does not extend to the other features of the Amendments – all medicines are required to report on the amended schedule of countries and to report price information net of all confidential rebates.

New Section 85 Price Regulatory Factors

3. The pharmacoeconomic value factor language was narrowed. The factor no longer refers to the pharmacoeconomic value of other medicines in the same therapeutic class. This change was made so that the PMPRB's ability to establish non-excessive prices for new medicines is not adversely impacted by existing medicines that are not subject to the pharmacoeconomic value factor.

4. The market size factor language was narrowed. The factor no longer refers to the size of the market for the medicine in other countries than Canada. This change was made because Canada's relative market size is already captured by the criteria that were used to construct the revised schedule of comparator countries.

Information Reporting Obligations Related to the New Section 85 Factors

5. Only high-cost medicines are to report information related to the new price regulatory factor of pharmacoeconomic value. A medicine is considered to be high-cost if, in any treatment scenario, the 12-month cost of treatment would exceed 50% of Canada's GDP per capita. This better aligns the reporting obligation with the medicines that are at highest risk of excessive pricing, where application of the pharmacoeconomic value factor is anticipated to be most needed.

6. Patentees are only required to report a cost-utility analysis that is both published and communicated to the patentee. Cost-utility analyses that are prepared by CADTH and INESSS will always satisfy this condition. This change therefore aligns with

those cost-utility analyses that are of highest relevance to inform the PMPRB's application of the pharmacoeconomic value factor, and clarifies that patentees are not obligated to expend efforts locating all cost-utility analyses that may have been performed.

7. Patentees are to report the un-redacted version of the cost-utility analysis. This change was made to ensure that the version of the cost-utility analysis that is provided to the PMPRB includes all economic and clinical information, assumptions and data that was used to construct the analysis. Cost-utility analysis is a methodological construct and the details of how the analysis was performed is necessary to understand how the findings were reached.

8. The market size information was narrowed to reduce administrative burden and give more clarity on the information to be provided. This included:

    - Specifying that market size refers to the total quantity of the medicine sold
    - Specifying that market size is to be calculated in such a way that it indicates the period of time that is being forecasted
    - Specifying that patentees are only required to submit a revised market size forecast when the medicine receives approval from Health Canada for a new or modified therapeutic use

Schedule of Countries

9. South Korea is not included in the revised schedule of comparator countries. The amended schedule now includes 11 comparator countries instead of 12. This adjustment responds to patentee and patient group feedback that access to new medicines in South Korea is not high enough to make it comparable to Canada.

Reduced Reporting Obligation for Low-Risk Medicines

10. The reduced reporting obligation was adjusted so that Schedule D medicines that do not require a prescription will continue to report actively to the PMPRB. Health professionals expressed that many of these medicines, such as patented insulins and vaccines, are of high importance to public health and safety, and that there have been recent examples of excessive pricing concerns.

Regulatory cooperation

The regulation of medicine prices is a common international practice, although there is significant variation in approach. These differences often arise from a need to tailor policy instruments to work within each country's unique legal and health care system.

While Canada closely monitors regulatory developments in other countries to keep abreast of international best practices, perfect alignment with any one country model is neither practical nor desirable. The regulation of ceiling prices for patented medicines is not subject to trade provisions.

Implementation, enforcement and service standards

The Regulations come-into-force on July 1, 2020. This allows patentees time to prepare for implementation of the new price regulatory factors and information reporting requirements. This date was chosen to align with the PMPRB's reporting periods of January 1 and July 1. Once the amended Regulations are published in the Canada Gazette, Part II, responsibility for implementation, enforcement and service standards are passed to the PMPRB. This is anticipated to include the finalization of a PMPRB-led stakeholder consultation on a revised *Compendium of Policies, Guidelines and Procedures* that will be used to reach an understanding of how the amended framework would be embodied in the form of specific price tests and qualifying information to be reported by patentees.

The new section 85 factors and information reporting obligations associated with those new factors do not apply to medicines that obtained a DIN in Canada prior to the publication of the Amendments in the Canada Gazette, Part II. This exemption does not extend to the other features of the Amendments – all medicines are required to report on the amended schedule of countries and to report price information net of all confidential rebates.

Performance Measurement and Evaluation

Upon coming-into-force, the PMPRB will continue to submit an annual report to Parliament, pursuant to section 88 of the *Patent Act*. That report will include information on the status and outcome of PMPRB-led consultations and all active and recently completed compliance and enforcement activities.

Contact

Karen Reynolds
Executive Director
Office of Pharmaceuticals Management Strategies
Strategic Policy Branch
Health Canada
Brooke Claxton Building, 10th Floor
70 Colombine Driveway, Tunney's Pasture
Ottawa, Ontario

K1A 0K9
Telephone: 613-957-1692
Email: PMR-Consultations-RMB@hc-sc.gc.ca