

Implications of the Proposed Changes to Canada's Pharmaceutical Pricing Regulations

Pre-release Chapter

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Executive summary

This essay provides an overview of the main elements of the Canadian regulatory process for biopharmaceuticals, including recent changes. It describes the role of the Patented Medicine Prices Review Board (PMPRB), the Board's Regulatory Process—including the Scientific Review Process and the Price Review Process—the proposed Amendments to the Regulations, and their potential consequences.

At the federal level, Canada regulates the prices of *all* patented medicines to ensure that the prices of patented drugs are not “excessive.” This extends to every patented drug, whether covered on an insurer's formulary or not. It is important to recognize the scope of this regulation: the prices of off-patent drugs are not regulated, and the regulations do not grant jurisdiction to regulate the prices of patented medicines throughout the distribution chain (from wholesaler to pharmacy to patient).

In May of 2017, Health Canada proposed an update to several aspects of the PMPRB regulations governing patented medicines. The proposed amendments included five important changes to the regulations: economics-based price regulation factors, an update of the reference country basket set used for international price comparisons, establishment of a complaints-based system of oversight for patented generic products, the pricing information required of patentees, and requirements for the provision of rebate and discount information on domestic prices.

The proposed changes raise some concerns. Specifically, PMPRB currently compares Canada's patented drug prices with those found in seven other countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States. Under the proposed changes, the reference countries would no longer include the United States or Switzerland, and would instead add seven other countries: Australia, Belgium, Japan, Netherlands, Norway, South Korea and Spain. The new reference country basket will significantly impact both the highest international price and the median international price comparison metrics. Fundamentally, the change will lower the maximum allowable price, requiring pharmaceutical innovators to lower their prices in Canada in order to be in compliance.

In addition, the proposed changes would incorporate new factors in the determination of whether a medicine is being or has been sold at an “excessive” price. With this change, the PMPRB will assess the “value” of new drugs by reviewing cost-effectiveness analyses submitted to the Canadian Agency for Drugs and Technologies in Health (CADTH). Drugs above the threshold risk not being insured. Crucially, PMPRB’s threshold is not specified in the proposed regulation amendments.

The Regulations would also be amended to require patentees to report to the PMPRB all indirect price reductions, promotions, rebates, discounts, refunds, free goods, free services, gifts, or any other benefit in Canada. This change runs the risk of increasing costs to public drug plans rather than reducing them. The proposed amendment would require biopharmaceutical manufacturers to report all confidential rebates and discounts provided to governments under their listing agreements. The PMPRB would then use this information to calculate “actual prices” in order to set a lower maximum price for new drugs. Notably, that new lower price will apply to all markets, essentially eliminating all incentives for manufacturers to offer such rebates.

Fundamentally, the proposed changes alter the role and responsibilities of the PMPRB, transforming how it operates as a national price control regulator for patented medicines. The outcome is likely a significant change in how the PMPRB carries out its dual mandate to safeguard against the potential for excessive pricing and report on pharmaceutical trends and R&D spending. Importantly, the new and expanded role of the PMPRB will negatively impact patients’ access to medicines as well as the viability of the Canadian life sciences sector.

Health Canada estimates that these changes will generate savings of CA\$12.6 billion over the next ten years through reduced prices for patented medicines. While the new regulations may ensure Canada doesn’t pay “excessive prices,” there is reason to worry that they may also reduce the availability of new therapies for Canadian patients. If biopharmaceutical innovators believe that the new regulatory framework prevents them from profitably marketing their drugs in Canada, they may elect not to launch new products in Canada. Instead of improving access, the new regulations may essentially become a further barrier to access to new medicines.

Profit both incentivizes innovation and helps fund research and development. Higher prices induce greater profit which allows for more investment, increased research and development, and more innovation and drug discoveries. Health Canada estimates that the innovative biopharmaceutical sector will lose CA\$8.6 billion in revenues over the next ten years. The proposed changes will reduce the financial capacity of patentees to invest in the Canadian life sciences sector.

In sum, while the 1987 amendments that created the PMPRB reflected a thoughtful balance across several policy objectives, protecting consumers from excessive patented medicines prices, while ensuring sufficient incentives

for patentees to introduce new medicines to Canada, the proposed changes are limited to solely lowering patented drug prices. As a result, the aforementioned policy balance is put at risk. The proposed changes clearly disincentivize innovative drug launches in Canada, potentially de-prioritizing Canada in the global launch sequences for new drugs. Moreover, the increasing reporting requirements represent an unnecessary regulatory burden and would increase the time to achieve public reimbursement. Such significant changes should not go without thoughtful examination, though in this case that appears lacking. Quite simply, rather than bolstering the Canadian healthcare system, the proposed changes only serve to undermine it.

Introduction

This essay provides an overview of the main elements of the Canadian regulatory process for biopharmaceuticals, including recent changes. It describes the role of the Patented Medicine Prices Review Board (PMPRB), the Board's Regulatory Process—including the Scientific Review Process and the Price Review Process—as well as proposed amendments to the regulations and their potential consequences.

At the federal level, Canada regulates the prices of *all* patented medicines to ensure that the prices of patented drugs are not “excessive.” This extends to every patented drug, whether covered on an insurer's formulary or not. “A maximum ex-factory price is determined at the federal level by reference to prices in other countries for the most innovative products, and by reference to prices of existing drugs in Canada for the less innovative ones” (Paris and Belloni, 2014).¹ It is important to recognize the scope of this regulation: the prices of off-patent drugs are not regulated, and the regulations do not grant jurisdiction to regulate the prices of patented medicines throughout the distribution chain (from wholesaler to pharmacy to patient).

The PMPRB was established in 1987 through amendments to the Patent Act. According to the Patent Act, the PMPRB has a dual mandate:

- ◆ Regulatory: To ensure that the prices charged by patentees for patented medicines sold in Canada are not excessive.
- ◆ Reporting: To report on pharmaceutical trends and on the research and development (R&D) spending by patentees.

1. An innovative drug is defined by Health Canada as “a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph” (Food and Drug Regulations, C.R.C., c. 870, at C.08.004.1(1)).

In May of 2017, Health Canada proposed an update to several aspects of the PMPRB regulations governing patented medicines.² These proposed amendments included five important changes to the regulations: economics-based price regulation factors, an update of the reference country basket used for international price comparisons, the establishment of a complaints-based system of oversight for patented generic products, the pricing information required of patentees, and requirements for the provision of rebate and discount information on domestic prices. Despite significant changes in the biopharmaceutical market, the regulations have not changed in more than 20 years (Canada, 2017b). This is the first time that the Canadian government has moved to amend the drug pricing regulations, and is intended to reverse the trend of recent increases in drug spending—from less than 10 percent of total health expenditures in 1998 to approximately 16 percent in 2017 (Brennan, 2017).³

2. A description of the proposed amendments to the Patented Medicines Regulations is provided by Health Canada: <<https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-regulations-patented-medicine-document/con1-eng.pdf>>

3. According to Health Canada, “[d]rugs include both prescription and nonprescription pharmaceuticals; biologically-derived products such as vaccines, blood derived products, and products produced through biotechnology; tissues and organs; disinfectants; and radiopharmaceuticals. According to the Food and Drugs Act, ‘a drug includes any substance or mixture of substances manufactured, sold or represented for use in: a. the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals; b. restoring, correcting or modifying organic functions in human beings or animals; or c. disinfection in premises in which food is manufactured, prepared or kept.’ Natural health products, such as vitamin and mineral supplements and herbal products for which therapeutic claims are made are also considered drugs at the level of the Food and Drugs Act; however, these products are regulated as natural health products under the Natural Health Products Regulations and not as drugs under the Food and Drug Regulations” (Canada, 2015).

The Patented Medicine Prices Review Board's regulatory process

It is the charge of the PMPRB to monitor prices charged by patent holders for patented drugs.⁴ Under the Patent Act, for each strength of each dosage form or each patented medicine sold in Canada, patent holders are required to file price and sales information about their patented drug products at introduction (first sale of the patented medicine) and twice a year thereafter.⁵ The PMPRB reviews the prices charged to wholesalers, hospitals, and pharmacies to ensure they are not excessive, but they do not regulate the prices of patented medicines throughout the distribution chain (from wholesaler to pharmacy to patient). Notably, patent holders are not required to obtain approval of the price before a drug is sold. The Appendix contains an overview of the pharmaceutical pricing and reimbursement policies of Canada, including descriptions of the in-patient and out-patient sectors (PMPRB, 2016).

4. While the PMPRB is responsible for overseeing the prices of patented medicines, Health Canada is the entity that oversees the regulatory process that brings therapeutic products from laboratory to market. Through two of its branches, Health Canada is responsible for approving new drugs for marketing. “The Therapeutic Productive Directorate approves and monitors prescription and non-prescription drugs derived from chemical manufacturing whereas the Biologics and Genetic Therapies Directorate is responsible for biological and radiopharmaceutical drugs including blood and blood products, viral and bacterial vaccines, genetic therapeutic products, tissues, organs and xenografts” (Lexchin, 2015). Lexchin (2015) provides a solid discussion of drug pricing in Canada. Canada (2006) provides an excellent overview of the regulatory process in Canada.

5. It is critical to recognize the distinction between filing pricing information and approving pharmaceutical prices. Currently, the PMPRB requires that firms file pricing information, but these prices are not approved before a drug is sold. The proposed changes include additional price review factors to determine whether the price of a patented medicine is excessive, though the specific manner in which this will be done remains to be determined.

The proposal to amend drug pricing regulations states:

When the Regulations were first conceived 30 years ago, policy makers believed that patent protection and price were key drivers of pharmaceutical R&D investment. The choice was thus made to offer a comparable level of patent protection and pricing for drugs as exists in countries with strong pharmaceutical industry presence, on the assumption that Canada would come to enjoy comparable levels of R&D. However, the percentage of R&D-to-sales by pharmaceutical patentees in Canada has been falling since the late 1990s and is at a historic low. By comparison, and despite Canada having among the highest patented drug prices, industry R&D investment relative to sales in the PMPRB7 countries is on average 22.8% versus 4.4% in Canada. (Brennan, 2017)

Scientific review

The scientific review is the first step in the PMPRB's regulatory process. This review assesses the level of therapeutic improvement of a new patented drug product which is used to determine a ceiling price, known as the Maximum Average Potential Price, at introduction. A committee of experts, the Human Drug Advisory Panel (HDAP), meeting four times a year, additionally recommends appropriate drug products to be used for comparison. As described by the PMPRB website (< <http://www.pmprb-cepmb.gc.ca/en/regulating-prices/scientific-review>>), the Scientific Review is conducted as follows:⁶

The PMPRB's scientific review provides recommendations on the level of therapeutic improvement of a patented drug product, which is used in the price review process.

The PMPRB created the Human Drug Advisory Panel to provide credible, independent, and expert scientific advice. The approach is evidence-based and the recommendations reflect medical and scientific knowledge and current clinical practice.

The HDAP reviews and evaluates scientific information available to the PMPRB including submissions by patentees, research prepared by a Drug Information Centre, and information obtained by Board

6. The PMPRB's Guidelines, the *Compendium of Policies, Guidelines and Procedures*, may be found at <http://www.pmprb-cepmb.gc.ca/CMFiles/Compendium_Feb_2017_EN.pdf>.

Staff. Members of the HDAP may also conduct their own research. The recommendations of the HDAP are based on the majority vote.

Price review

On an ongoing basis, the PMPRB staff review pricing information for all patented drug products sold in Canada in order to ensure that the prices charged by patent holders comply with the established Guidelines. The Guidelines, based on the price determination factors in Section 85 of the Act, were developed by the PMPRB in consultation with stakeholders, including the provincial and territorial Ministers of Health, consumer groups, and the pharmaceutical industry. As described by the PMPRB website (< <http://www.pmprb-cepmb.gc.ca/en/regulating-prices/price-review>>), the Price Review is conducted as follows:

Patentees are required by law to file information about the prices and sales of their patented drug products in Canada at introduction and then twice a year until the patent expires. The Patent Act along with the Patented Medicines Regulations set out the filing requirements.

The PMPRB reviews the average price of each strength of an individual dosage form of each patented medicine. In most cases, this unit is consistent with the Drug Identification Number (DIN) assigned by Health Canada at the time the drug is approved for sale in Canada.

There are five factors used for determining whether a drug product is excessively priced, as outlined in section 85 of the Act:

- the prices at which the 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;
- changes in the Consumer Price Index;
- any other factors that may be set out in regulations.

The Compendium of Policies, Guidelines and Procedures details the various price tests used to determine whether a price falls within the maximum allowable price.

Proposed changes to the regulatory process

In the spring of 2017, Health Canada proposed an update to several aspects of the PMPRB regulations governing patented medicines. The description of the proposed amendments notes that in the past twenty years, the global market for biopharmaceuticals has changed significantly. Of particular relevance are (1) the emergence of higher cost drugs such as biologics and genomics, and (2) a growing discrepancy between public list prices and lower actual market prices due to the increased utilization of confidential discounts, rebates, and other reimbursements (Canada, 2017c). The proposed amendments include five changes to the regulations to provide the PMPRB with new regulatory tools and information. **Table 1** describes the essence of each of the five proposed changes.

Table 1: Proposed changes to the patented medicines regulations

<p>Changes to reference countries</p>	<ul style="list-style-type: none"> • Addition of Australia, Belgium, Japan, Netherlands, Norway, South Korea, Spain. • Removal of United States, Switzerland. • Summary of proposed comparator countries: Australia, Belgium, France, Germany, Italy, Japan, Netherlands, Norway, South Korea, Spain, Sweden, United Kingdom.
<p>Additional economics-based price review factors Additional price review factors to take into account in determining whether the price of a patented medicine is excessive</p>	<ul style="list-style-type: none"> • Pharmacoeconomic value of the medicine in Canada. • Size of the market for sale of medicine in Canada and other countries. • GDP & GDP per capita in Canada.
<p>Reporting requirements Related to additional economics-based price review factors</p>	<ul style="list-style-type: none"> • Information regarding pharmacoeconomic value. • Information respecting market size.
<p>Reduced reporting requirements For patented generic, veterinary, and over-the-counter drugs</p>	<ul style="list-style-type: none"> • Absent a specific PMPRB request, the reporting requirements would not apply to such products.
<p>Reporting of third-party price rebates</p>	<ul style="list-style-type: none"> • Prices and revenue information reported by patentees must net all price or other adjustments including discounts, rebates, and free goods and services made by the patentee or “any party that directly or indirectly purchases or reimburses for the purchase of the medicines.” • Includes confidential pricing agreements with provinces, etc. (that is, any third-party payer.)

Beyond the five regulatory changes identified in table 1, the Patented Medicine Prices Review Board also released a Guidelines Scoping Paper. The purpose of the Guidelines Scoping Paper is “to provide stakeholders and interested members of the public with an outline of the PMPRB’s preliminary thoughts on how best to operationalize the proposed changes to the Regulations, through non-binding Guidelines as contemplated by s.96 of the Patent Act, within the context of the existing and proposed legislation and the PMPRB’s ongoing efforts at reform” (Canada, 2017e). The document outlines a potential framework for determining non-excessive prices based on the proposed regulatory changes. As described by Glennie (2018), these are presented in [table 2](#).⁷

Table 2: Components of the draft PMPRB Guidelines Framework

<p>1. Interim International Price Reference Test Introductory price test based on new PMPRB12 basket of reference countries; products with Canadian prices exceeding the median would be considered potentially excessive.</p> <p>2. Screening Classification of drugs as either high or [medium and] low priority based on their anticipated impact on Canadian consumers.</p> <p>3. High Priority Drugs Assess the cost per quality-adjusted life-year (QALY) against explicit threshold and expected impact on payers within first three to five years.*</p> <p>4. Medium and Low Priority Drugs PMPRB could employ revised Therapeutic Class Comparison requiring each successive entrant to reduce price from preceding entrant.</p> <p>5. Re-benching Periodic re-benching to ensure previous price ceilings or determinations of excessive pricing.</p>

Source: Glennie, 2018.

*“With the addition of a pharmacoeconomic evaluation factor to the Regulations, the PMPRB could introduce, in Guidelines, the concept of a fixed cost per QALY threshold in Canada. In order to minimize regulatory burden on patentees and uphold a common standard of evidence, the definition of a cost per QALY would be consistent with the economic guidance provided by the Canadian Agency for Drugs and Technology in Health’s (CADTH)” (Canada, 2017c).

7. As noted by Glennie (2018), “[s]pecifics for each component are very vague at this point, and the PMPRB intends to work out the details for the new framework via consultations.”

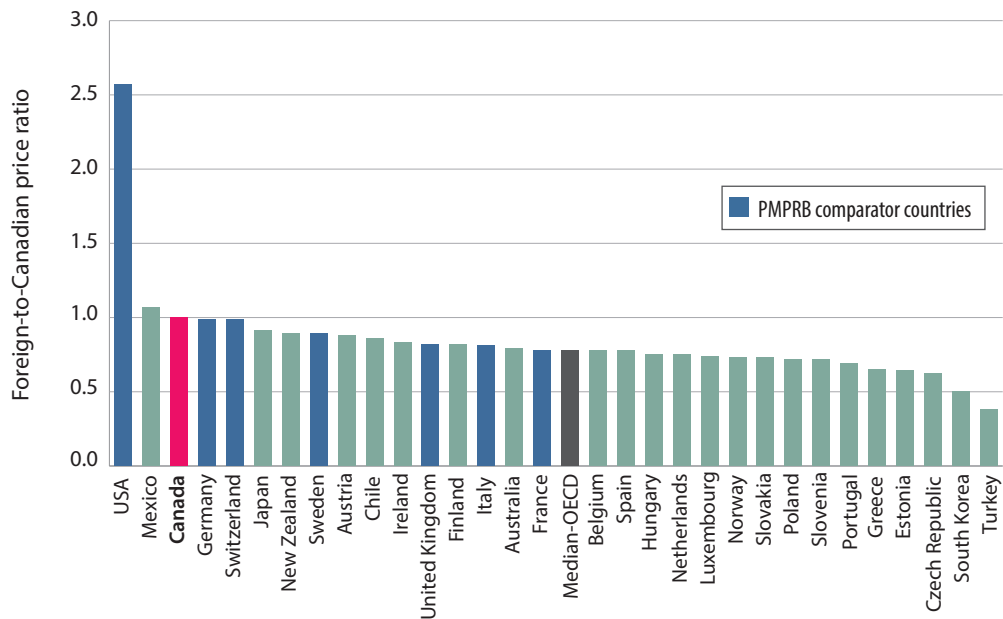
Consequences and concerns

Changes to reference countries

Canadian drug prices are among the highest in the world. According to a comparison across all 35 OECD member countries, only the United States and Mexico have higher prices for patented drugs (**figure 1**). In 2015, the median prices for patented drugs in OECD member countries were 22 percent below those in Canada (Canada, 2017c).

Figure 1

Average foreign-to-Canadian price ratios, patented drugs, OECD, 2015



Source: Canada, 2017c.

PMPRB currently compares Canada's patented drug prices with those found in seven other countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States.⁸ Under the proposed changes, the reference countries would no longer include the United States or Switzerland, and would instead add seven other countries: Australia, Belgium, Japan, Netherlands, Norway, South Korea, and Spain (Brennan, 2017).

The change to the list of countries which the PMPRB uses for international price comparisons amounts to a change to the reference nations ultimately utilized to determine a fair market price for patented medicines. While the change expands the list of comparison countries from seven to twelve, it is important to recognize that the United States and Switzerland—nations that typically have higher prices than Canada—are no longer included.⁹ The new reference country basket will significantly impact both the highest international price and the median international price comparison metrics. Fundamentally, the change will lower the maximum allowable price, requiring pharmaceutical innovators to lower their prices in Canada in order to be in compliance.

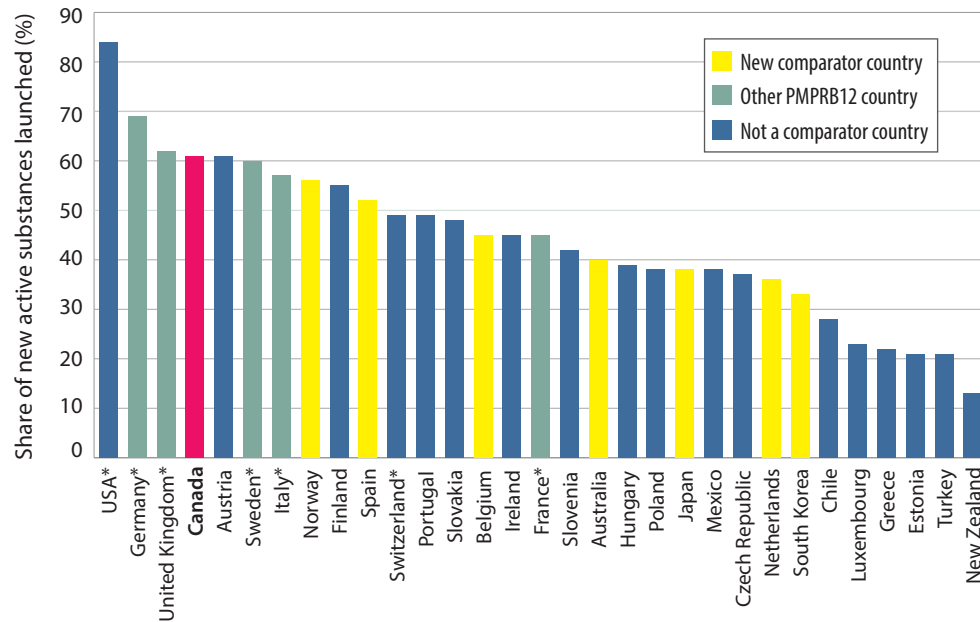
Given that Canada is a frequent reference country for other nations who utilize international price comparisons, this change has the potential to impact pricing in other jurisdictions. If the proposed changes have the anticipated effect of lowering the maximum allowable price in Canada, it can be expected that the impact will ripple across other reference-price based regimes, potentially lowering drug prices across numerous markets. In addition, given that Canada is an important reference country in other nations' reference pricing formulas, a lower drug price in Canada may encourage innovative pharmaceutical companies to forego sales in Canada.

Finally, it is worth noting that the new collection of countries is unreflective of Canada's economic position. The proposed Schedule is comprised of nations that have fewer new product launches (poorer access) and significant launch delays, relative to Canada. "Based on PMPRB's own analysis ... all of the new proposed comparator countries have worse access than Canada to new drugs as measured by products launched" (Innovative Medicines Canada, 2017). This is clearly shown in [figure 2](#). For example, less than 40 percent of new active substances have been launched in Japan, the Netherlands, and South Korea between 2009 and 2014, compared with 61 percent in Canada.

8. In 1987 these nations were selected because they were countries that had or aspired to have a strong national presence of the pharmaceutical industry (Paris and Belloni, 2014).

9. While Switzerland's price ratio is lower in 2015, as shown in [figure 1](#), historically it has been higher.

Figure 2
New drugs launched: Share of new active substances launched by OECD country, 2009–14 (as of fourth quarter 2015)



* indicates current PMPRB7 countries

Source: Innovative Medicines Canada, 2017; adapted from PMPRB Meds Entry Watch 2015, Appendix 1, Figure 1.1.

Economics-based price regulation factors

In addition, the proposed changes would also incorporate three new factors in the determination of whether a medicine is being or has been sold “at an excessive price: a pharmacoeconomic evaluation for a medicine with a fixed cost per quality-adjusted life year (QALY) threshold in Canada, the size of the market for the drug in Canada and in other markets, and the gross domestic product of Canada” (Brennan, 2017).¹⁰

With this change, the PMPRB will assess the “value” of new drugs by reviewing cost-effectiveness analyses submitted to the Canadian Agency for

¹⁰. While the PMPRB intends to work out the details for the new framework via consultations and the specifics are currently very vague, Health Canada reports that “[w]ith the addition of a pharmacoeconomic evaluation factor to the Regulations, the PMPRB could introduce, in Guidelines, the concept of a fixed cost per QALY threshold in Canada. In order to minimize regulatory burden on patentees and uphold a common standard of evidence, the definition of a cost per QALY would be consistent with the economic guidance provided by the Canadian Agency for Drugs and Technology in Health’s (CADTH)” (Canada, 2017c).

Drugs and Technologies in Health (CADTH). Except for Quebec, CADTH makes recommendations to all public drug insurance plans about reimbursement. While it is the drug manufacturers, not CADTH, that sets drug prices, CADTH frequently recommends substantial price reductions. In the PMPRB's assessment of a new drug's value, it will apply a dollar threshold to CADTH's cost-effectiveness assessment. Drugs above the threshold risk not being insured. Crucially, PMPRB's threshold is not specified in the proposed regulation amendments.

According to Rawson (2018b), “[t]hresholds of this type have been abandoned by every developed country that has adopted or considered them because they fail to reflect considerations, such as patient and insurer willingness to pay and health trade-offs, that should guide insurance coverage decisions.” Moreover, given that the PMPRB is not a payer, it is difficult to justify this as the right point in the drug review process for incorporating the proposed pharmacoeconomic factors. It is the public drug plans and private insurers that already fill this role.

Given that a particular new drug satisfies the cost-effectiveness assessment, an additional evaluation gauges the anticipated size of the market for the first three to five years of use against Canada's per-capita gross domestic product. This calculation serves as a “proxy for buying power at the level of the individual” (Canada, 2017c), allowing for an evaluation of the impact of the drug's proposed price on patient and insurer costs.¹¹ As in the case of the cost-effectiveness assessment, if the potential impact is judged to be too high, the drug's price may be further adjusted. Again, how that process will be applied is not specified. These new evaluations fail to adequately account for the fact that the number of potential patients in Canada is frequently small and, consequently, prices in Canada may justifiably be higher than the prices found in larger markets such as the United States or the European Union.

Modernizing reporting requirements

The Regulations would be amended to require patentees to provide the information necessary for PMPRB to operationalize the new factors as proposed. As described by the Government of Canada (2017c), in the context of “the pharmacoeconomic evaluation for the medicine and other medicines in the same therapeutic class in Canada and in countries other than Canada, the

11. According to Health Canada, “[i]n this context, growth in Canadian GDP can be taken as indicator of the country's ability to pay year-over-year, whereas per capita GDP is a proxy for buying power at the level of the individual. Both can serve as analytically sound ways to assess a drug's affordability, as a marker for potentially excessive prices” (Canada, 2017c). Again, the specifics of how this assessment will be done remain vague.

Regulations would be amended to require patentees to submit: the cost utility analysis by approved indication of the medicine, where that information is available to the patentee (and) ... the estimated uptake of the medicine, by approved indication, in Canada without restraint on utilization (e.g. market/budget impact analysis in any relevant market), where that information is available to the patentee.”

Complaints-based system of oversight

Another proposed amendment would reduce generic drug manufacturers’ regulatory burden, “only requiring the identity and price information of these drugs in the event of a pricing complaint or at the request of the PMPRB” (Brennan, 2017). For patented generic drugs, which receive market authorization from Health Canada through an Abbreviated New Drug Submission, this would “remove the requirement for generic drug manufacturers to systematically report information pertaining to the identity and price of these drugs to the PMPRB” (Canada, 2017c).

Rebates and discounts reporting requirements

The Regulations would also be amended to require patentees to report to the PMPRB all indirect price reductions, promotions, rebates, discounts, refunds, free goods, free services, gifts, or any other benefit in Canada. Currently, the Regulations only require patentees to provide the PMPRB with information on reductions in prices at the first point of sale. That is, patentees are not required to report the rebates and discounts that are provided to third party payers such as provincial drug plans which are their largest buyers. Absent this information, the PMPRB essentially sets price ceilings based on list prices rather than actual prices paid in the market.

This change runs the risk of increasing costs to public drug plans rather than reducing them. The proposed amendment would require biopharmaceutical manufacturers to report all confidential rebates and discounts provided to governments under their listing agreements. The PMPRB would then use this information to calculate “actual prices” in order to set a lower maximum price for new drugs. Notably, that new lower price will apply to all markets, essentially eliminating all incentives for manufacturers to offer such rebates (Critchley and Owens, 2018).

Summary

Fundamentally, the proposed changes alter the role and responsibilities of the PMPRB, transforming how it operates as a national price control regulator for patented medicines. The outcome is likely a significant change in how the PMPRB carries out its dual mandate to safeguard against the potential for excessive pricing and report on pharmaceutical trends and R&D spending. Importantly, the new and expanded role of the PMPRB will negatively impact patients' access to medicines as well as the viability of the Canadian life sciences sector. According to the evaluation presented in an industry study, “[b]ased on launch and reimbursement data from other countries, the changes would restrict access to new innovative medicines for Canadian patients. The proposed changes would greatly reduce patentee financial capacity to invest in Canada. They are also unnecessarily complex and would obstruct the effective functioning of mechanisms that Canadian payers already use to negotiate drug savings” (Innovative Medicines Canada, 2018). The negative impact will be felt by both patients and the innovative pharmaceutical industry. For patients, new product launches would likely be delayed even further than they already are.¹² For the industry, the financial capacity to invest in Canada would be reduced while unnecessarily increasing the complexity of the regulatory mechanisms. Globally, the new reference country basket will significantly impact both the highest international price and the median international price comparison metrics. The change will lower the maximum allowable price, requiring pharmaceutical innovators to lower their prices in Canada in order to be in compliance, a factor that may be a further impetus for manufacturers to delay launches in Canada or decide not to launch.

12. Since 2005, Health Canada's approval times have been relatively similar to those of the European Medicines Agency and the US Food and Drug Administration. However, 80 percent of the drugs approved between 2002 and 2016 by all three agencies were submitted to Health Canada later than to the other two agencies, resulting in a median delay of a year between the agency first giving approval and Health Canada's approval (Rawson, 2018a).

Social and economic implications

Restricted access to innovative medicines

An extensive body of empirical work establishes that there is a negative relationship between price controls and investment, innovation, launch times, employment, and patient well-being (Kyle, 2003; Vernon, 2004, 2005; Abbot and Vernon, 2007; Kutyavina, 2010; Cressanthis, 2016; Kessler, n.d.). According to a report by Innovative Medicines Canada (2018), the proposed changes will restrict access to new innovative medicines for Canadian patients. The report notes that “the pharmacoeconomic value factor alone will prevent many new products from being launched in Canada.” This is further supported by research conducted by Ernst & Young (2018) which indicates that the potential price reduction on a per-product basis would likely range from 15 percent to 90 percent in order to meet the proposed cost-effectiveness thresholds. These constraints on profitability will reduce the attractiveness of the Canadian market. Reduced prices combined with the uncertainty associated with the proposed amendments will certainly discourage the introduction of new medicines in Canada.

Currently, the “pricing and reimbursement of innovative pharmaceuticals in Canada is controlled at three levels: by the federal PMPRB, by the 17 federal, provincial and territorial public drug plans and by the Common Drug Review.¹³ This system means that an innovative manufacturer must obtain the

13. According to the CADTH (2018), “[o]nce Health Canada has approved a drug for use in Canada, the country’s public drug plans must decide if the drug will be eligible for public reimbursement. The CADTH Common Drug Review (CDR) plays an important role in their decision-making processes. Through the CDR process, CADTH conducts

approval of 19 different bodies for the price of a new drug in Canada” (Bonner and Daley, 2010). This labyrinth of regulations is a significant hurdle for biopharmaceutical innovators and likely impairs Canadian patients’ access to medicines. The proposed changes will almost certainly worsen this situation.

Health Canada estimates that these changes will generate savings of CA\$12.6 billion over the next ten years through reduced prices for patented medicines (Glennie, 2018). While the new regulations may ensure Canada doesn’t pay “excessive prices,” there is reason to worry that they may also reduce the availability of new therapies for Canadian patients. If biopharmaceutical innovators believe that the new regulatory framework prevents them from profitably marketing their drugs in Canada, they may elect not to launch new products in Canada. Instead of improving access, the new regulations may essentially become a further barrier to access for new medicines. Ironically, Health Canada describes one objective of the proposed changes as follows: “We will support more timely access to the latest medicines, while continuing to ensure their safety, quality and efficacy.” (Canada, 2017a)

Reduced innovation

Profit both incentivizes innovation and helps fund research and development. At a fundamental level, higher prices induce greater profit which allows for more investment, increased research and development, and more innovation and drug discoveries. The grant of temporary monopoly power for the innovators of new prescription medicines enables innovator companies to raise prices above the level of production costs and realize economic profits to compensate for the investment in pharmaceutical R&D, including R&D in failed drug development programs. Reducing these prices translates into reduced revenues and reduced innovation. As described by Frank and Ginsburg (2017), “[t]here has been a variety of evidence assembled regarding the relationship between profitability and innovation in the pharmaceutical industry. One major strand of evidence involves natural experiments

thorough and objective evaluations of the clinical, economic, and patient evidence on drugs, and uses this evaluation to provide reimbursement recommendations and advice to Canada’s federal, provincial, and territorial public drug plans, with the exception of Quebec. Reviews are undertaken for new drugs, as well as existing drugs approved for new indications. To shorten the time between Health Canada regulatory approval and a CADTH reimbursement recommendation, a CDR application may be made while a drug is still being reviewed by Health Canada; however, the CADTH drug reimbursement recommendation is not issued until Health Canada approves the drug for use in Canada.” Notably, the CDR only makes recommendations regarding price reductions. The pan-Canadian Pharmaceutical Alliance (pCPA), established in 2010, is the price negotiation organization for all 13 provinces and territories and, since January 2016, the federal government.

regarding industry responses to growth in the size of markets. The logic behind this quasi-experimental approach is simple: larger markets generate greater revenues that in turn create expectations of more profits to manufacturers, which expand investment in new drugs to pursue those profits.” Health Canada estimates that the innovative biopharmaceutical sector will lose CA\$8.6 billion in revenues over the next ten years (Glennie, 2018). The proposed changes will reduce the financial capacity of patentees to invest in the Canadian life sciences sector (Innovative Medicines Canada, 2018). Ultimately the proposed regulatory changes will result in reduced innovation and fewer drugs in development.

Conclusion

Critics of Canada’s approach to drug coverage note the high degree of administrative duplication, the patchwork approach to public and private outpatient drug coverage, disparities across public plans, and the unequal access to marketed medicines for patients across the country (Bonner and Daley, 2010). Given changes in the linkages between patent protection, price, and pharmaceutical research and development in Canada since the creation of the PMPRB and in the global pharmaceutical sector, a reevaluation of the PMPRB Regulations is clearly in order. However, the proposed amendments fail to examine the experiences of other jurisdictions and draw from their practices in order to better balance innovation and healthcare costs. As described by Glennie (2018), “[m]any of the proposed regulatory changes appear to take the PMPRB away from its core mandate, create duplication of effort, and potentially encourage decision-making based on flawed data. It is important to seriously consider stakeholder input to generate more coherent reforms that do not undermine innovation in the Canadian and/or global pharmaceutical system.”

Concern about undermining innovation in the Canadian biopharmaceutical industry is real and justified. According to a recent study by Ernst & Young (2017), the activities of the Innovative Medicines Canada members added more than CA\$19.2 billion of gross value to the Canadian economy in 2016. The study estimates that for every \$1.00 attributed directly to participating member firms, another \$0.59 is generated indirectly through activities in the supply chain, and an additional \$0.44 of induced impact is “supported by the employment income and associated spending across the Canadian economy” (Ernst & Young, 2017: 1). These contributions are certainly at risk. Even Health Canada’s conservative estimates calculate a significant loss of revenue for the innovative biopharmaceutical sector, with losses approaching CA\$8.6 billion over the next ten years due to lower prices (Glennie, 2018).

While the 1987 amendments that created the PMPRB reflected a thoughtful balance across several policy objectives, protecting consumers from excessive patented medicines prices, while ensuring sufficient incentives for patentees to introduce new medicines to Canada, the proposed changes are limited to solely lowering patented drug prices. As a result, the

aforementioned policy balance is put at risk. The proposed changes clearly disincentivize innovative drug launches in Canada, potentially deprioritizing Canada in the global launch sequences for new drugs. Moreover, the increasing reporting requirements represent an unnecessary regulatory burden and would increase the time to achieve public reimbursement (Critchley and Owens, 2018).

The proposed regulatory changes fundamentally alter the role and responsibilities of the PMPRB, in ways that are harmful to patients, the industry, and innovation. This paper has described that new and expanded role, examining the proposed changes and their potential consequences. The changes will likely reduce Canadian patients' access to medicine, stymie the biopharmaceutical industry's incentive to innovate, and decrease the jobs and income generated in the life sciences sector. Such significant changes should not go without thoughtful examination, though in this case that appears lacking. Quite simply, rather than bolstering the Canadian healthcare system, the proposed changes only serve to undermine it.

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Appendix: Pharmaceutical pricing and reimbursement policies, in- and out-patient sectors

Health Canada: Drug Approval

Grants the authority to market new drugs in Canada once they have met the regulatory requirements for safety, efficacy, and quality.

The Patented Medicine Prices Review Board (PMPRB): Pricing (factory gate level)

Regulates the price of all patented medicines sold in Canada to ensure that they are not excessive. Reviews the prices charged to wholesalers, hospitals and pharmacies. The PMPRB published its Strategic Plan for 2015-2018, which will enable the PMPRB to better advance its goal of a sustainable health system in Canada. In spring 2016, the PMPRB launched consultations with Canadian stakeholders that were expected to result in the creation of a new regulatory framework to be implemented in January 2018. For information on legal matters currently before the Board, as well as complete documentation on past matters, please visit <<http://www.pmprb-cepmb.gc.ca/en/hearings/the-hearing-process>>.

In-Patient

All drugs administered in hospitals are fully funded by the Medicare system at no cost to patients under the Canada Health Act. Canadian hospitals operate under fixed budgets, and typically procure drugs through purchasing programs that establish group contracts for set prices. The hospital then directly purchases drugs from the manufacturer at the contract price.

Out-Patient

Prescription drug costs in Canada are covered by a blend of **public and private** drug plans, as well as **out-of-pocket payers**.

Public (43%)

Each of the 10 Canadian provinces and 3 territories provide public coverage with a focus on seniors, lower-income earners or those with high drug costs in relation to their income. Federal coverage is provided for Veterans, First Nations and Inuit, Royal Canadian Mounted Police and the military.

pan-Canadian Pharmaceutical Alliance (pCPA)

Since 2010, provincial and territorial governments have implemented individual policies aimed at reducing the price of drugs. More recently, through the pCPA initiative, they have been working together to achieve greater value for brandname and generic drugs. Through these policies and the pCPA initiative, the prices of generic drugs have been reduced to levels as low as 18% of the reference brand-name prices.

Brand-name drugs

The pCPA conducts joint provincial/territorial negotiations and enters into confidential Product Listing Agreements (PLAs) for brand-name drugs for publicly funded drug plans. These negotiations are based on the health technology assessments conducted by the national review processes: Common Drug Review (CDR) or Pan-Canadian Oncology Drug Review (pCODR). As of February 29, 2016, 93 joint negotiations have been completed.

Generic drugs

The pCPA also conducts joint negotiations for top-selling generic drugs. The PanCanadian Generic Value Pricing Framework was implemented effective April 1, 2014. As of April 1, 2016, 18 commonly-used generic drugs have been reduced to 18% of their brand-name prices. In addition, a pan-Canadian Tiered Pricing Framework was developed that sets the prices of new generic products based on the number of products available in the Canadian market (if a generic drug is sold by one manufacturer, the framework allows for 75-85% of brand price; for generics produced by two manufacturers, the percentage drops to 50% of brand, and for three, the percentage of brand falls to 25% for oral solids and 35% for other dosage forms). In 2014, the average generic price in Canada was 36% of their brand-name counterpart.

Wholesale and pharmacy markups

About half of the provinces/territories regulate wholesale margins, while others are unregulated. Most public and private drug plans reimburse a

pharmacy markup. For public drug plans, the markup ranges from 4% to 8.5% of the drug ingredient cost.

The Common Drug Review (CDR) and pan-Canadian Oncology Drug Review (pCODR)

Through the pCODR and CDR processes, the Canadian Agency for Drugs and Technologies in Health (CADTH) evaluates the clinical, economic, and patient evidence for cancer drugs (pCODR) and other drugs (CDR). Based on these evaluations, CADTH provides reimbursement recommendations and advice to Canada's federal, provincial, and territorial public drug plans (with the exception of Quebec), as well as to the provincial cancer agencies. The recommendations are not binding but are considered by the public drug plans when making formulary listing decisions. As of April 1, 2016, CADTH will no longer accept confidential submitted prices for the CDR and pCODR reviews. The submitted price will be disclosed in all applicable reports.

Patient eligibility and cost-sharing

These vary widely according to the plan design. Some public plans provide income-based coverage, while other focus on seniors and lower-income earners. Costsharing structures also vary depending on the plan design, with a blend of deductibles, co-insurance and/or co-payments.

Recent analysis of select Canadian public drug plans calculated that of the \$7.7 billion in prescription drug expenditures in 2012/13, drug costs accounted for 74.4%, pharmacy dispensing fees for 21.4% and markups for the remaining 4.2%. Prescription drug expenditure levels differ widely among provincial drug plans. This is mainly due to variations in the size of the beneficiary populations, but also reflects the demographic and disease profiles of the populations, as well as differences in plan designs. On average, public drug plans paid 82.0% of the overall prescription drug cost for their beneficiaries, with the remainder being paid by the beneficiaries either out-of-pocket or through a third-party private insurer.

Private (35%)

Most employers provide private drug insurance for working-age beneficiaries and their dependants.

Brand-name drugs

Private plans do not negotiate the prices of brand-name drugs collectively and do not benefit from the discounts/rebates available for public plans.

Generic drugs

The generic prices that are negotiated by the pCPA are available to both the private and out-of-pocket markets.

Manulife DrugWatch

DrugWatch responds to the climbing prescription drug prices through the implementation of a new approval process, which ensures new drugs meet a clinical effectiveness standard in relation to their price. The scrutiny of drugs in the DrugWatch program is intended to give Manulife more leverage to negotiate prices with drug manufacturers. Nearly 3.8 million Canadians have drug coverage through one of the company's plans. The program is unique to Canada in that it will be the standard process for all Manulife's clients, without them opting in or out.

Wholesale and pharmacy markups

No policies exist. These may be negotiated by individual insurers (e.g. Preferred Pharmacy Networks).

Coverage

Private plans generally cover all prescription drugs, although private formulary plans do exist, in which case, private drug plans make their own listing decisions.

Cost-sharing

Cost-sharing structures take the form of co-insurance, copayments, deductibles, and maximums. Recent concerns over the long-term sustainability of private plans in Canada have resulted in an increased use of cost management mechanisms, such as mandatory generic substitution, greater use of managed formularies, prior authorization and multi-tiering (promoting the use of more cost-effective medicines), preferred pharmacy networks, increased cost sharing, pooling of high-cost beneficiaries, and the elimination of retiree benefits, among others.

Canadian Drug Insurance Pooling Corporation

Twenty-four insurance companies across Canada share the costs of very expensive and recurring drug treatment claims. This approach is intended to set affordable premiums for fully insured employer drug plans as well as shelter their employees from the full financial burden of prescription drug treatments. Since 2013, the new pooling mechanism paid more than \$4,000 prescription drug claims of over \$25,000. Several individual claims exceeded \$500,000. One was over 1.2 million.

Out-of-pocket (22%)

Individuals not covered by a public or private plan, or those with deductible or co-payment costs.

The information in this Appendix is from the Patented Medicine Prices Review Board, <http://www.pmprb-cepmb.gc.ca/CMFiles/News%20and%20Events/Speeches/PPRI_Poster_2016_en.pdf>.

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