

June 28, 2017

The Honourable Jane Philpott, P.C., M.P.  
Minister of Health  
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Brooke Claxton Building  
Tunney's Pasture  
Ottawa, Ontario, K1A 0K9

Sent by email: [PMR-Consultations-RMB@hc-sc.gc.ca](mailto:PMR-Consultations-RMB@hc-sc.gc.ca)

Dear Minister Philpott:

BIOTECCanada is responding on behalf of its members to your request for feedback on proposed changes to the *Patented Medicines Regulations*. The industry appreciates your launch of this consultation and the opportunity to provide input.

The biotechnology industry is at the forefront of leading advances in science to diagnose disease and develop precision therapies and medicines. These medicines deliver substantial cost savings to the healthcare system by treating, preventing and curing diseases and reducing expensive hospital stays. BIOTECCanada is committed to work with Health Canada in seeking to integrate these new technologies into the healthcare system in the context of your focus on the affordability, accessibility and appropriate use of prescription medicines.

The biotechnology industry recognizes and supports the government's priorities of affordability, accessibility and appropriate use of prescription medicines. Governments across Canada, and indeed throughout the world, are tackling the challenges in ensuring optimal healthcare for their populations; among these challenges is the fiscal pressure arising from an aging population, new technologies and budget needs in other areas.

Today, producers of medicines already navigate a complex, time consuming and expensive path in Canada to gain market access following a vigorous Health Canada regulatory review for safety and efficacy. The time and complexity of bringing new products to market delays a patient's access to new medicines. These access delays reflect, in large part, the proliferation of new review processes since the Patented Medicine Prices Review Board's (PMPRB) inception that manufacturers must now also navigate. These include the Canadian Agency for Drugs and Technologies in Health's (CADTH) health technology assessment (HTA), joint price negotiations through the pan-Canadian Pharmaceutical Alliance (pCPA) and individual provincial product listing agreement processes.

The development of a federal Innovation Agenda is now underway with health and biosciences identified in Budget 2017 as one of six Economic Strategy Tables to seek out innovation opportunities and promote the growth of Canadian companies. With the ability to map the human genome, new innovative medicines and therapies are being brought forward for patients that are

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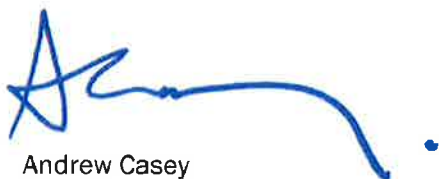
significantly changing how healthcare is delivered. In developing the Innovation Agenda the government has signalled its recognition of the economic opportunity biotechnology innovation represents both on its own and in enhancing the competitiveness of other Canadian economic sectors.

The existing biotechnology ecosystem in Canada is well positioned to be a major contributor to solutions for the challenges in healthcare. However, moving from a great idea to global commercial success is highly dependent on the company's ability to attract partners, investors and talent to drive the innovation forward. Canada must do all that it can to be as competitive as possible to support companies in meeting their efforts to commercialize innovation. In this context, Canada must remain globally competitive with other jurisdictions in order to attract investors, pharmaceutical partners and talent. While industry plays a lead role in attracting investment, government policy establishes the hosting conditions that attract capital. Canada should be at the leading edge in healthcare in a high technology economy.

In addressing the specific issue of the prices of patented medicines, it will be important to consider the impact on all health care priorities and also the wider national and pan-Canadian objectives to develop a healthcare industry of the future. Canada is one of the leading countries in its infrastructure, support for research and clinical trials in a high quality regulatory system. While the Canadian pricing and reimbursement system is seen as tough and rigorous by international standards, it is on par with our leading trading partners. The industry is concerned the proposals for PMPRB reform if made in isolation of other priorities on innovation, by creating regulatory overlap, duplication and market uncertainty by seeking to position Canada in the mid-range of the OECD, will upset this delicate balance and discourage investment in the health and biosciences.

The biotechnology industry is prepared to work with you in developing forward-looking approaches to manage the difficult issues of pricing and reimbursement of these products. It is hoped your consultation paper is the beginning of a larger dialogue.

Sincerely,



Andrew Casey  
President and CEO

Enclosure:

BIOTECanada Comments to Health Canada - Patented Medicines Regulations Consultations

BIOTECCanada Submission to Health Canada  
Consultation on Proposed Amendments to the Patented  
Medicines Regulations

## Executive Summary

- BIOTECanada supports the Minister of Health's objective to address the affordability, accessibility and appropriate use of prescription medicines and would like to work with governments to further those goals.
- The industry is concerned the proposed regulatory amendments will not achieve the Health Minister's specific objective to align regulatory processes to speed up access for patients to breakthrough treatments and those goals are furthermore **inconsistent** with the government's Innovation Agenda.
- The proposals would introduce **regulatory overlap and duplication** with existing provincial and FPT drug pricing and reimbursement systems.
- The proposals are **vague** and would create market uncertainty and lack of clarity on pricing rules and thresholds throughout a product's lifecycle.
- The result will be **delays** in the launch of innovative therapies in Canada and harm to investments in clinical research.
- The proposals are likely to **disrupt provincial policies** to extract maximum value in drug coverage decisions based on local circumstances and needs.
- The legal framework of the PMPRB, as a quasi-judicial tribunal, is not appropriate for assessing the new economic factors proposed. The legal uncertainties with these proposals and pricing rules would put manufacturers at such high risk when launching new products that it may discourage them from doing so.
- The proposals would add to the uncertainty in the business environment at a time when other major policies are under review, including the upcoming NAFTA trade negotiations and implementation issues with CETA.
- The government has not provided any information on the **impact assessment** of the proposals and on the possible unintended consequences such as delays to access important medicines.
- These proposals have far-reaching and significant impact but Health Canada has limited consultation to a six-week period, an insufficient time given the complexity of the issues and potential impacts on the regulated industry, patients, public and private payers and access to health care.

## The Biotechnology Industry

BIOTECanada is the national industry association for Canada's health, industrial and agricultural biotechnology sectors. The Association's 230 members are reflective of Canada's biotechnology ecosystem located in every province of the country and includes emerging research-focused small and medium sized enterprises, universities, investors, incubator and accelerator organizations and multi-national corporations.

The past century has seen remarkable achievements by Canada's biotechnology sector in developing new health technologies and improving the lives of Canadians and people throughout the world, achievements such as:

- The discovery of insulin in 1922;
- Discovery of diphtheria vaccine;
- The licensing of the first polio vaccine in 1955;
- Stem cell technologies;
- Visudyne for the treatment of age-related macular degeneration; and
- More recently, significant contributions to the development of an Ebola vaccine.<sup>1</sup>

The benefits from biotechnology in contributing to improved health outcomes are well known. In the past generation, diseases such as HIV/AIDS, Hepatitis C, certain cancers and some rare diseases have shifted from being fatal diseases to being treatable and in some cases to being preventable and even curable. Advances in vaccines development have included the HPV vaccine, which has reduced the incidence of cervical cancer by 50% in the past decade.<sup>2</sup> Many Canadians are living longer, more productive and higher quality lives today because of drug therapy advances over the past 30 years.

Today's biotechnology ecosystem is much more than a research lab in an established pharmaceutical company. It includes early stage catalysts and incubators, investment capital, over 500 early stage biotechnology companies, and partnerships with global companies.

The Government of Canada has recognized the importance of this sector to Canada's future in its Innovation Strategy. As announced in Budget 2017, the government has targeted health and bio-sciences as one of six innovation superclusters that have the greatest potential to accelerate economic growth. The industry is excited by this challenge and the opportunity to build on recent initiatives such as JLABS Toronto, MaRS, Institute NEOMED, Centre for Drug Research and Development (CDRD), Accel-Rx, and Institute for Research in Immunology and Cancer – Commercialization of Research (IRICoR). These partnerships and investments are now underpinning a vibrant biotech ecosystem that is positioned to become a leading part of Canada's high technology future and economic growth.

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<sup>1</sup> <http://ottawacitizen.com/news/national/the-canadian-vaccine-how-scientists-in-a-country-without-a-single-case-of-ebola-wrestle-the-deadly-disease-to-the-ground>

<sup>2</sup> <http://www.stuff.co.nz/world/australia/83779246/10-years-on-hpv-vaccine-halves-cervical-cancer-rates>

## Issues and Opportunities for Policy Change

In response to concerns in 1987 that *Patent Act* amendments could lead to higher drug prices, Parliament created the PMPRB to ensure patentees did not abuse their patent rights to charge excessive prices. The PMPRB program is unique; there is nothing comparable in all other countries that also have IP protection nor in all the other industries that benefit from IP laws.

A singular focus on drug costs ignores the benefits Canadians receive from new drug therapies on health and quality of life. New biotechnology derived drug treatments offer significant improvements in health outcomes allowing Canadians to lead longer and more productive lives and reduce burdens on other components of health care and social programs. Vaccines are being developed to treat diseases such as Ebola and the Zika virus; new oncology drugs are prolonging the lives of people with cancer; and biotechnology treatments for rheumatoid arthritis. We need to work together to find new treatments to save lives today and invest in future innovations.

Today, the major policy concerns raised by federal and provincial health ministers are about the “affordability, accessibility and appropriate use” of pharmaceuticals. These factors are interrelated. BIOTECanada is committed to working collaboratively with governments in support of these broad policy goals. The proposals for PMPRB reform attempt to address only one component of the broader policy issue; if addressed in isolation, there is risk policy change in this area will produce unanticipated and negative impacts on patients and the other elements of the Canadian biotechnology ecosystem.

The government's proposals are supported in large part by claims about escalating drug costs in Canada. According to the Canadian Institute for Health Information (CIHI), total health expenditures in Canada have remained relatively flat as a share of total drug spending over the past decade or more. In 2014, prescribed drug spending represented 13.6% of health care spending, the same as in 2004 and 2005.<sup>3</sup> Of greater relevance, given that the PMPRB mandate is over manufacturer *pricing* of patented drugs and not total *costs* of all drugs (which includes utilization), the PMPRB has reported overall prices of patented drugs have been stable over the past two decades, with annual average changes ranging between minus 2.2% and plus 0.7%. Relative to the countries in the current foreign basket, Canadian prices declined to their lowest level, 18% **below** the international median on average, in 2015.<sup>4</sup> For patented new active substances introduced between 2010 and 2014, Canadian

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<sup>3</sup> CIHI, National Health Expenditures, Data Tables, G.14.3 Expenditure on Drugs by Type as a Share of Public, Private and Total Health Expenditures, by Source of Finance, Canada, 1985 to 2016, <https://www.cihi.ca/en/national-health-expenditure-trends>

<sup>4</sup> It is significant that while prices for patented drugs remain stable, prices for some non-patented drugs have not. According to the PMPRB, prices to public drug plans for new non-patented drugs, which do not fall under PMPRB jurisdiction, rose 18% over the period 2009-10 to 2015-16. Canadian prices for generic drugs remain high compared to other countries. See PMPRB, NPDUIS CompassRx, 3rd Edition, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1314&lang=en>



prices in 2015 were not only below the foreign median, but were tied with Italy for fifth spot, lower than Germany, the U.K., Switzerland and the U.S. and only one percent above Sweden.<sup>5</sup>

It is true the advances in new drug technology have led to more specialized high cost drugs coming to market in Canada and elsewhere. These developments have required payers to update their policies to allow appropriate allocation of resources through the expanded use of pharmacoeconomics as a means of assessing value and increased exercise of buying power (notably by all public drug plans in Canada through the pan-Canadian Pharmaceutical Alliance). Similarly, private insurance carriers and associated pharmacy benefits managers are also actively adapting their business models to allow for better assessment of value through pharmacoeconomics, more appropriate utilization through plan management and affordability through confidential listing agreements.

Manufacturers engage in negotiations with public and private payers to establish the appropriate net pricing and conditions for coverage that meet the payers' value requirements. That is the appropriate place for price to be determined – between the supplier and the payer, taking into account all the relevant factors and variables.

#### **Proposal #1 – New Price Determination Factors**

##### *Pharmacoeconomic Evaluation*

BIOTECanada recognizes that pharmacoeconomic evaluations are used frequently by payers in price and coverage negotiations throughout Canada and elsewhere in the world. Pharmacoeconomics is recognized in the literature as a tool to assist drug plans to make decisions, but not as a tool to set prices. We are not aware of any country where a pharmacoeconomic evaluation is used outside the reimbursement system to fix the maximum allowable price of a drug.

In Canada, the principal bodies that use pharmacoeconomics in evaluating drugs are CADTH and INESSS. Beginning in the early 1990's, Canada and Australia were the first jurisdictions in the world to develop and use pharmacoeconomics in drug evaluation. Its use expanded in 2003 when FPT governments outside Quebec created the Common Drug Review (CDR), a program of CADTH, and agreed they would rely on the CDR's recommendations in considering new drugs for public coverage. Subsequently Quebec implemented its own pharmacoeconomic evaluation by INESSS and the other provinces created the pan-Canadian Oncology Drug Review and merged it with CADTH.

CADTH and INESSS conduct sophisticated pharmacoeconomic assessments and are recognized among the leaders in the world. Both programs have evolved constantly over time in response to payer needs. Today, they are the cornerstone of the pricing and reimbursement system for Canada's public drug plans. Under the pCPA, public drug plans will not consider a drug for potential reimbursement until it has been reviewed by CADTH or

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<sup>5</sup> PMPRB, Meds Entry Watch, 2015, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1307#met>

INESSS. More recently, some private insurers have introduced plans to also rely on CADTH recommendations while others rely on their own assessments.

The consultation paper provides no details on how the PMPRB would use pharmacoeconomics in carrying out its mandate. To establish a maximum non-excessive price for purposes of bright guidelines requires a precise calculation. That is not possible in the case of pharmacoeconomics because it is not a precise science. Assessments are based on a multitude of assumptions and are dependent on the perspective employed. The industry is not aware of any jurisdiction in the world attempting to establish a nation-wide maximum non-excessive price for a medicine based on pharmacoeconomics, so there are no precedents allowing us to contemplate how it might be applied by the PMPRB.

The proposed regulation would require consideration of “the pharmacoeconomic evaluation for the medicine and other medicines in the same therapeutic class in Canada and in countries other than Canada.” This requirement would create a large additional regulatory burden for the PMPRB and manufacturers. In Canada, pharmacoeconomic assessments by CADTH and INESSS are conducted in the specific context of the participating public drug programs; assessments for private payers may differ, as they must be tailored to the perspective and needs of the plan sponsor. For example, a private payer may put more value on the impact of the drug in allowing a patient to return to work faster and less value on the savings that might be achieved in physician services and hospital stays.

The consultation paper states the PMPRB could introduce a fixed cost-per-QALY threshold. This is highly problematic for the reasons described above. It would also be unprecedented. Information on cost-per-QALY is only used as input into subsequent negotiation on price and conditions for coverage. No country has attempted to use a fixed cost-per-QALY to establish a regulated maximum price.

### *Drugs for Rare Diseases*

The use of HTA and, in particular, a cost-per-QALY threshold is particularly inappropriate for drugs for rare and ultra-rare diseases. It is well established the prevailing methodologies used in pharmacoeconomic evaluations do not adequately address drugs for small patient populations.

Because of the small number of patients involved, development of drugs for rare diseases is much more expensive on a cost-per-patient basis and the quality of evidence generated is not as complete. For this reason, most countries, except Canada, have adopted orphan drug policies to incentivize research and development in this area. Because traditional pharmacoeconomic models are based on assessing drugs intended for a large patient population, many countries, and some Canadian provinces, use separate review and funding mechanisms for drugs for rare diseases. An innovative approach in reimbursement is coverage with evidence development whereby funding is conditional on ongoing monitoring of effectiveness and adapting or stopping treatment as may be warranted by the evidence.

In addition to saving lives and improving quality of life, effective treatments for rare diseases can reduce indirect costs and societal burden. Standard pharmacoeconomic analysis does



not take all these factors into consideration. For the PMPRB to apply the same cost effectiveness or cost utility standard to establish an excessive price threshold for orphan drugs as it applies to other drugs risks excluding such products from Canada to the detriment of people with rare disorders.

### *Willingness and ability-to-pay*

All public drug programs and most private payers in Canada require information on the budget impact of new listings and take it into consideration in negotiating price and deciding on coverage. Consideration of budget impact by the PMPRB would unnecessarily overlap, produce delays and duplicate work.

Willingness and ability-to-pay are highly variable based on the payer's financial circumstances and need. The pCPA record demonstrates it does a good job of assessing ability to pay and value for purposes of public drug plans. The pCPA reports it has not concluded letters of intent for 61 or 29% of the new drugs it has considered for listing agreements as of April 30, 2017 (private insurers do not typically publish information on their decisions not to cover treatments due to cost.).<sup>6</sup> There is no stronger evidence that ability and willingness to pay are being addressed in the market. Duplication of that effort by the PMPRB will serve no added value but may create delays and market uncertainty.

Similarly, there is no apparent value in asking the PMPRB to make price assessments based on GDP. Payers take their own financial capacity and the anticipated value of a product in meeting their health needs into consideration in negotiating price and coverage for drugs. Canada's GDP and relative economic strength are relevant factors to consider in selecting appropriate countries for price comparisons; they are not appropriate in regulating a maximum non-excessive price of a unique product.

### **Proposal #2 – “Basket” of Countries:**

#### *The Criteria to Select Countries for Comparisons*

The PMPRB has reported Canadian prices for patented drugs are 22% higher than the median of OECD countries and the Minister has pointed to specific examples of savings if prices for certain drugs in Canada were at the same level as France. In proposing to amend the basket of countries used by PMPRB, the Minister is signaling a clear intention to lower prices in Canada.

BIOTECCanada recognizes it may be appropriate to review the basket of countries and this is the first time in 30 years it is being done. The industry also agrees with the approach of starting by identifying the criteria to select the countries. Those criteria should be aligned with Canadian policy goals.

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<sup>6</sup> <http://www.pmprovinceterritoires.ca/en/initiatives/358-pan-canadian-pharmaceutical-alliance>

The proposed criteria in the consultation do not address key policy areas. The PMPRB is created under the *Patent Act*, an important element of Canada's IP policy. The legislation and regulations governing the PMPRB should reflect it is part of Canada's policies to support innovation; they should also reflect major policy objectives such as Canada's Innovation Strategy, which has highlighted health and bio-sciences as one of six key components.

The criteria should also reflect the major policy objectives in health. The Minister has stated her policy goals clearly in addressing the "affordability, accessibility and appropriate use" of pharmaceuticals. While the PMPRB reform proposals are intended to address the "affordability" part, they should also be examined in terms of their impact on the other components and we should look at other countries who share similar policy goals.

IP policy is a major component of the international trade agreements in which Canada participates. These agreements reflect the strong trading relationships Canada has with its partners and provide mechanisms to address trade issues. They include countries with whom we share common standards of framework policies such as IP and trade rules.

It is not clear if the government examined best practices in other countries to select comparator countries for drug price comparisons. It is estimated about 30 countries take international comparisons into consideration in some fashion. A recent European Union study found that the common characteristics of the countries used are: (a) geographic proximity and (b) comparable economic conditions.<sup>7</sup> The proposed criteria attempt to address the second factor but not the first.

In reviewing the PMPRB basket of countries, BIOTECanada recommends the government modify the selection criteria to add the following:

- a) Policies to promote and improve health outcomes;
- b) Trading relationship with Canada through established agreements such as NAFTA and CETA; and
- c) Geographic proximity;
- d) Innovation policies.

### *Proposed Countries*

Once agreement is reached on the criteria, it would be appropriate to review and reassess the countries proposed. It appears the current list of proposed countries was selected because the median of prices in those countries aligns with the OECD median. As a member of the G7, Canada is a more highly developed country than most of the OECD countries. A better approach is to select comparator countries based on the above criteria.

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<sup>7</sup> European Commission, Study on enhanced cross-country coordination in the area of pharmaceutical product pricing, December 2015, page 26  
[http://ec.europa.eu/health/sites/health/files/systems\\_performance\\_assessment/docs/pharmaproductpricing\\_trep\\_en.pdf](http://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/pharmaproductpricing_trep_en.pdf)

The application of the criteria and selection of countries is a complex matter. The consultation paper does not provide any information on how the proposed criteria were applied to result in the proposed list. The PMPRB has completed a detailed report on the evaluation of the basket of countries but that report has not been made public. BIOTECanada is requesting it be made available to all stakeholders before this consultation is completed.

It is necessary to flag the proposed exclusion of the U.S. from the list. The U.S. is arguably the most appropriate comparator to Canada: It is our largest trading partner. There are several ongoing or potential policy issues that impact the other country such as reimportation of drugs; the NAFTA agreement is about to be renegotiated; the U.S. is our closest comparator in terms of mixed public-private sources of funding for prescription drugs; the shares of public funding for drugs in Canada and the US are similar, 43% for Canada and 42% for the US in 2014, compared to 70% to 90% in much of Europe.<sup>8</sup> The U.S. is sometimes referred to as an outlier because prices for patented medicines there are substantially higher than in Canada, but that fact proves how successful current Canadian policies are in controlling prices. The U.S. is not an insignificant market; according to the most recent PMPRB Annual Report it represents about 45% of the total global market for drugs compared to 2% for Canada.

#### *Additional Comments*

Industry members have expressed concern about the ability to propose specific countries without knowing how the PMPRB will use international price comparisons in future.

The Industry also questions the added regulatory burden an expanded basket will impose in light of Health Canada and government-wide objectives to reduce regulatory burden.

#### **Proposal #3 – Patented Generic Drugs:**

BIOTECanada agrees with the objective of “an increased PMPRB focus on drugs that are at greatest risk of excessive pricing due to the degree of market power held by the patentee.” The corollary is there should be less focus on drugs that do not have a high degree of market power.

The proposal only goes part way. There are many multisource drugs, patented and non-patented, subject to marketplace competition and without benefit of market exclusivity or a high degree of market power. The circumstances for these drugs are the same as for patented generic drugs. The industry is of the view the proposal to reduce the regulatory burden for patented generic drugs should be extended to all multisource drugs.

In addition, the regulatory burden should be reduced for those products that are purchased through tendering and price negotiation such as vaccines and blood products.

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<sup>8</sup> 15 OECD (2016), OECD.Stat (database), Health expenditure and financing: [http://stats.oecd.org/index.aspx?DataSetCode=HEALTH\\_STAT#](http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT#) (data extracted on Apr. 5, 2017).

To limit this proposal to generic drugs is arbitrary and unfair as there may be cases where a multisource market includes patented generic and brand name drugs. It is inconsistent and unreasonable to regulate the prices of some drugs in that market and not others.

**Proposal #4 – Reporting Requirements:**

As discussed above, Proposal #1 would introduce regulatory overlap, delays and duplication and therefore the proposal to require supporting information is unwarranted.

Even if the factors in Proposal #1 were adopted, the proposed filing requirements are unnecessary and would impose an undue regulatory burden and expanded cost. Information on pharmacoeconomic evaluations and budget impact is currently provided to CADTH, INESSS and pCPA to inform the pricing and coverage negotiations of public plans. Similar information is also provided to major private payers and pharmacy benefits consultants in accordance with their needs.

These assessments are developed for payers reflecting the requirements of the circumstances, e.g., for use in a limited population on specific criteria. A requirement to develop a model for PMPRB purposes to estimate the “uptake of the medicine, by indication, without restraint on utilization” for all relevant markets in Canada would be unnecessary to assess “excessive” price and unreasonable.

**Proposal #5 – Reporting Third Party Rebates:**

The consultation paper provides a vague and theoretical justification for this proposal but has not provided an impact analysis, in particular the impact on the joint negotiation practices of the FPT drug programs.

The requirement for such information is inconsistent with the mandate of the PMPRB to regulate “excessive” price. Taking into account a third-party rebate will only lower the calculated price below the maximum non-excessive price. How will that protect consumers?

Payers in most, if not all, other developed countries require negotiated terms and conditions for coverage of new drugs including confidential rebates. Canadian public payers did not seek confidential rebates prior to 2006 when Ontario introduced the practice by legislation. Subsequently, all public payers have joined the pCPA consortium in order to use their combined buying power to negotiate larger rebates. In her May 16 speech, Minister Philpott noted the federal government has “signed on to 43 more agreements – in less than a year” since joining the pCPA.

Private payers are also negotiating confidential rebates and conditions in their agreements to cover new drugs.

The proposal to require patentees to report third-party rebates to PMPRB risks disturbing the current framework for price negotiation and rebates; provinces and territories risk losing some of the value they receive from this system.

## Conclusion

BIOTECanada is supportive of the government's policy intent to address the affordability, accessibility and appropriate use of prescription medicines. The industry has serious concerns however, that amendments to the *Patented Medicines Regulations* as currently proposed will not advance those goals and will have unintended negative consequences on optimal health outcomes and on government policies to make Canada one of the leading innovative economies of the future.

The proposals would create an unnecessary regulatory burden, they would introduce overlap and duplication with regulations and policies of provincial and territorial governments and they may negatively impact their ability to maximize value in listing negotiations for new drugs. The proposals would create added barriers to patient access to drugs for rare diseases and potentially delay or even foreclose the entry to Canada of major new breakthrough treatments in the future.

We encourage Health Canada to conduct further analysis of the issues regarding drug pricing in Canada and to conduct multi-stakeholder consultations to ensure there is a better understanding of the issues and potential policy options and anticipated impact.

June 28, 2017