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SUBMISSION TO THE
PATENTED MEDICINE PRICES REVIEW BOARD



EXECUTIVE SUMMARY

Innovative Medicines Canada appreciates the opportunity to engage as part of the Patented Medicine Prices Review Board's (PMPRB) public consultation regarding possible reform to its *Compendium of Policies, Guidelines and Procedures*. The PMPRB has laid out a broad-based consultation document to modernize and simplify its regulatory framework in order to remain relevant in a "dynamic and evolving pharmaceutical market". While the *Discussion Paper* implies greater regulatory intervention is required, it is ambiguous about which specific policy failures or specific issues that the PMPRB hopes to resolve.

Access to medicines and vaccines is a key component to a quality health system. For this reason, virtually all stakeholders agree that Canadians should have the best possible access to medicines. The role of the PMPRB can only be reviewed in the full view of the complex, varied and evolving Canadian health and pharmaceutical pricing and reimbursement system, so that the federal price regulatory regime complements and supports the rest of the health system.

The role and function of the PMPRB is strongly linked to Canada's patent regime and the elimination of domestic compulsory licensing. When Parliament created the PMPRB, it was not intended to leverage Canadian prices downward for consumers or payers, but to ensure patentees could not abuse their market positions by charging excess prices. The changes that led to the creation of PMPRB were bold, optimistic and visionary. There were dramatic health and industrial policy objectives and the changes resulted in significant improvements in both the health research enterprise in Canada and the availability of innovative medicines for Canadians and the resulting improvements in health outcomes.

At that time, PMPRB was the only mechanism that provided Canadians an assessment of the "reasonableness" of the price of a patented medicine in Canada. Since then, many tools, mechanisms and agencies have been established to refine and enhance payers' understanding of the value of medicines in the Canadian market. Today, the prices of patented medicines in Canada remain below the median of the prices in the PMPRB comparator countries (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the USA).

PMPRB has indicated it will focus its activities on addressing affordability and value for money. While it is clear that the sustainability of Canada's healthcare system and the management of healthcare budgets is a priority for Canadians and policy makers, introducing affordability as a new concept into the PMPRB's assessment of non-excessive prices is problematic.

Innovative Medicines Canada does not believe that the PMPRB is the appropriate agency to decide upon the affordability of medicines in Canada. The PMPRB is not accountable for spending decisions, does not select drugs for reimbursement, does not pay for medicines, and does not have visibility into drug and health budgets. Other agencies and jurisdictions within the current environment are charged with these roles, and better placed to work with and/or negotiate with the industry to answer these questions.



Since the creation of the PMPRB, the overall operating environment affecting pricing and access decisions for patented medicine manufacturers has changed dramatically. While the PMPRB plays the discrete role of determining a ceiling pricing for a patented medicine, several other agencies and processes have been established and expanded over the last two decades to assist governments to make funding decisions, particularly the evolution of Health Technology Assessments and the introduction and expansion of product listing agreements and joint negotiations.

Innovative Medicines Canada strongly suggests that PMPRB should not overlap the functions of CADTH/INESSS, or pCPA through a change to its price oversight or reporting function. We caution against creating mechanisms that would duplicate or overlap with the ongoing work of processes that support the assessment of value of money for patented drugs.

In making reimbursement decisions, all governments recognize the importance of providing additional help to citizens who need it the most, including those on social assistance and seniors. Innovative Medicines Canada strongly believes that the current system of differential pricing, which preferentially benefits public payers as custodians of those individuals they have deemed to be society's most vulnerable, is fully aligned with Canada's social contract, which supports preferential targeting of resources to protect against an inability to pay. At the same time, privately funded drug plans have the tools at their disposal to assess value, negotiate reimbursement terms and ensure drug plan sustainability within their own parameters and the objectives of their clients.

Expenditures on patented medicines are not disproportionately contributing to the growth in health system spending, and in fact contribute to savings downstream. However, even though the vast majority of Canadians are covered under a public or private drug plan, some Canadians struggle with affordability because they have inadequate levels of drug coverage.

The challenge today is to recognize the common objectives of all parties — patients, healthcare professionals, policy makers, payers, administrators, and industry — and find ways to build solutions that reflect the unique properties of the Canadian system and provide the best possible access to new medicines for Canadians.

A similar challenge exists when it comes to our members' economic presence in Canada. The ambitious policy change that expanded patent protection and saw the creation of the PMPRB resulted in substantial expansion of both the economic footprint of innovative companies and the health research enterprise in Canada. There is no doubt, however, that there have been substantial and profound changes to the business and regulatory environments in Canada and globally. Innovative Medicines Canada and its members remain committed to exploring ways with governments, health research institutes, biotechnology companies and researchers to expand our R&D and investment footprint in Canada in the coming years and into the future.

In making any reform to the pricing and reimbursement system, we should remember that Canada is a wealthy G7 country with a high quality healthcare system. We should be building a system that makes available the widest array of health technology choices and provides optimal access to the most



appropriate choices for individuals. It is true that technological advances require tough choices to be made, but we are much better off for the progress that science has produced.

Innovative medicines are increasingly viewed solely as a cost driver. While the clinical value of our medicines is often acknowledged, the systems being established to pay for medicines are treating medicines as a commodity as opposed to an investment. We are approaching a point where the incremental evolution of the pharmaceutical reimbursement landscape will no longer yield the best health or economic outcomes for Canada.

While recognizing fiscal constraints, we should collectively aspire to more ambitious goals. We should aspire to create a marketplace that encourages market entry of novel medicines. This approach will benefit both payers and patients. Payers will benefit from greater levels of competition, and patients will benefit from having more options available to them and their health care practitioners.

Innovative Medicines Canada is prepared to work with governments in Canada to build a predictable, stable and sustainable role for the innovative pharmaceutical industry and ensuring Canadians continue to get value from their expenditures. In particular, we are keen to engage with public and private payers, Health Canada, CADTH and INESSS to help evolve the drug review mechanisms to address issues of clinical value and value for money, with the objective of improving timely and affordable access of innovative medicines to Canadians.

Innovative Medicines Canada and its member companies believe that all Canadians should have access to the medicines they need, without affordability as a barrier. We are committed to working as a strategic partner with government and other stakeholders to reach this objective and bring forward solutions to address the gaps in the system. However, we do not believe that changing the PMPRB Guidelines to reduce pricing thresholds for patented medicines will solve the problem of individuals facing affordability challenges due to lack of or insufficient drug coverage in Canada. Solving this problem will require innovative collaboration between the federal, provincial and territorial governments, the pharmaceutical industry, and private insurers.

TABLE OF CONTENTS

Executive Summary	i
1. Introduction.....	1
2. The Role and Mandate of the PMPRB	2
a. Origins of the PMPRB	2
b. Scope of PMPRB Mandate	4
c. Expanding Mandate to Include “Affordability”	4
d. Approach to Modernizing the PMPRB Guidelines	6
3. Evolution of Canada’s Pharmaceutical Landscape	8
a. Changing Pricing and Reimbursement Environment for Public Payers.....	8
b. Differential Pricing for Public and Private Markets.....	9
c. Trends in Utilization and Expenditures of Patented Medicines in Canada	10
d. Outstanding Access Gaps to Medicines.....	13
4. Value that Medicines and the Pharmaceutical Industry Bring to Canada	14
a. Value of Innovative Medicines.....	14
b. Pharmaceutical Research & Development and Investment in Canada	14
5. PMPRB Discussion Paper Themes	15
a. Therapeutic Benefit	15
b. International Price Comparisons	17
c. Domestic Price Comparisons	21
d. Price Increases Based on Changes in the Consumer Price Index.....	22
e. Frequency of Reviews	23
f. Any Market Price Reviews.....	23
Conclusion	24
Endnotes.....	25



1. INTRODUCTION

As the national voice of Canada's innovative pharmaceutical industry, Innovative Medicines Canada appreciates the opportunity to engage as part of the Patented Medicine Prices Review Board's (PMPRB) public consultation regarding possible reform to its Compendium of Policies, Guidelines and Procedures (Guidelines), as outlined in the *PMPRB Guidelines Modernization - Discussion Paper* (Discussion Paper). On behalf of our members, we advocate for policies that enable the discovery, development, and delivery of innovative medicines and vaccines to improve the lives of Canadians, while supporting our members' commitment to be meaningful partners in the Canadian healthcare system.

Our members are pleased that the PMPRB does not have any preconceived models for changes to the Guidelines, and that a fulsome consultation with impacted stakeholders is being undertaken. The PMPRB has laid out a broad-based consultation document, and has indicated that they are seeking input from a wide variety of interested parties. The objective is to modernize and simplify its regulatory framework in order to remain relevant in a "dynamic and evolving pharmaceutical market". The *Discussion Paper* raises a number of areas that may inform Guidelines changes. Further, the *Discussion Paper* implies greater regulatory intervention is required, but is ambiguous about which specific policy failures or specific issues that the PMPRB hopes to resolve. Finally, it is not clear whether the PMPRB is seeking to correct for problems that have been experienced with "outlier" products that PMPRB believes the current Guidelines are not well equipped to assess, or whether the modernization is intended to modify the regime for all of the products under the PMPRB's jurisdiction.

The assumptions, rationales, data sources and proposed changes in the *Discussion Paper* inform the public record on which the PMPRB will base their decisions. It is our view that this public record should be enhanced by more proactive and ongoing collaboration among all stakeholders. Innovative Medicines Canada is ready to work with the Board and other stakeholders on these critically important issues in the coming months as required by the legislation that governs the PMPRB's operations.

We note that the PMPRB plans to establish working groups for the final phase of consultations. We strongly believe that these working groups should be established earlier on, in order to facilitate a common understanding of the data sources and definitions, the rationale for specific changes in each of the issue areas, and practical issues related to Guidelines implementation. This will allow our members as well as other health system stakeholders, including patients, to provide more informed and meaningful input.

In particular, working groups would review the role of the PMPRB in the context of the complex, varied and evolving Canadian health and pharmaceutical pricing and reimbursement system, so that federal pricing management regulatory approaches continue to complement and support the rest of the health system.



As part of this review, Innovative Medicines Canada is committed to being a genuine and respected partner to governments, health systems and Canadian patients. We have a constructive history of working with the PMPRB to successfully resolve regulatory issues.

In this context, as a first step in engaging on the *Discussion Paper*, our submission begins by examining the role and mandate of the PMPRB and describing of the evolution of Canada’s pharmaceutical landscape since the establishment of the PMPRB in 1987. We then discuss the value that medicines and the pharmaceutical industry bring to Canada and we also provide some preliminary comments on each of the issues raised in the Discussion Paper.

We expect that there will be further opportunities to provide additional inputs throughout the consultation process, especially as part of the working groups. Finally, we are pleased to offer throughout our submissions additional considerations, recommendations and questions that we believe will better inform the PMPRB’s guidelines modernization initiative over the coming months. Our input will continue to be refined as the consultation process unfolds.

Working groups should be established early on in the consultation process in order to facilitate a common understanding of the data sources and definitions, the rationale for specific changes in each of the issue areas, and practical issues related to Guidelines implementation.

2. THE ROLE AND MANDATE OF THE PMPRB

a. Origins of the PMPRB

As outlined in the Discussion Paper, the role and function of the PMPRB is strongly linked to Canada’s patent regime and the elimination of domestic compulsory licensing in the context of Canadian trade treaty obligations. In this regard, we would like to emphasize the objectives of this regime. Specifically, the patent “bargain” is a concept underlying the theory that a patent is granted to encourage innovation. This patent protection seeks to provide an incentive for pharmaceutical companies to take the risk to make the enormous research and development investments necessary for new medicines and vaccines.¹ In the absence of this protection, inventors would not assume the risks required to bring the invention to market.

The Supreme Court of Canada has reaffirmed this policy several times, stating that “[i]n Canada the granting of a patent means the kind of contract between the Crown and the inventor in which the latter receives an exclusive right to exploit his invention for a certain period in exchange for complete

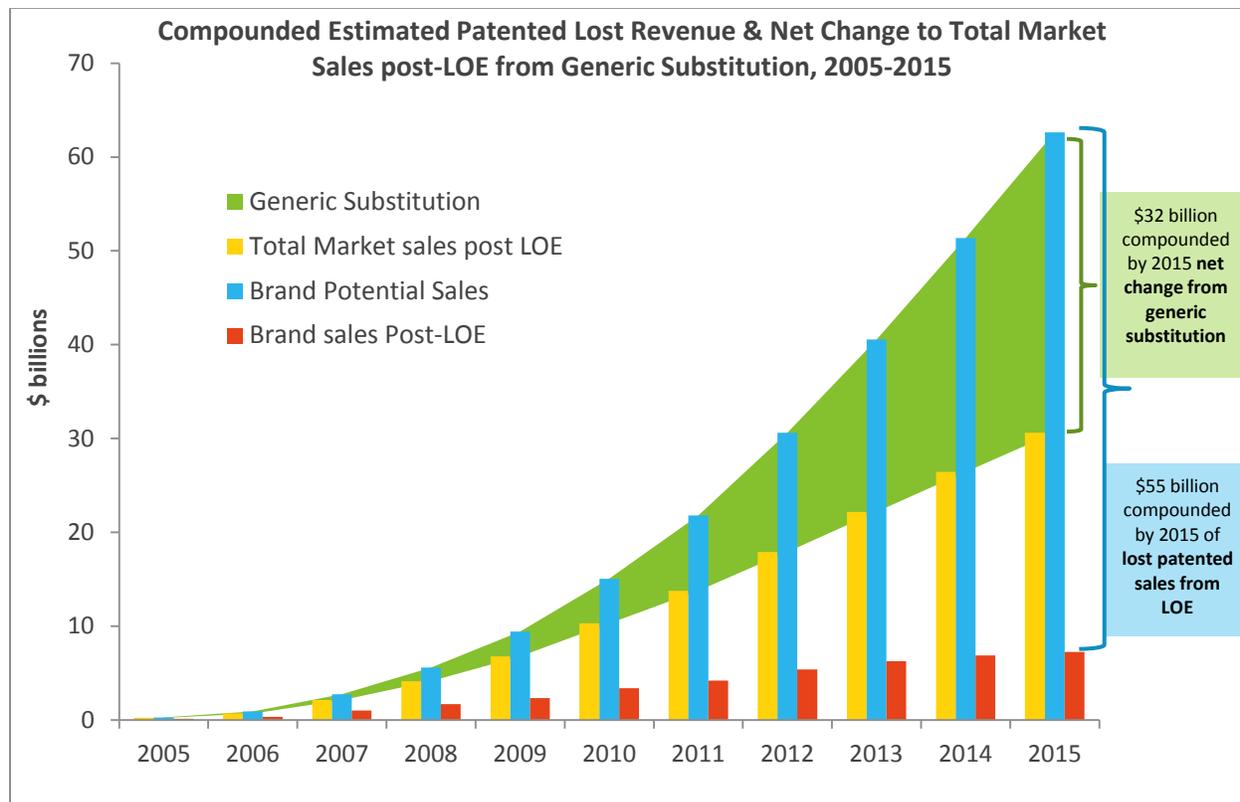


disclosure to the public of the invention and the way in which it operates”,^{1,2} and more recently that the patent system is based on a “bargain”, or *quid pro quo*: “the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge. This is the basic policy rationale underlying the [Patent] Act”.^{2,3}

The protections offered by both Canadian and non-Canadian patent systems are time limited. This limitation is especially relevant with respect to pharmaceutical patents, where a significant portion of the patent term is consumed in development and regulatory processes before a medicine is even approved by Health Canada, and still further patent time is expended during Health Technology Assessment (HTA), pan-Canadian Pharmaceutical Alliance (pCPA) negotiations, and public and private payer listing processes.

Once the period of patent exclusivity has expired, other manufacturers may enter the market with copies of the medicine. Since 2005, generic market entry has resulted in \$55 billion in lost revenue for originator molecules, and net savings to pharmaceutical budgets of \$33 billion. (**Figure 1**) This cycle of innovation drives the development of novel medicines and expands the availability and accessibility of medicines over time.

Figure 1 – Estimated Net Savings of Generic Market Entry and Resulting Patented Medicine Revenue Loss, 2005-2015⁴





When Parliament created the PMPRB, its intention was to ensure there was a safeguard against the potential that patentees might charge excessive prices. Excessive prices are formally defined as *prices set significantly above competitive levels as a result of monopoly or market power*.⁵ The PMPRB was not established to leverage Canadian prices downward for consumers or payers, but rather to ensure patentees could not abuse their market exclusivity positions. Parliament certainly did not intend to establish the lowest possible price. This intent is also supported by section 92 of the *Canadian Constitution Act, 1867*, which places price regulation under the jurisdiction of the provincial governments. Parliament also established factors in section 85 of the *Patent Act* that the PMPRB must take into account when determining the appropriate threshold for a price to be considered “excessive” and whether a product exceeds this threshold to warrant punitive action. This includes the price of the medicine, prices of other medicines in the same therapeutic class, the range of international prices, and changes in the Consumer Price Index (CPI), or inflation.

At the time of its creation, PMPRB was the only mechanism that provided payers and consumers an assessment of the “reasonableness” of the price of a patented medicine in Canada relative to international prices of the same medicine. Since then, many new and effective tools, mechanisms and agencies have established to refine and enhance payers’ understanding of the value of medicines in the Canadian market. More details on this evolution since 1987 are provided below.

b. Scope of PMPRB Mandate

The primary mandate of PMPRB is to ensure that the ex-factory prices of patented medicines are not excessive, to report on pharmaceutical trends of all medicines, and to report on R&D spending by pharmaceutical patentees. Since its creation in 1987, the PMPRB has effectively delivered on the first element of its defined mandate and ensured that Canadian prices for patented medicines have remained comparable to the international prices, particularly in comparison to nations with a similar level of economic development as Canada. Moreover, Canadian prices have declined relative to each of the countries in the PMPRB⁶ and in 2015 remained below the median of the basket of international prices.⁷ (*Figure 6*)

In light of the evolution of the Canadian pharmaceutical environment, and the multiplicity of checks against the pricing power of patentees, the PMPRB’s original mandate remains appropriate.

c. Expanding Mandate to Include “Affordability”

Based on the *Strategic Plan*, and the *Discussion Paper*, it appears that the PMPRB intends to focus its activities and regulatory approach on the objective of addressing the issue of affordability and “value for money”. Many of the recurring themes in the *Discussion Paper* and the list of questions point to the urgency and need for a dialogue on the issue of sustainability and consumer protection in the context of prices of patented drugs and ability to pay for the jurisdictions.



It is clear that the sustainability of Canada's healthcare system, the management of healthcare budgets, and the affordability of inputs to the system – including medicines – is a priority for Canadians and policy makers. However, introducing “affordability”⁸ as a new concept into the PMPRB's assessment of non-excessive prices is problematic for the reasons outlined below.

First, and as noted above it is a clear departure from the PMPRB's establishment and role as intended by Parliament, and therefore inconsistent with its legislative mandate.⁹

Second, affordability is closely related to cost, which is determined by utilization as well as price. A price regulator, whose mandate and scope are limited to the assessment of price independent from cost, cannot make a valid judgment with respect to cost. This would amount to the price regulator making judgments on price based on the quantity of medicines, which is not only duplicating the role of payers but also acts as a disincentive to the introduction of new innovative medicines to Canada.

Third, affordability, i.e. the ability to pay the cost of a medicine within a budget, is best determined by the payers, which are the budget holders and already have the tools in place to appropriately determine or evaluate affordability.¹⁰ Constitutionally, each province and territory is accountable to its constituents for deciding how to allocate its public dollars. As budget holders, they are best able to make determinations of what is affordable within their own programs, health care systems and/or their own economies. This is because affordability is a subjective and relative concept: what may be deemed an appropriate price to pay for one institution/jurisdiction may be different from another.^{11, 12} This is particularly relevant to Canada's federal structure and mixed public and private drug funding systems. No single agency can make an assessment of affordability of innovative medicines on behalf of everyone else, since there is no “single payer” in Canada. For medicines, most provincial governments make this determination as to what is affordable for their constituents and set this as the basis for their public drug plan eligibility. As such, the rates and eligibility criteria vary by province as they do across private drug plans. With each drug plan the rationale for coverage, the economic and fiscal environment, population demographics and the health needs of the individuals covered are different. As a result, the value placed on individual drugs also differs accordingly.

As discussed previously, while the PMPRB determines a ceiling price for a patented medicine in Canada, many other agencies and initiatives – such as Canadian Agency for Drugs and Technology in Health (CADTH), the Institut national d'excellence en santé et en services sociaux (INESSS) and the pan-Canadian Pharmaceutical Alliance (pCPA) – have evolved over the decades since the PMPRB's creation to help the federal government, provinces and territories (F/P/T) make funding decisions. Each one of these agencies and initiatives has its own role and mandate created out of a set of carefully constructed compromises between federal, provincial and territorial governments to meet the characteristics of each jurisdiction, their respective needs and health priorities. Private insurers have also put in place a number of mechanisms to help them make funding decisions on the reimbursement of medications.



We do not believe that the PMPRB is the appropriate agency to decide the appropriate threshold for the affordability for medicines for Canadian payers. The PMPRB is not accountable for spending decisions, does not select drugs for reimbursement, does not pay for medicines, and does not have visibility to drug and health budgets. Other agencies and jurisdictions within the current environment are charged with these roles, and are better placed to work collaboratively and/or negotiate with the industry to answer these questions. Considerations and determinations of affordability are best left to budget holders who are able to make trade-off decisions based on their needs and objectives and are accountable to their constituents. A change of the PMPRB's Guidelines to work itself into this system would broaden its jurisdiction into areas where responsibility rests with other agencies and jurisdictions and the manufacturers from whom they purchase medicines (e.g. CADTH/INESSS, pCPA, the F/P/Ts, and the private insurance industry), creating confusion, overlap and duplication in mandates as well as loss of formal accountability of federal and provincial/territorial governments in health care.

Finally, the notion that the PMPRB would assess the affordability rather than the excessiveness of pricing is inconsistent with other federal regimes that regulate rates. Indeed, an analysis of the relevant legislation depicts a federal regulatory environment that seeks to promote reasonableness and trade. The Canadian Dairy Commission, for example, is mandated by legislation to establish and operate a program in respect of the prices of milk or cream "necessary for the competitive international trade in, and the promotion and facilitation of the marketing of, dairy products"¹³. Other goods and services that are subject to similar federal regulated industry pricing oversight include wheat¹⁴, postage¹⁵, telecommunications¹⁶, oil and gas¹⁷, sources of natural energy¹⁸, and air transportation¹⁹. All of these regimes were established to regulate or monitor price thresholds more stringent than PMPRB, but none of them attempts to measure or assess for affordability.

The scope of the PMPRB mandate should not be expanded to include the notion of "affordability". Affordability is best determined by the budget holders that already have the tools in place to appropriately determine or evaluate affordability.

d. Approach to Modernizing the PMPRB Guidelines

Innovative Medicines Canada encourages PMPRB to explore mechanisms to best complement the work of CADTH/INESSS, pCPA and private payers through its price oversight and reporting function while maintaining its mandate. We caution against creating mechanisms that would duplicate the ongoing work of processes that support the assessment of value of money for patented drugs.

Any discussion with respect to the mandate of the PMPRB and potential changes to the Guidelines should have a clearly stated objective and be supported by analysis that there is a clear problem that



needs to be addressed and, importantly, that PMPRB is best placed to address the problem. We must be mindful of the environment in which PMPRB operates and the implications these mandate changes may cause across the health care system.

In making any reform to the pricing and reimbursement system, we should remember that Canada is a wealthy G7 country with a high quality healthcare system. We should be building a system that makes available the widest array of health technology choices and provides optimal access to the most appropriate choices for individuals. While it is true that technological advances require tough choices to be made, we are much better off for the progress that science has produced.

The intellectual property changes that led to the creation of PMPRB were bold, optimistic and visionary. There were dramatic health and industrial policy objectives and the changes realized significant improvements in both the health research enterprise in Canada and the availability of innovative medicines for Canadians and the resulting improvements in health outcomes. Life expectancy and mortality rates have improved significantly as a result of investments made by Canadian governments and payers in innovative medicines²⁰ and diseases that were once a life sentence are now manageable illnesses that enable Canadians to continue contributing to the economy and society.

The innovative pharmaceutical industry is poised to continue to make significant contributions to the health of Canadians and to Canada's economy. The science of medicine continues to make significant advancements in multiple areas. Canada will need a system to assess, understand, and make the best use of emerging and future technologies like gene therapies, personalized medicines or bioelectronics. Canada will need a system designed to make best use of these innovative medicines.

Innovative medicines are increasingly viewed solely as a cost driver. While the clinical value of our medicines is often acknowledged, the systems being established to pay for those medicines are treating them as a commodity as opposed to an investment in health outcomes. We are approaching a point where the incremental evolution of the pharmaceutical reimbursement landscape will no longer yield the best health or economic outcomes for Canada.

While recognizing fiscal constraints, we should collectively aspire to more ambitious goals. We should aspire to create a marketplace that encourages market entry of new medicines. This approach will benefit both payers and patients. Payers will benefit from greater levels of competition, and patients will benefit from having more options available to them and their health care practitioners.

Innovative Medicines Canada is prepared to work with governments in Canada to build a predictable, stable and sustainable role for the innovative pharmaceutical industry and ensuring Canadians continue to get value from their expenditures. In particular, we are keen to engage with public and private payers, Health Canada, CADTH and INESSS to help evolve the drug review mechanisms to address issues of clinical value and value for money, with the objective of improving timely and affordable access of innovative medicines to Canadians.



The PMPRB should ensure that its activities complement, not duplicate or overlap with, the work of CADTH, INESSS, pCPA and private payers through its price oversight and reporting function.

3. EVOLUTION OF CANADA'S PHARMACEUTICAL LANDSCAPE

Innovative Medicines Canada and its members acknowledge some of the underlying challenges and contextual issues raised in the *Discussion Paper* – namely the sustainability and management of healthcare budgets. At the same time, the policy case for substantial changes to how the Guidelines function merits closer examination, beginning with a better understanding of the evolution of Canada's pharmaceutical landscape since the creation of the PMPRB, including:

- changing pricing and reimbursement environment for public payers;
- differential pricing for public and private markets;
- trends in utilization and expenditures on patented medicines in Canada; and
- Outstanding access gaps to medicines.

a. Changing Pricing and Reimbursement Environment for Public Payers

Since the creation of the PMPRB, the overall operating environment for pricing and access decisions for patented medicine manufacturers has changed dramatically. While the PMPRB plays the important role of determining a ceiling price for a patented medicine, several other agencies and processes have been established and modernized over the last two decades to assist the governments to make sometimes difficult funding decisions, including:

- **Health technology assessment agencies:** The CADTH makes reimbursement recommendations to Canada's provinces and territories (except Québec) on the medicine's cost-effectiveness, or value-for-money. INESSS does the same for Québec. These recommendations assist public drug plans in making coverage decisions. Drug plans are the ones that hold the ultimate power to decide if and how a medicine will be reimbursed, based on that government's priorities and budget, and at what price.
- **Pricing agreements:** Following a recommendation from CADTH and/or INESSS, the reimbursement "price" is often determined through negotiation of product listing agreements between public drug plans and manufacturers. Public drug plans are now also jointly negotiating the terms of these agreements with manufacturers through the pan-Canadian Pharmaceutical Alliance (pCPA).²¹ Formed at the direction of the Premiers at the Council of the Federation, the pCPA includes all provinces and territories and the federal drug plans. As of



April 2016, an estimated \$712 million in combined savings annually has been realized for publicly funded drug plans (on 95 patented medicines and 18 generic drugs).²²

With the introduction of product listing agreements and the pCPA, price negotiation is now a common part of the reimbursement process to assess affordability and ensure appropriate coverage for the vulnerable populations who are beneficiaries of the public drug plans in Canada. Governments also use various plan management tools that restrict coverage for medicines to limited circumstances based principally on cost-effectiveness determinations.

Role	Organization	Action	Standard of measure
Market Approval	Health Canada	Evaluates, Decides	Safety, Effectiveness, Quality
Price Review	PMPRB	Reviews	Non-excessive prices
HTA	Common Drug Review (CDR)	Evaluates, Recommends	Clinical & Cost Effectiveness
HTA	pan-Canadian Oncology Drug Review (pCODR)	Evaluates, Recommends	Clinical & Cost Effectiveness
HTA	INESSS	Evaluates, Recommends	Clinical & Cost Effectiveness and population & system impacts
Negotiation	pCPA	Negotiates	Cost, expenditure, affordability
Listing decision	Drug Plan	Decide	Access to new medicines, manage expenditures, determine affordability

b. Differential Pricing for Public and Private Markets

In making reimbursement decisions, all governments recognize they have an obligation to provide more help to their most vulnerable citizens. While publicly funded drug plans vary across Canada in eligibility and reimbursement, those on social assistance and seniors are consistently eligible recipients. While Canadians older than age 65 account for less than 15% of the population, 66% of seniors are taking five or more prescription medicines and account for 45% of public health care spend.²³ Given that the vast majority of health care spending is borne by public financing and that publicly funded drug plans cover society's most vulnerable populations, preferential pricing is provided to public sector payers. Provincial governments initiated negotiated rebates in order to achieve better access to drugs and to achieve optimal value for taxpayers' money.²⁴ The pCPA was established to further advance this



objective and increase access to new medicines, improve consistency of decisions, reduce duplication, and lower drug costs through collective negotiations.²⁵

Innovative Medicines Canada strongly believes that this system of differential pricing, which preferentially benefits public payers as custodians of those individuals they have deemed to be society's most vulnerable, is fully aligned with Canada's social contract, which supports preferential targeting of resources to protect against an inability to pay.

At the same time, private drug plans have introduced a number of tools to assess value, negotiate reimbursement terms and ensure drug plan sustainability. Various industry players, such as pharmacy benefit managers and insurance carriers, conduct their own health technology assessment to determine, based on their own plan sponsors client profile, the value of a particular medicine (e.g. TELUS Health and ReVue, Manulife and DrugWatch, Medavie and its Medication Advisory Panel). Like public drug plans, they too negotiate drug prices with innovative medicines manufacturers to determine the best value for their members. In addition, they offer a variety of formularies and plan design features not seen in the public sector to manage the cost of their drug plans and overall health benefits plans. This includes multi-tiered formularies, prescribing appropriateness and cost-sharing mechanisms, case management programs, adherence programs, preferred provider networks, and industry level pooling.²⁶

Private drug plans are most often managed by large for-profit insurance carriers and/or pharmacy benefit managers. Each has the incentive structure, program design and capability to negotiate with innovative medicines companies to achieve best value for its clients in a commercial setting. They are well positioned to make their own value judgments and to negotiate accordingly. Similar to the public sector, the terms of these arrangements can include the conditions of a medicine's coverage as well as the price of a medicine. However, unlike the public sector, confidential negotiations enable benefit providers to market highly competitive plans to their existing or prospective clients²⁷. These arrangements are beyond just the price of innovative medicines, but also include negotiations with specialty distribution channels and retail pharmacy for preferred provider arrangements. These are some of the ways that private payers have unique opportunities to control the overall costs of drug plans while increasing their competitiveness in the marketplace.²⁸

c. Trends in Utilization and Expenditures of Patented Medicines in Canada

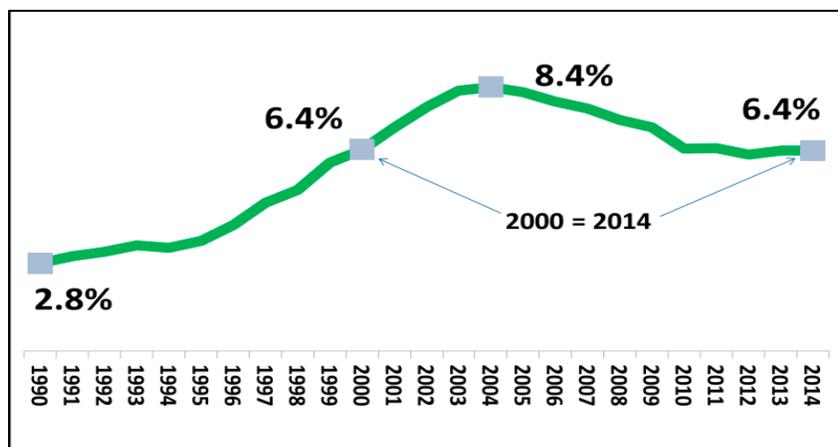
Spending on patented medicines represents a small and declining proportion of total health spending and of GDP, and has been growing at a much slower rate than other components of health spending that account for much larger proportions of health spending.

In 2014, patented drugs accounted for 6.4% of total health spending in Canada in 2014 – the same percentage as in the year 2000 (see **Figure 2** next page).



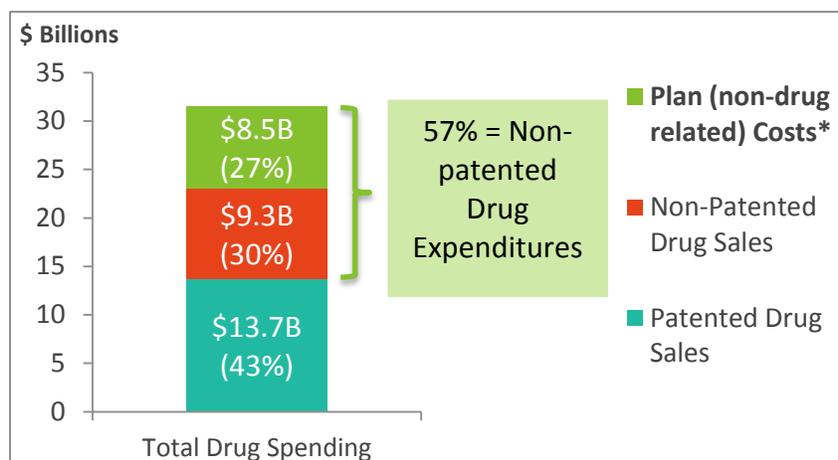
Of note, payers and Canadian patients spend a considerable amount in addition to patented medicines, on other items such as generic medicines, pharmacist dispensing fees, distribution costs, which add up to **more than** the spending on patented medicines (*Figure 3*).

Figure 2 - Patented drugs percentage of total health spending (national, public + private in Canada, 1990-2014)²⁹



Spending on patented drugs has grown much slower than spending on the rest of healthcare. From 2009 to 2014, per capita spending on patented drugs grew by only 0.5% in total over the entire period. By comparison, per capita spending on all other health care (excluding patented drugs) grew by 13.1% (*Figure 4* next page).

Figure 3 - Total Prescription Drug Spending, by Category, 2014³⁰



Although the total market is expanding, per capita spending on patented drugs accounted for less than 1 percent (0.69%) of 2014 per capita GDP, which is roughly the same as 15 years ago (0.67%).³¹

Canada's market for pharmaceuticals has many unique characteristics compared to other jurisdictions. It is one of

the few countries that have both a substantial public reimbursement system as well as a significant private insurance system.³² It is estimated that prescription drug spending in Canada is 43% public drug plans, 36% private insurance, and 22% out of pocket.³³



Figure 4 - Total Health Care Spending per capita, by Category, 2014³⁴

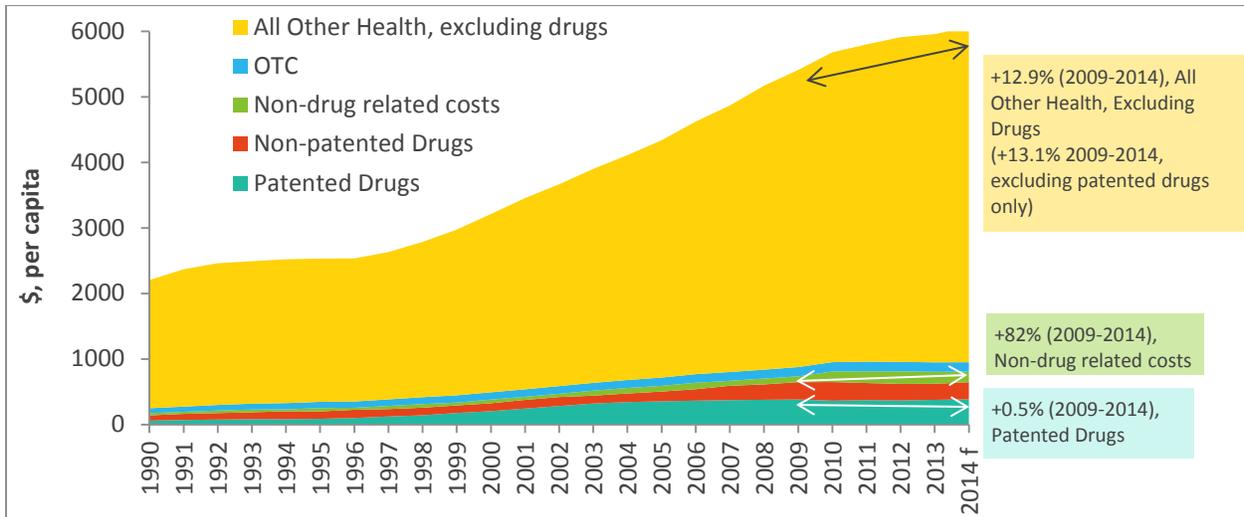
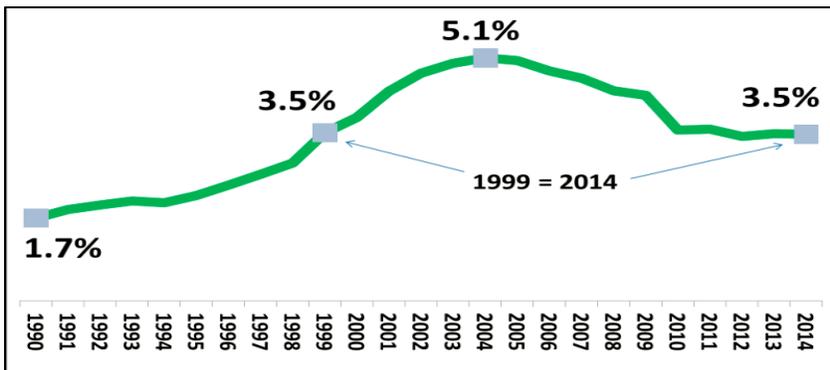


Figure 5 – Estimated public drug plan spending on patented drugs as a percentage of total Provincial government health spending, 1990-2014³⁵



It is estimated that total public drug plan spending on *patented* prescribed drugs represented 3.5% of the total spending by provincial-territorial governments on all health care in 2014 – the same percentage as in the year 1999 (Figure 5).

An estimated one fifth of prescription pharmaceutical spending in Canada is cash payments by individuals (\$5.1 billion in 2014).³⁶ This amount includes the direct costs of medicines and additional prescription costs (dispensing fees and mark-ups) paid in full by some individuals, as well as the cost-sharing portions of prescriptions like deductibles, co-pays, and co-insurance.

Canadian individuals pay nearly as much out of pocket on total health services as private insurance (\$30.5 billion in 2014).³⁷ However, prescription drug expenditures (\$5.1 billion) represent only 17% of total out of pocket health spending for Canadians. Canadians spent even more on non-prescription medicines and health supplies (\$6.1 billion),³⁸ which are typically not covered by insurance plans, although the largest out of pocket spending for Canadian individuals is other professionals, representing 30% of total health care out of pocket spending.³⁹ Out of pocket household spending on prescription medicines across Canada has *declined* in recent years by 17%, and on average is \$408 per household per year.⁴⁰



Expenditures on Patented Medicines are not disproportionately contributing to the growth in health system spending. The growth comes mainly from other segments of health care.

d. Outstanding Access Gaps to Medicines

Innovative Medicines Canada recognizes that while many mechanisms — described above — exist within the Canadian system to successfully address the price and affordability of innovative medicines, concerns remain. Although the vast majority of Canadians are covered under a public or private drug plan, some Canadians struggle with affordability because they have inadequate levels of drug coverage: they are uninsured or underinsured. It is these individuals who bear the burden of paying the full cost of their innovative medicines out-of-pocket.

However, the scope and the causes of this issue are not known.⁴¹ Depending on the definition used, anywhere from 1%⁴² to 20%⁴³ of Canadians are uninsured or underinsured and 10% indicate they cannot afford their medicines.⁴⁴ This can be for a variety of reasons: individuals who have high deductible payments or copayments, medicines that are not covered under their drug plan, those who cannot afford to purchase private insurance, and those who choose not to insure.

In recognition of this, the members of Innovative Medicines Canada have long established and maintained a variety of support programs to make their products available to those individuals at no fee or reduced fee. Between 2010 and 2014, KPMG has measured more than \$770 million in product donations by member companies made through compassionate use and special access programs in Canada.⁴⁵ Of note, this amount does not include the substantial financial considerations, through co-payment assistance, etc. made to individuals in need.

Innovative Medicines Canada believes that all Canadians should have access to the medicines they need, without affordability as a barrier. We are committed to working as a strategic partner with government and other stakeholders to help define the scope of this problem and bring forward solutions to address this gap in the system. However, we do not believe that changing the PMPRB Guidelines to reduce pricing thresholds for patented medicines will solve the problem of individuals facing affordability challenges due to lack of or insufficient drug coverage in Canada. Solving this problem will require innovative collaboration amongst the federal, provincial and territorial governments, the pharmaceutical industry, and private insurers.



4. VALUE THAT MEDICINES AND THE PHARMACEUTICAL INDUSTRY BRING TO CANADA

a. Value of Innovative Medicines

Access to medicines is a key component to a quality health system. There is no doubt that innovation in medicines has made a significant contribution to improving health outcomes in Canada and around the world. For this reason, virtually all stakeholders agree that Canadians should have the best possible access to innovative medicines.

With daily advances in modern medicine, Innovative Medicines Canada's members play an integral role in the health of Canadians by providing new and innovative therapies. Innovative medicines are one of the most cost effective means to deliver quality health care to Canadians. There is also ample evidence that pharmaceutical innovation improves individual and population health outcomes, reduces potential health system costs and reduces indirect societal costs like economic productivity losses from untreated or under-treated illness. In recent years we have seen significant advancements in treatments across several therapeutic areas, many filling a previously unmet medical need.

Innovative medicines make substantial contributions to patients' lives and the health care system. They help prevent, manage and often cure diseases while also avoiding or reducing costly hospital stays, invasive surgical procedures, and a lifetime of chronic illness. For example, with a \$1.2 billion expenditure on 6 classes of innovative medicines in 2012, there was a return of \$2.4 billion in health care savings and productivity gains.⁴⁶ Recent analysis also demonstrates the societal and corporate benefits of specialty medicines⁴⁷ as well as the reduction in hospital stays with the introduction of innovative cancer medicines.⁴⁸

Today, the challenge is to recognize the common objectives of all parties — payers, administrators, policy makers, healthcare professionals, patients, and industry — and find ways to build solutions that reflect the unique properties of the Canadian system and provide the best possible access to new medicines for Canadians.

b. Pharmaceutical Research & Development and Investment in Canada

The research and development (R&D) model for innovative medicines has changed significantly since the PMPRB was established. In 1987, the dominant R&D model was in the form of large, centralized research facilities and this is the type of investment PMPRB captures in its reporting. Today, the focus is on collaborative models of innovation with partnerships among public and private research institutions.

At the center of all this has been the emergence of clustered networks of academic and research institutes – along with start-ups and spin-offs, commercialization centers and virtual research labs that combine skills and know-how across disciplines and distance. Unfortunately, however, the vast majority of these investments in Canada are not captured by the PMPRB.



In recognition of the significant improvement to the investment climate for patented pharmaceuticals PMAC (Innovative Medicines Canada's predecessor) undertook to increase investments in Canada. This included increasing research & development intensity in Canada to 10% of sales (R&D to Sales ratio) and several investment targets totaling approximately \$5.5 billion over the next 15 years.⁴⁹ All of these undertakings assumed no substantial change to international and national business and regulatory environments. In 1998⁵⁰ the Auditor General of Canada noted, "the [PMPRB] reported that the brand name pharmaceutical industry had met its commitment" and recommended a review of "whether the reporting of pharmaceutical R&D expenditures continues to be relevant."

In 2011, there was general agreement on the need to gain a better understanding of the full spectrum of R&D spending in Canada. A Committee was formed, chaired by Industry Canada (now Innovation, Science and Economic Development) with membership from the Canadian Institutes of Health Research (CIHR), PMPRB, and Innovative Medicines Canada. Using criteria set by this committee to capture R&D not reported by the PMPRB, KPMG has measured in excess of **\$1 billion** in R&D expenditures since 2010 has not been counted by the PMPRB methodology.⁵¹ These include: investments made via Canadian venture capital; direct investments by foreign affiliates; contributions to university endowments; and costs associated with a company in development phase with no products on the market. It should also be recognized that none of the substantial research activities conducted by pre-commercial companies is measured by PMPRB, as these companies are not "patentees" and are therefore not subject to PMPRB oversight.

The ambitious policy change was most certainly a success for many years, with substantial expansion of both the economic footprint of innovative companies and the health research enterprise in Canada. There is no doubt, however, that there have been substantial and profound changes to the business and regulatory environments in Canada and globally.

Innovative Medicines Canada remains committed to exploring ways with governments, health research institutes, biotechnology companies and researchers to expand our R&D and investment footprint in Canada in the coming years.

5. PMPRB DISCUSSION PAPER THEMES

The Discussion Paper identifies several issues regarding how the PMPRB Guidelines are operationalized, which touch upon current price tests, including how patented drugs are categorized for therapeutic benefit, which jurisdictions and markets are appropriate for comparison and review purposes and how patented drugs are scrutinized on an ongoing basis. We provide preliminary comments on each of these areas below.

a. Therapeutic Benefit

The current rules already allow the Board to categorize drugs based on therapeutic benefit, and determine a ceiling price that it believes reflects the level of innovation. If the Board determines that a



product has “little or no” added therapeutic benefit, relative to other drugs that are available, the price cannot exceed that of the other drugs within the category. If the Board decides that there is added therapeutic benefit, then prices can be set higher, but there are several other factors that continue to limit the ceiling price throughout the life cycle of patented medicines. Higher pricing is only permitted when a new drug in an existing class is shown to add therapeutic value or improvement, and ongoing prices are limited by the maximum price in the PMPRB countries.

In other words, the PMPRB Guidelines and regime already ensure protection against potential abuse of a statutory monopoly by establishing a clear, predictable ceiling price in Canada, under which health systems and consumers can determine their own affordability and reimbursement terms and incentivize new entrants into therapeutic classes that compete for market share and demonstrating payer and patient value through the HTA and payer reimbursement systems.

The *Discussion Paper* suggests a new approach, substituting measures of the potential for abuse of monopoly for the categorization based on therapeutic benefit. A new factor is suggested to trigger regulatory scrutiny (and regulatory relief – presumably lower regulated ceiling prices), for drugs that have a launch price that exceeds a “pre-established threshold or that is likely to cause rationing by public and private drug plans based on cost or projected usage,” or which has “few, if any, competitors in its therapeutic class[...].” The rationale for enhanced regulatory scrutiny is market concentration among patentees and increased spending on “high cost” specialty drugs. We are aware of no other jurisdiction that takes such an approach.

As with the question of affordability, we do not believe it is appropriate for PMPRB to attempt to assess or make determinations about rationing or budget impact in establishing a non-excessive price determination.

The therapeutic benefit of a medicine is central to determining the cost benefit, clinical benefit, the role in therapy and the opportunity cost of not using the medicine. Therapeutic benefit is also central to determine the comparative benefit of competing products, therapies, and treatments. It is difficult to foresee how a model that does not consider or rely on therapeutic benefit might function.

Having said that, the foundation for the proposed changes merits additional analysis. The Discussion Paper includes a summary question on therapeutic benefit, inquiring whether PMPRB should adapt its guidelines to questions of “market dynamics, high prices or affordability” and “prioritize its enforcement resources on cases where payers are most in need of regulatory relief.” A “risk-based” approach that employs a tiered level of regulatory oversight may be appropriate, and most efficient.

For many products under PMPRB jurisdiction, there are clear external price signals, including those with generic competitors, slight or no improvement category medicines, and those with robust HTA assessments. For one example, the PMPRB should take the guidelines modernization opportunity to consider reducing oversight in selected cases, for example, for multi-source patented products. As noted above, if the PMPRB only reviewed single-source patented products, Canadian prices drop



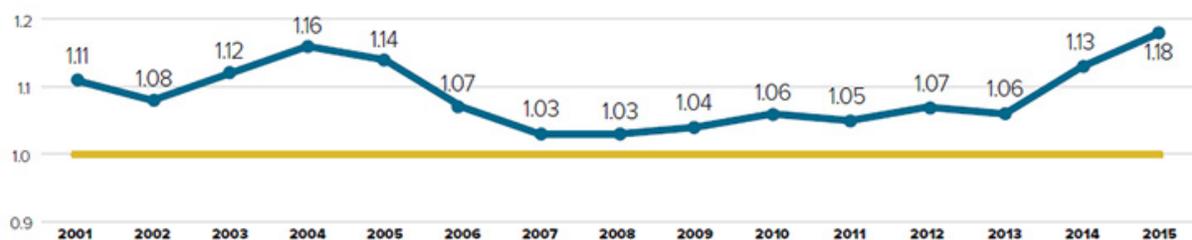
further relative to the median for the same drugs across PMPRB comparator countries. The Board already has significant discretionary power on what should be part of its scope of reviews – and consequently has decided to require limited price reporting from patented veterinary, over-the-counter, and multi-source medicines. Reducing the scope of its regulatory mandate to focus on only drugs that are exclusive due to a patent would be consistent with the policy rationale for the Board’s excessive pricing safeguard function.

b. International Price Comparisons

One of the factors in the *Patent Act* for the PMPRB to consider when conducting price reviews is the comparable international prices of the medicine in question. The PMPRB is questioning the rationale for this approach and the currently-used methodology to achieve its “consumer protection” mandate.

As the PMPRB itself notes, the ex-factory prices of patented medicines in Canada remain below or equal to the median of international prices (*Figure 6*) as defined by our comparator countries as per the *Patented Medicine Regulations*: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the USA^{52,53} (the PMPRB7). Canada’s ranking⁵⁴ has fluctuated over time, and has never been reported to be the highest nor the lowest among the PMPRB7 on average. It should be noted that the PMPRB’s Strategic Plan relied and referenced data for one single year, and ranking can change dramatically from one year to the next. Notably, the ranking of 2013 has since changed in an opposite direction (*Figure 7* next page).

Figure 6 - Average Ratio of Median International Price (MIP) to Canadian Price, at Market Exchange Rates, 2001–2015⁵⁵



Source: PMPRB

Using public list prices, the PMPRB reports that Canadian prices actually declined relative to the PMPRB7 over the past two years (*Figure 7* next page). Since 1994, the year when the PMPRB first implemented international reference pricing rules in its Guidelines, average ex-factory prices in Canada have been consistently lower than the median prices across the PMPRB7.⁵⁶ In its 2015 Annual Report, the PMPRB reported that median international prices were 18% higher than Canadian prices (*Figure 6*).



This is the lowest Canadian prices have ever been in relation to comparator countries in PMPRB reported history (since 1994). In a country-to-country comparison, Canada was tied with Switzerland, ranking third/fourth, behind both Germany and the United States.⁵⁷ (Figure 7)

Figure 7 - PMPRB Assessment of Patented Medicines Relative Prices, Canada vs Individual Comparator Countries, 2005 vs 2015 (left), and 2005 vs 2013 (right)⁵⁸

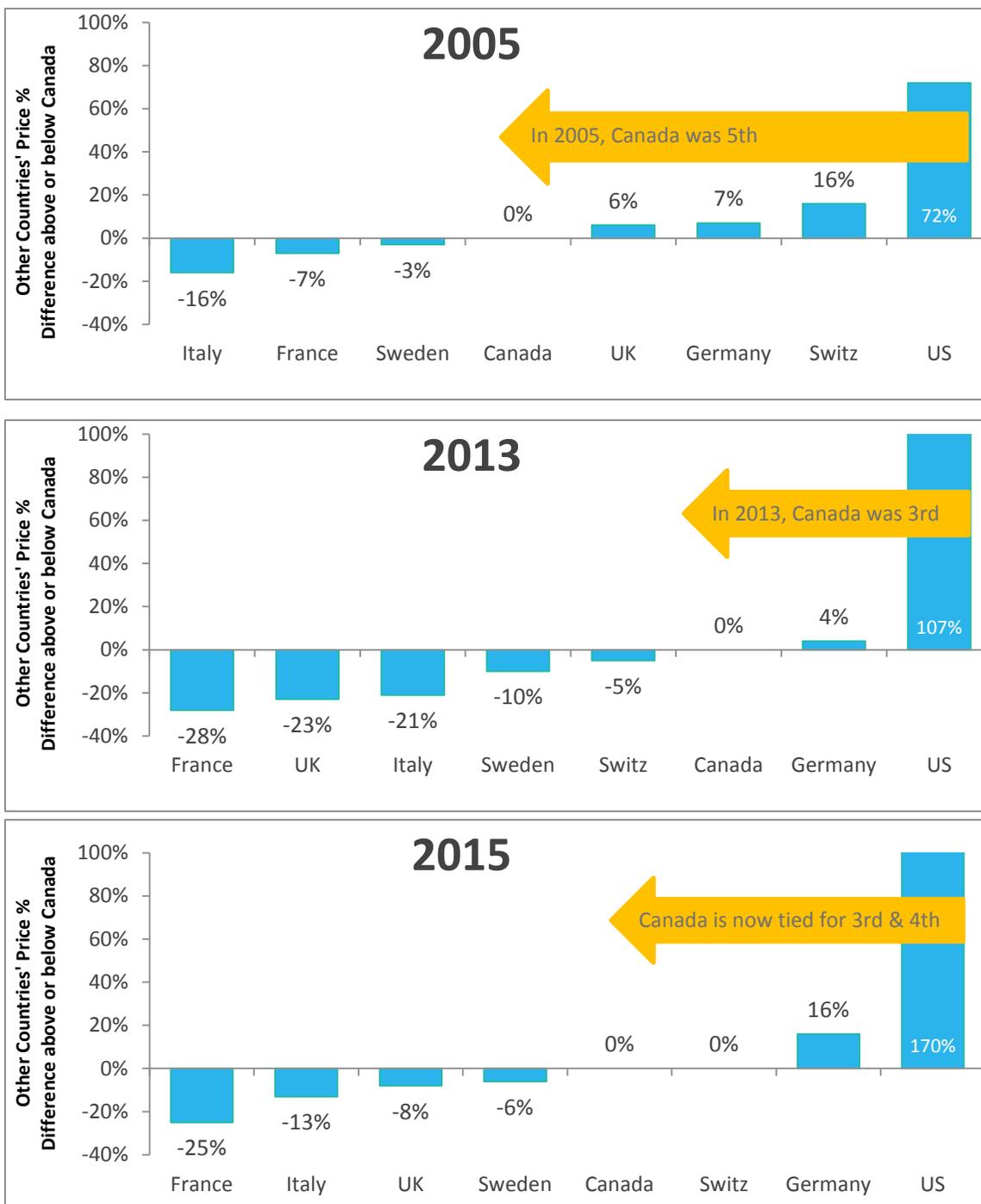
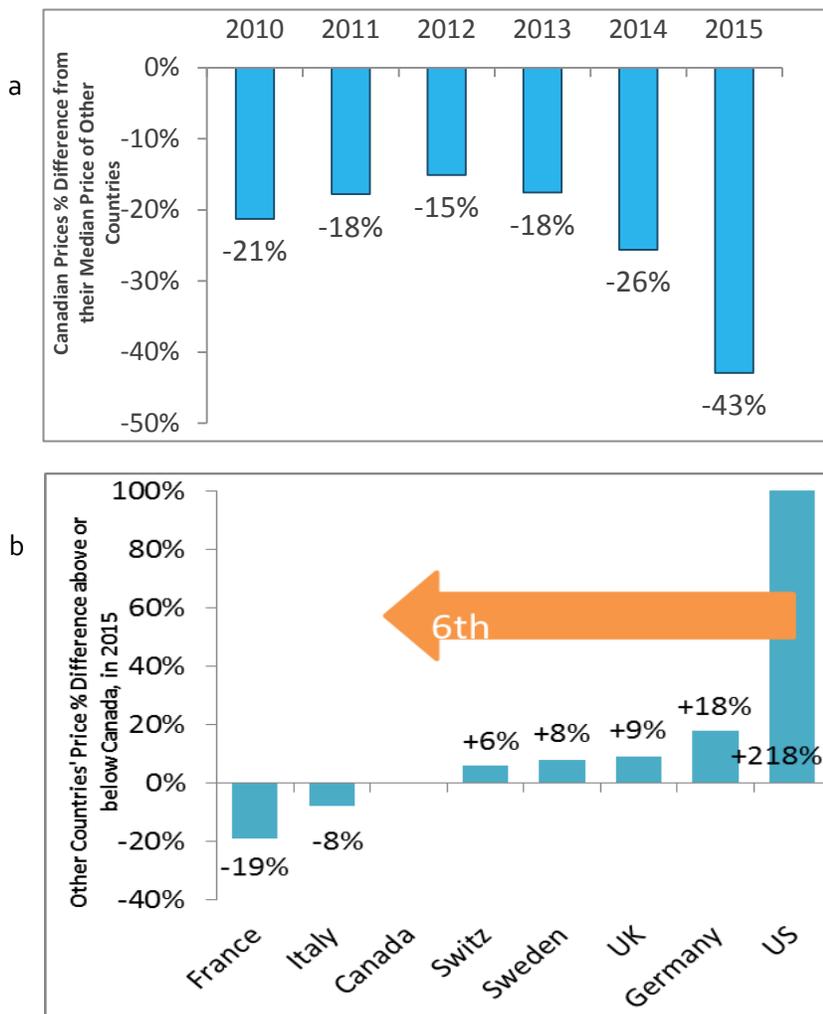




Figure 8 - Market-Exclusive Patented Medicines (no generic competitors) Relative Prices, Canada vs Individual Countries



If one compares Canadian relative prices to its more appropriate comparators (i.e., the PMPRB7), then Canadian payers have in fact already saved billions of dollars since 1994 (i.e., the year that international reference pricing was put in place), and in 2015 alone, payers saved \$2.7 billion compared to the median price (Figure 9b next page). Cumulatively since 1994, Canadian payers and consumers have potentially saved \$18.1 billion (estimated double that if using the average).⁵⁹ (Figure 9a & b next page)⁶⁰

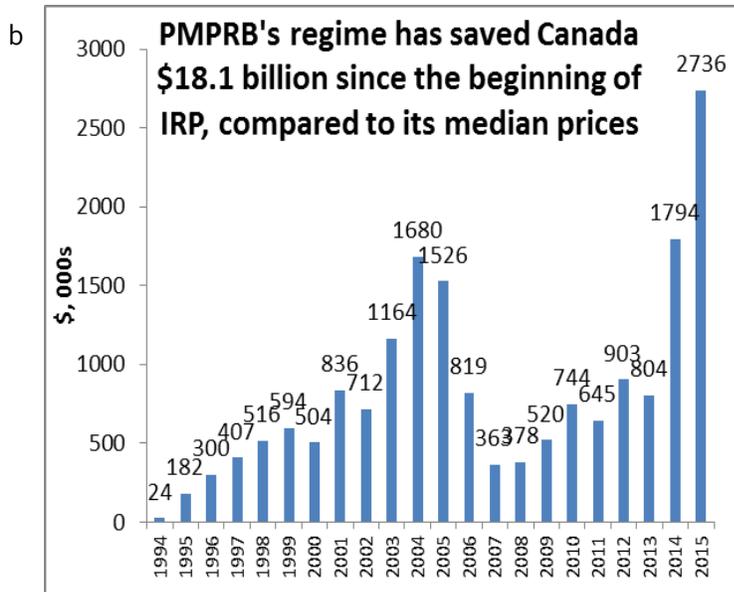
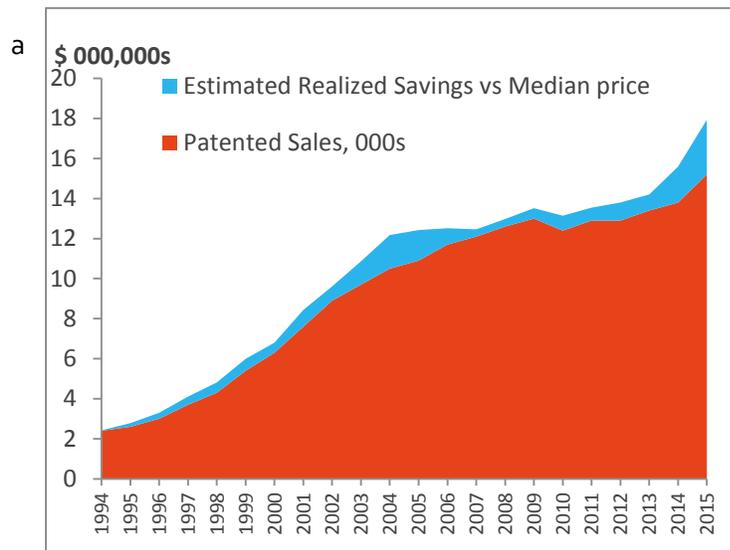
Innovative Medicines Canada believes that any potential changes to the basket of comparator countries (the PMPRB7) or the methodology to reduce price ceilings relative to the PMPRB7 needs to consider and thoroughly analyze, to the extent possible given the confidential nature of

the commercial terms within product listing agreements, the Canadian pharmaceutical market, our trading relationship with the United States and Europe, and our collective capacity to invest in healthcare and new technologies, including pharmaceuticals.

In addition, we should remember that Canada and the US are very similar in the proportion of the pharmaceutical market covered by private insurance, unlike most other countries. The United States is by far Canada's biggest trading partner. We share the world's largest border with the US, and rely heavily on free trade in goods and services between the two countries. Canada benefits mightily from this geographic location as a trading nation and in terms of access to new pharmaceutical products at a significantly reduced rate in terms of the public ex-factory list price. As many as 10% of products under PMPRB jurisdiction are only available in the United States in Canada, and are not even sold in the European Union or other nations.⁶¹ There are also many important similarities in the practice of medicine between the two countries, particularly with respect to the utilization of medicines.



Figure 9 - Realized Savings, Canadian Prices Relative to the Median, 1994-2015



There are many countries that engage in international reference pricing. The selection of countries to reference is largely based on proximity, and/or similarity of economies. Similar and close European countries reference one another's prices.⁶² It makes sense, then, that Canada would reference prices in countries close and similar to its own, including the United States, as well as similar European economies. It should also be noted that Canada, via the PMPRB, is not the only country that takes therapeutic innovation into consideration in relation to pricing – however, Canada is unique in that innovation is directly tied to international prices.⁶³

In sum, there are challenges in making international price comparisons; however, PMPRB has applied price ceilings in a way that has generally allowed patentees to sell their products in Canada and adjust for exchange rate fluctuations and other uncertainties. There is no strong evidence to support changing the comparator countries for the sole purpose of lowering Canadian patented drug prices.

As Canada's most important partner in terms of trade and regulatory cooperation, retain the United States within the basket of countries that are used for international comparison purposes.



c. Domestic Price Comparisons

The Discussion Paper presents varying perspectives on the relevance of the domestic therapeutic class comparison test when applied to the “slight or no improvement” category of drugs. These products include a new alternative in an existing therapeutic class or disease category, a new line extension of an existing molecule, or a new entrant in a class that already faces generic competition. The Discussion Paper notes that these products already “face some measure of competition” and acknowledges that payers, patients and clinicians are best positioned to determine which products should be prescribed in a given therapeutic class.

As noted above, patented drugs already face significant HTA and payer scrutiny and obstacles, and these obstacles are even higher when other therapeutic alternatives exist. Naturally, this forces prices down – both list prices and confidential negotiated prices – below what would be permissible under the PMPRB ceiling, which does not allow for any patented medicine to be priced higher than the comparator products.

The Discussion Paper provides no data to support its suggestion that there is a problem in how it applies domestic price comparisons. There is a suggestion that Canada faces an “upward drift” in prices, but no data is presented to show that this is the case, or that prices are generally priced at the top of the therapeutic class for subsequent entrants. In fact, prices in Canada have increased very little year-over-year since the inception of the PMPRB e.g. 0.1% in 2015.

Finally, any proposed changes should also consider the impacts of more aggressive price regulation on subsequent entrants in a class of products. We note several positions taken by PMPRB staff in an ongoing hearing, related to applying economic factors⁶⁴ to determine “excessive”, and seeking to apply a “lowest international price” comparison⁶⁵. Lower price ceilings, whether applied through domestic price comparisons or international price comparisons, or otherwise, could disincentivize companies from marketing subsequent product class therapies in Canada, reducing competition and unnecessarily limiting the range of innovative therapies available to Canadian patients and would also limit competition as fewer competitors may be marketed in a given class. Finally, it would also reduce the number of marketed alternatives that are part of a solution to addressing drug supply shortages, which Canada has experienced in recent years.

If any specific changes in how domestic price comparisons are proposed, analyze implications, especially with respect to market dynamics, incentives for price and product differentiation within therapeutic classes and security of Canada’s supply of patented medicines.

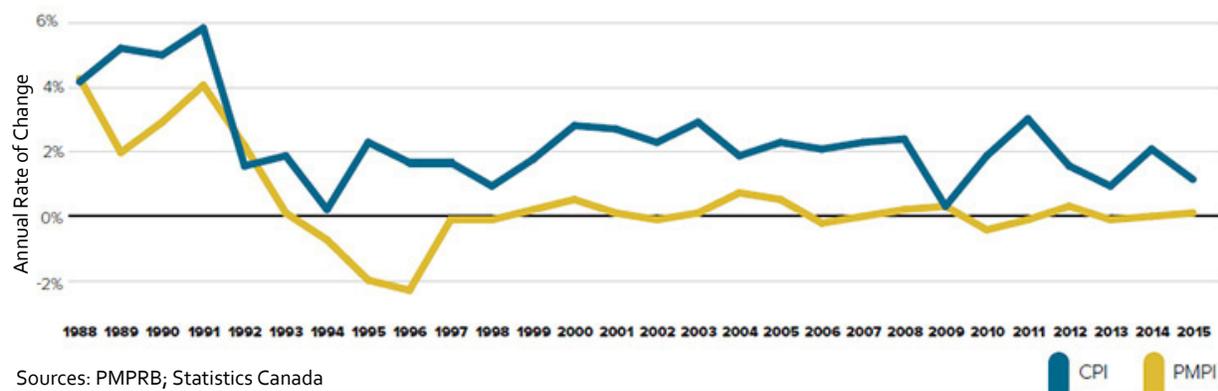


d. Price Increases Based on Changes in the Consumer Price Index

The *Patent Act* requires the PMPRB to take into consideration changes in the Consumer Price Index (CPI) in determining if a price is excessive. This provision was intended to address the fact that drug prices in Canada were increasing at much higher rates at the time the PMPRB was created.

The PMPRB Guidelines limit allowable price increases to be no higher than the Consumer Price Index (CPI). Data actually shows that patented medicines have been increasing at rates at or below 0% since 1993, and consistently below CPI since 1988⁶⁶. (*Figure 10*)

Figure 10 - Annual Rate of Change, Patented Medicines Price Index (PMPI) and Consumer Price Index (CPI), 1988–2015



The limit on price increases to changes in the CPI has been a key feature of the PMPRB throughout its history. Over time, we have seen that other market forces and payer policies have also constrained price increases and as a result, prices have never risen by more than CPI since 1993. According to the PMPRB’s own reports, prices on the whole have shown essentially no increases, and sometimes even declined, since that time. (*Figure 10*)

Although the Discussion Paper refers to some policies in European countries that require price reductions in some circumstances, no supporting evidence is provided showing how these reductions were applied or sustained. Instead, as noted above, price levels in the PMPRB7 appear to fluctuate within a relatively small band from year to year and in comparison to Canada have actually risen in all comparator countries relative to Canada between 2013 and 2015. (*Figure 7* page 18)

Given that prices for patented medicines do not increase substantially after their introductory price, and Canadian payers are already imposing effective limits on price increases in their price negotiations, it is unclear why this long-established and successful element of the PMPRB program would be re-evaluated.



e. Frequency of Reviews

Reassessment of the price of innovative medicines already exists in the current system in Canada. In both public and private markets, it is generally accepted practice that confidential negotiations for innovative medicines are re-negotiated. This will occur for a number of reasons. For example, contract terms generally require revision after a pre-specified period of time to level set, review the experience to date and ensure both parties achieve the desired outcome going forward. Also, when a new indication for a medicine is approved a re-negotiation of terms will be based on an assessment of the combined benefit or risks the medicine now offers. This is only after the new indication has gone through a stringent health technology assessment via CADTH, INESSS or the respective private drug plan benefits manager. Finally, when market dynamics change significantly, a contract can be opened and re-negotiated in light of this new environment. In all of these cases, these contract re-negotiations act as a form of “re-benchmarking” for payers to ensure that over time they are achieving the best value to meet the needs and objectives of their drug plan. This is the appropriate venue for re-assessment to occur over time, as responsibility and accountability sits with the budget holder. It is unclear what value a change in PMPRB’s Guidelines would add to the existing system.

f. Any Market Price Reviews

The role of the PMPRB is to look at the price sold to ex-factory customers. When doing so, the PMPRB regulates the average transaction price. Regulation of an average price allows flexibility within the market and across customer classes to offer benefits while ensuring that the average price to any specific class of customer or region is not excessive. This is a practical necessity in light of commercial realities and the downstream distribution chain for innovative medicines. For example, prices to wholesalers may differ based on quantities ordered and hospitals may negotiate different contracts with time-limited benefits (thus lowering average price in those markets). At the same time, provinces each have their own pricing policies with respect to price increases over time (thus permissibly increasing average price in some markets, but not others).

As mentioned by the PMPRB in its Discussion Paper, the Patent Act already “empowers the PMPRB to evaluate whether the price of a patented medicine is excessive ‘in any market’ in Canada”. This enables PMPRB to investigate and scrutinize prices at the wholesaler, pharmacy and hospital levels and in each province and territory to ensure that the average price paid is not excessive. Movements by the PMPRB toward a single price are counter to past PMPRB positioning where benefits to customers are encouraged (e.g. the introduction of the DIP methodology in the 2010 Guidelines) as well as previous Federal Court rulings that differential pricing is an attribute of the current legislative regime⁶⁷. Changes that would require price parity remove the opportunity and incentive to offer benefits to customers and risk serious unintended consequences within the distribution chain.



In the absence of specific and demonstrable challenges or issues, retain the current approach that limits federal regulatory price reviews and reductions in “any market.”

CONCLUSION

In summary, the Canadian pharmaceutical environment has changed considerably compared to when the PMPRB was created. There now appears to be some duplication and overlap between the PMPRB and other agencies that review drugs for safety and efficacy, cost-effectiveness, and price negotiations for reimbursement. PMPRB continues to play an important role as a safeguard against the potential risk of excessive prices on patented medicines sold in Canada. This role does not duplicate the efforts of other agencies, does not hinder competition in the market, and allows Canadian patients to potentially have access to more innovative medicines, thereby improving health outcomes.

We support and will continue to support Canadian patients, governments and payers in finding solutions to affordability and sustainability. The issues are bigger than *price*, however, and broader than patented medicines. Collaborative approaches are required to find solutions that first and foremost benefit patients and are sustainable for payers, the health care system, the economy, and industry.

The proposed changes to the Guidelines proposed by the PMPRB are not all supported by evidence and do not address a clearly-defined objective or problem statement. More analysis is needed to ensure that any changes to the PMPRB Guidelines consider all relevant factors and views, and have the desired outcomes without leading to unintended consequences.



ENDNOTES

¹ In *Apotex Inc. v. Wellcome Foundation Ltd.*, Binnie J. explained the value of assuming the risks: “A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the *quid pro quo* for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*”.

² *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*, [1989] 1 S.C.R. 1623, at p. 1636.

³ *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, [2012] 3 S.C.R. 625, at 32.

⁴ Sources: Brand Loss of Exclusivity (LOE) value from IMS Brogan Pharmafocus 2020, Section 9, Figure 18. Generic sales resulting from LOEs, and Generic substitution calculated by Innovative Medicines Canada based on data from PRA Pricing Monitor, February quarterly issues for 2006, 2007, and 2016 and from NPDUIS, Generics 360, 2016. Assumptions include: 50% generic share of utilization in year 1, 85% yearly thereafter. Brands retain 15% of market share 2 years after LOE. Generic prices adjusted yearly to reflect brand price ratio reductions over time.

⁵ Glossary of Industrial Organisation Economics and Competition Law, OECD, <http://www.oecd.org/regreform/sectors/2376087.pdf>

⁶ Schedule, Patented Medicines Regulations: France, Germany, Italy, Sweden, Switzerland, United Kingdom, United States

⁷ In contrast, Canadian prices for generic medicines are consistently above international comparator prices. Source: PMPRB Annual Report 2015, NPDUIS Generics360, February 2016.

⁸ PMPRB Strategic Plan 2015-2018, “A sustainable pharmaceutical system where payers have the information they need to make smart reimbursement choices and Canadians have access to patented medicines at affordable prices.”

⁹ The Regulatory Impact Assessment Statement accompanying the Patented Medicines Regulations, 1994 – which specifies the information that patentees must file with the PMPRB so that it may conduct price reviews in line with the above criteria – creates an important distinction between the terms ‘excessive’ and ‘affordable’. It indicates that excessiveness is the cause, and affordability the effect, of the Board’s decisions:

*The current reporting requirements and timeframes lead to inefficiencies in the price review process and, hence, potentially longer timeframes during which drugs may be sold at excessive prices. This can directly affect consumers’ ability to afford the medicines they require and cause delays or refusals by, or costs to, public drug plans relative to the listing of new drugs for the purpose of reimbursement. For these reasons, the status quo is not an acceptable option*⁹. [Emphasis added.]

¹⁰ The Institute on Governance, in its evaluation of the governance of the PMPRB in terms of its adherence to both the letter and the intent of the *Patent Act*, concluded that the Board had expanded its original purpose without legislative approval: *We can find no documentary evidence that the PMPRB has, as part of its mandate, the*



responsibility to prevent a major shift in pricing (unless of course it believes, after the fact, that this shift has created an excessive price for a specific drug), to ensure price stability, to maintain the sustainability of the health care system or to see to it that Canadians have the ability to afford the drugs they need. Canada Gazette, Part I, Regulations Amending the Patented Medicines Regulations, 1994, Vol. 141, No. 40 – October 6, 2007 at 2878.

¹¹ Hancock KE. 'Can pay? Won't pay?' or Economic Principles of Affordability. *Urban Studies* 1993; 30: 127-45.

¹² Even the definition of affordability itself is fraught with debate, as it is considered arbitrary and vague within the context of health care. Some argued it is a normative issue that has no basis in an economic foundation. Bradley R. Comment - defining health insurance affordability: unobserved heterogeneity matters. *J Health Econ* 2008; 27: 1129-40 doi:10.1016/j.jhealeco.2008.02.004 pmid: 18359526.

Stone ME. What is housing affordability? The case for the residual income approach. *Housing Policy Debate* 2006; 17: 151-84 doi:10.1080/10511482.2006.9521564.

¹³ *Canadian Dairy Commission Act*, RSC 1985, c C-15 at Subsection 9(1).

¹⁴ *Canadian Wheat Board Act*, RSC 1985, c C-24 at Subsection 7(1).

¹⁵ *Canada Post Corporation Act*, RSC 1985, c C-10 at Subsection 19(2).

¹⁶ *Telecommunications Act*, SC 1993, c 38 at Subsection 27(1).

¹⁷ *Canada Oil and Gas Operations Act*, RSC 1985, c O-7 at Subsection 13.05.

¹⁸ *National Energy Board Act*, RSC 1985, c N-7 at Section 62.

¹⁹ *Air Transportation Regulations*, SOR/88-58, at Subsection 111(1).

²⁰ Lichtenberg, Frank. The Benefits of Pharmaceutical Innovation: Health, Longevity, and Savings. Montreal Economic Institute, June 2016. Available at: http://www.iedm.org/files/cahieroz16_en.pdf

²¹ The pan-Canadian Pharmaceutical Alliance. The Council of the Federation <http://www.pmprovinceterritoires.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance>

²² The pan-Canadian Pharmaceutical Alliance. The Council of the Federation <http://www.pmprovinceterritoires.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance>

²³ CIHI NHEX 1975-2014.

²⁴ Hon. George Smitherman, Legislative Assembly of Ontario, Thursday 13 April 2006

²⁵ Pan Canadian Drugs Negotiations Report, March 22, 2014

²⁶ To help fully insured drug plans – mostly made up of small employers – who experience unexpected high costs, the Canadian Drug Insurance Pooling Corporation (CDIPC) was established by all insurance carriers across Canada to help “facilitate affordable drug coverage while maintaining a competitive health insurance market”. It provides protection both at the plan sponsor level and at the insurance carrier level, creating an industry-wide pool that spreads the risk across the whole insurance carrier market.



²⁷ While these contracts and the terms are confidential in nature, some of them have been made public. For example, Remicade preferred pricing agreements with Sun Life and Manulife.
https://www.sunlife.ca/Canada/smallbusiness/Focus+news/2014+issues/Sun+Life+has+a+new+arrangement+with+Janssen+Inc+to+reduce+costs+on+REMICADE?vgnLocale=en_CA

²⁸ Health insurer's U.S.-style plan seeks to 'manage' members' drug costs. National Post. **July 25, 2012.**
<http://news.nationalpost.com/news/canada/health-insurers-u-s-style-plan-seeks-to-manage-members-drug-costs>

²⁹ Skinner, B.J. Spending on patented drugs in Canada 1990 to 2014.
<http://www.canadianhealthpolicy.com/products/spending-on-patented-drugs-in-canada-1990-to-2014-.html>

Note that we use 2014 data as this is the most recently available non-estimated data point from CIHI (total healthcare spending for 2015 was estimated in 2015; at the time, 2014 data point was much more precise).

³⁰ Plan (non-drug related) Costs include mark-ups, dispensing fees, plan administration costs, and research expenditures.

Drug Acquisition Cost = sales made at ex-factory prices directly from manufacturer. Represents the revenues to pharmaceutical manufacturers from drug sales (excluding confidential rebates). Total Drug Spending includes hospital sales as a proxy for total hospital spending on drugs in Canada. This is added to the total reported prescription drug spending by CIHI of \$28.7 billion, to reach \$31.5 billion in 2014.

Source: CIHI NHEX 1975-2015, PMPRB Annual Report 2014, and IMS Brogan Canadian Drug Stores and Hospitals. Estimates and analysis by Innovative Medicines Canada.

³¹ Skinner, B.J. Spending on patented drugs in Canada 1990 to 2014.
<http://www.canadianhealthpolicy.com/products/spending-on-patented-drugs-in-canada-1990-to-2014-.html>

³² The United States, France, and Slovenia, are the only other countries with comparable importance of the private drug coverage market. Source: OECD Health at a Glance 2015.

³³ Source: CIHI NHEX 1975-2015

³⁴ Skinner, B.J. Spending on patented drugs in Canada 1990 to 2014.
<http://www.canadianhealthpolicy.com/products/spending-on-patented-drugs-in-canada-1990-to-2014-.html>

³⁵ Skinner, B.J. Spending on patented drugs in Canada 1990 to 2014.
<http://www.canadianhealthpolicy.com/products/spending-on-patented-drugs-in-canada-1990-to-2014-.html>

³⁶ Source: CIHI NHEX 1975-2015

³⁷ Source: CIHI NHEX 1975-2015 and 1975-2014 (Table 3), CLHIA. Estimates by Innovative Medicines Canada.

³⁸ Source: CIHI NHEX 1975-2015

³⁹ Source: CIHI NHEX 1975-2015 and 1975-2014 (Table 3), CLHIA. Estimates by Innovative Medicines Canada.

⁴⁰ Survey of Household Spending (SHS) Table 203-0021, Statistics Canada



⁴¹ Depending on the definition used, anywhere from 1% to 20% of Canadians are uninsured or under-insured

⁴² Skinner, BJ; Rovere, M; Mohindra, M; and Tran, K (2015). Pharmacare: what are the costs for patients and taxpayers? *Canadian Health Policy*, September 24, 2015. Toronto: Canadian Health Policy Institute (CHPI).

⁴³ Health Canada ADM, HESA hearing, April 2016. Data sourced from 2000 study commissioned by Health Canada.

⁴⁴ Law, Cheng, Dhalla, Heard, Morgan. The effect of cost on adherence to prescription medications in Canada. *CMAJ* 2012.

⁴⁵ KPMG, R&D Spending and Investments by IMC Members - Product donations to patients through compassionate use and special access programs

⁴⁶ Hermus, G. et al. Reducing the Health Care and Societal Costs of Disease: the Role of Pharmaceuticals. Conference Board of Canada 2013. <http://www.conferenceboard.ca/e-library/abstract.aspx?did=5598>

⁴⁷ Conference Board of Canada 2016. The Value of Specialty Medications: An Employer Perspective. http://www.conferenceboard.ca/temp/93c4d2c3-6647-42ec-a55a-f7677e647253/8157_specialty-medications_rpt.pdf

⁴⁸ Lichtenberg, Frank. The Benefits of Pharmaceutical Innovation: Health, Longevity, and Savings. Montreal Economic Institute, June 2016. Available at: http://www.iedm.org/files/cahier0216_en.pdf

⁴⁹ PMAC Letter to Minister of Industry, Science & Technology, June 10, 1993

⁵⁰ 1998 September Report of the Auditor General of Canada, Chapter 17 – PMPRB

⁵¹ Summary of 2013 R&D Spending and Investments by Rx&D Members

⁵² PMPRB Frequently Asked Questions, Updated June 2016; see: <http://www.pmprb-cepmb.gc.ca/about-us/frequently-asked-questions#1404>

⁵³ PMPRB Discussion Paper, p. 16.

⁵⁴ “Ranking” is a very simplistic way to compare prices in Canada to other countries. It is influenced year to year by many factors not directly related to pricing, including exchange rate fluctuations and the inconsistent basket of products that are being compared to other countries, as well as sales patterns in Canada.

⁵⁵ PMPRB Annual Report 2015.

⁵⁶ PMPRB Annual Reports (2001-2015). France, Germany, Italy, Sweden, Switzerland, United Kingdom, United States.

⁵⁷ PMPRB Annual Report 2015.

⁵⁸ PMPRB Annual Reports



⁵⁹ Based on PMPRB data from PMPRB 2015 Annual Report. Canadian patented sales, and the median to Canadian price ratio. If Canada used the average of PMPRB7 instead of the median, Canada would have saved at least double, based on “mean” data reported by PMPRB.

⁶⁰ Based on PMPRB data from PMPRB 2015 Annual Report. Canadian patented sales, and the median to Canadian price ratio. If Canada used the average of PMPRB7 instead of the median, Canada would have saved at least double, based on “mean” data reported by PMPRB.

⁶¹ Source: Form 2 Block 5 data submitted to PMPRB, July-December 2015, Innovative Medicines Canada members.

⁶² OECD Health Policy Studies. Pharmaceutical Pricing Policies in a Global Market. 2008.
<http://apps.who.int/medicinedocs/documents/s19834en/s19834en.pdf>

⁶³ OECD Health Policy Studies. Pharmaceutical Pricing Policies in a Global Market. 2008.
<http://apps.who.int/medicinedocs/documents/s19834en/s19834en.pdf>

⁶⁴ Expert Report of Sumanth Addanki, Dated 16 February 2016

⁶⁵ Decision of the Board on the motion of Board Staff to Amend the Statement of Allegation and Strike Certain Portions of Will-Say Statement: June 10, 2016

⁶⁶ PMPRB Annual Report 2015.

⁶⁷ Leo Pharma Inc. v. Canada (Attorney General), 2007 FC 306 (CanLII), par. 56