



June 28, 2017

Health Canada
Attention: Patented Medicines Regulations Consultations
70 Colombine Driveway, Tunney's Pasture
Mail Stop 0910, Floor 10, Building Brooke Claxton Building
Ottawa, Ontario K1A 0K9
Canada

By email: PMR-Consultations-RMB@canada.ca

RE: AstraZeneca Canada response to Health Canada consultation on proposed amendments to the Patented Medicines regulations

EXECUTIVE SUMMARY

AstraZeneca Canada (AZC) is a proud Canadian organization with a long history in Mississauga, Ontario. We employ more than 720 Canadians across the country who go to work every day to make healthcare in this country better. We are science-focused and research-driven, bringing innovative medicines (defined as “new” medicines with a patent) to market that help millions of Canadians live longer, better lives.

The cost of innovative pharmaceuticals make up 6.5% of total health spending in Canada¹ and deliver a clearly demonstrated return on investment for the health and economy of Canadians.² New treatments prevent or cure disease, extend lives, relieve suffering and improve an individual’s quality of life. Innovative medicines when used appropriately allow patients to avoid other costlier services, such as emergency room visits, hospital stays and surgeries, and delay the need for long-term care.

From the discovery of insulin in Canada and HIV treatments, to the latest hepatitis C and oncology drugs, our industry and the research we conduct and fund are transforming care and turning what were once terminal diseases into chronic or curable ones. These advancements in science can only occur in a competitive environment that provides incentives for innovation and delivers much needed medicines to patients when they need them.

New medical innovations and advances are reflecting entirely new ways of treating disease. AstraZeneca Canada is excited about the future impact our pipeline of medicines will have, but we are concerned that Canadian patients’ access to these medicines may now be negatively impacted due to the unintended consequences of proposed amendments to the Patented Medicines regulations.

¹ *Canadian Health Policy Institute*, Spending on Patented Drugs in Canada 1990-2014, February 23, 2016

² Reducing the Health Care and Societal Costs of Disease: The Role of Pharmaceuticals. Conference Board of Canada, July 2013. <http://www.conferenceboard.ca/e-library/abstract.aspx?did=5598>

Health Canada has proposed a sweeping set of changes to the mandate of the Patented Medicine Prices Review Board (PMPRB). These proposed changes are the most significant for the biopharmaceutical industry in more than 20 years and, if implemented as proposed, would have notable consequences on the industry that would result in a negative impact for patient access to medications. These market changes would directly result in Canadians being forced to wait longer to benefit from new treatments, or never gain access to certain new treatments due to 1) the delayed launch of products into the Canadian market, and 2) fewer new products being launched in Canada overall.

The innovative biopharmaceutical sector employs nearly 15,000 Canadians and supports an additional 31,000 indirect jobs.³ Additionally, there are currently 4,500 clinical trials happening across Canada.⁴ Changes of the magnitude proposed by the Government could impact highly skilled jobs across the healthcare ecosystem, and reduce both clinical trial and health sciences research and development (R&D) in Canada. **Given the notable impact of these proposals, we are requesting that no changes be made to the PMPRB's mandate until bi-lateral meetings can be held between industry CEOs and the Government of Canada.**

Our central concerns with the proposed changes include:

- **The policy rationale for these changes is unclear and inconsistent with the Government's Health and Innovation Agendas.** The changes are directly at odds with innovation and economic policy objectives of the Government of Canada as outlined in the mandate letter for the Minister of Innovation, Science and Economic Development.⁵ We believe the impact of these changes also runs counter to the Minister of Health's mandate letter to both improve "access to necessary prescription medications" and "outcomes and quality of care for Canadians."⁶
- **There appears to be significant overlap and duplication between Canadian organizations** such as the Canadian Agency for Drugs and Technologies in Health (CADTH), the Institut national d'excellence en santé et en services sociaux (INESSS), and the Pan-Canadian Pharmaceutical Alliance (pCPA). There is no clear rationale or patient benefit to duplicate these functions within PMPRB.
- **There is no clear indication or evidence that these changes will improve care or affordability for Canadians as PMPRB does not have responsibility for drug reimbursement, healthcare budgets, health system policy or social programs for vulnerable populations.** These are all addressed at a provincial level where the jurisdiction for healthcare decisions and funding resides.

³ <http://innovativemedicines.ca/resource/economic-footprint-members-of-innovative-medicines-canada/>

⁴ <http://innovativemedicines.ca/resource/number-of-clinical-trials-in-canada/>

⁵ <http://pm.gc.ca/eng/minister-innovation-science-and-economic-development-mandate-letter>

⁶ <http://pm.gc.ca/eng/minister-health-mandate-letter>

Given the significance of the changes proposed, the absence of detailed implications articulated within the proposed amendments, and the very short timelines for consultation, AZC is concerned that the regulations will be unbalanced and will negatively impact patient health and the Canadian economy.

Our recommendations are as follows:

- **That the Ministers of Health, Finance, and Innovation, Science and Economic Development embark on a collaborative consultation with Canadians about the gaps in Canadian pharmaceutical policy that must be addressed** and how we should best address them. If we focus solely on the cost of siloed inputs (drugs, hospitals, physicians) – which has been the primary focus of pharmaceutical and overall health policy over the last 10 years – then we will never realize the great health and economic benefits that new medicines can deliver.
- **That proposals #1, #4, and #5 should not be implemented as they will neither improve patient outcomes or payer affordability.** Rather, they will lead to an increase in the number of new medicines that are either launched much later in Canada or will never be made available to Canadians. These proposals increase the regulatory burden for biopharmaceutical companies, create further duplication in an already highly regulated environment, and are likely to discourage future clinical research and investment in Canada.
- **That Proposal #2 not be implemented as the objective is not clear and could have significant negative impact.** The proposal as written would remove a significant amount of the value of the innovative biopharmaceutical market and gives no consideration to the impact this will have on Canadians' access to medicines. **Each of the seven new countries in the proposed PMPRB12 basket have delayed market entry for new products relative to Canada.**⁷ If Canada aspires to have a first-class healthcare system and to be a leader in the innovation economy we believe it should value innovative medicines commensurate with its wealth and standing within the global economy. For these reasons, we do not agree with the proposed PMPRB12 basket.
- **That the risk-based approach in Proposal #3 be implemented and apply to all brand patented drugs that lose their exclusivity** and become multi-source drugs with generic competition. All multi-source drugs, whether brand or generic, would then be subject to the same level of risk-based regulation.

We have a unique opportunity to redefine how pharmaceutical policy can best serve Canadians. AstraZeneca Canada requests a meeting between the aforementioned Federal Ministers and industry CEOs to begin discussions on what a new policy framework can be. **We believe we can foster a first-class healthcare system that improves patient care, while also supporting a world-**

⁷ National Prescription Drug Utilization Information System (NPDUIS) Database http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/NPDUIS_MedsEntryWatch_2015_e.pdf

class biopharmaceutical economy and providing predictability for payers. As a company, AZC remains committed to the delivery of value-based healthcare that is accessible to all Canadians.

DISCUSSION OF PROPOSED AMENDMENTS TO THE PATENTED MEDICINES REGULATIONS

AstraZeneca Canada welcomes the opportunity to provide input on the proposed changes to the Patented Medicines regulations⁸, first announced on May 16th, 2017. As a member of Innovative Medicines Canada (IMC), we support its submission to Health Canada and actively participated in its development. Additionally, as one of the leading biopharmaceutical companies in Canada, it is important that we submit our specific feedback on the proposals as well. We want to thank PMPRB, Health Canada and the Health Minister's office in advance for their consideration of our viewpoints on these significant matters. We are also sharing our response directly with the Minister of Finance, Minister of Innovation, Science and Economic Development, and other stakeholders to ensure full transparency of our feedback.

Having considered these issues deeply, we have an important message.

If enacted as written, these reforms will significantly delay, and likely stop, many new innovative medicines from entering Canada.

The detrimental impact on our ability to launch or commercialize products in Canada is not a consequence we raise lightly or in self-interest. As we will discuss below, the sweeping reforms proposed, if enacted, would lower Canada's attractiveness for securing future research investments and impair our ability to bring new products to market. AstraZeneca Canada would see itself shift from an early wave launch market to a later wave launch market alongside countries like Argentina, South Korea and Turkey – a shift that could result in a 12 to 25-month delay in future regulatory filings and launches.

The global pharmaceutical market is highly competitive and there is fierce competition within global organizations for research investments and launch sequencing. Two fundamental requirements underpin every investment decision: 1) the favourability of a commercial environment, including pricing, intellectual property and patient access policy, and 2) the quality of scientific research.

In her May 2017 speech, the Minister of Health stated "we can save \$3.5B by bringing down prices."⁹ Based on 2015 sales for innovative medicines in Canada¹⁰ this would represent a 23% decrease in industry revenue. Based on this we have concluded that the intent of the proposed regulatory amendments as presented in the Minister's speech and the consultation document is to potentially eliminate over 20% of the overall value of the innovative Canadian

⁸ *Protecting Canadians from Excessive Drug Prices*. Health Canada. May 2017

⁹ <https://www.periscope.tv/HealthCanada/1djGXAwkXmEJZ>

¹⁰ PMPRB Annual Report, 2015.

biopharmaceutical industry. This would severely impact commercial viability for many future products and any associated research investments.

From a global perspective, these changes would lead to the de-prioritization of Canada in AstraZeneca's launch sequence planning. We expect this will be the case for most global biopharmaceutical companies. As a result, we would anticipate that many Canadians working in the innovative pharmaceutical industry and the healthcare ecosystem would be impacted, research partnerships would be reduced and new clinical trials would be impacted as Canada shifts away from being an early launch market. An unintended consequence of these changes would be fewer medicines entering Canada which would lead to payers being less likely to benefit from competition on price from new entrants in a class.

The most important impact, however, is that all Canadians would have reduced access to new innovative medicines – the result of both the delayed launch of new innovative medicines and fewer new medicines entering the Canadian market.

Proposal #1 and Proposal #4 – Introducing New Factors to Determine Whether a Price is Excessive and Modernizing Reporting Requirements

PMPRB has proposed adding three new factors to aid in the determination of “excessive pricing,” as well as enhanced reporting requirements to inform their work. These new factors include pharmacoeconomic evaluation, comparisons of Canadian market size for a product vs. other countries, and country comparisons of Gross Domestic Product (GDP). Each of these factors increase the regulatory burden and add further complexity into the drug approval pathway, with no clear benefit to patient access or payer affordability.

QUALITY ADJUSTED LIFE YEAR (QALY):

PMPRB has proposed shifting from a therapeutic valuation model to a strictly pharmacoeconomic model by adopting a measure of Quality Adjusted Life Year (QALY) and implementing a “fixed cost per QALY threshold in Canada.”¹¹ A pharmacoeconomic analysis compares the cost and benefits trade-off between two or more treatment options. The determination of whether an intervention represents a cost-effective allocation of resources depends on the decision-maker's cost-effectiveness threshold for a QALY gained.¹² These analyses are commonly used in the context of reimbursement decisions to make an assessment on the value of a new intervention, in addition to other considerations including a clinical or therapeutic assessment, budget impact analysis, etc. Indeed, although Canada and many of the PMPRB7 countries consider QALY's in the context of funding decisions, none of these countries use them in isolation as a means to regulate list pricing. These decisions must integrate considerations beyond cost-effectiveness and QALY's alone, such as clinical safety and effectiveness, burden of illness, patient needs, willingness-to-pay and ability-to-pay.

Furthermore, a fixed threshold for a QALY as a means to regulate pricing for Canadians is inappropriate. The healthcare system in Canada is highly decentralized, with drugs being funded by private, public and cash payers, all of whom will assess the value of a new treatment

¹¹ *Protecting Canadians from Excessive Drug Prices*. Health Canada. May 2017

¹² <https://www.cadth.ca/guidelines-economic-evaluation-health-technologies-canada-4th-edition>

differently. Further, the determination of a cost-effectiveness ratio for new technologies can vary considerably based on how the utilities and patient preferences are elicited and do not capture all dimensions of health benefits.¹³

Inevitably, the result of adding a fixed cost-per-QALY threshold will leave some Canadians, such as those with rare or more complex diseases, marginalized and without treatment options as most treatments for such conditions are unlikely to be deemed to be cost-effective under a fixed threshold. Few countries use explicit fixed thresholds across diseases, and those that do presently use them downstream in the public payer funding context as one of many factors. Hence, pharmacoeconomic analysis should not be incorporated in the PMPRB regulations as an additional price determination factor. A therapeutic valuation model remains more appropriate given that PMPRB is not a payer and cost-effectiveness is already evaluated in Canada by CADTH and public payers downstream in their funding decisions.

MARKET SIZE:

PMPRB has also suggested that the size of the market for a medicine in Canada and other countries be an important input into how we determine Canadian prices. It is notable to highlight that all new indications for a medicine are supported by a robust clinical trial program and a new, separate regulatory filing, both of which require significant investments in infrastructure and talent. Imposing further price reductions due to additional indications could discourage further investment in discovery and innovation.

The development of innovative medicines is also costly and has a high risk of failure – with no reimbursement by the Government to offset these failures. It is estimated, for example, that only 12% of investigative medicines entering clinical trials are ultimately approved.¹⁴ Finally, value derived from subsequent indications is already presently addressed through negotiations at the Provincial and Private payer level.

PMPRB's intervention on this matter would be duplicative and potentially limit access to medicines for smaller patient populations, by creating an incentive to avoid introducing new uses for smaller patient populations. This aspect of the proposed changes would put Canada out of step with other innovative economies like the United States, United Kingdom, France, and Germany. This would again result in fewer new medicines and/or new uses of existing medicines being available for Canadians.

The changes are directly at odds with the innovation and economic policy objectives of the Government of Canada as outlined in the mandate letter for the Minister of Innovation, Science and Economic Development.¹⁵ They also run counter to the Minister of Health's mandate letter

¹³ Knapp M. "Economic outcomes and levers: impacts for individuals and society" *Int Psychogeriatr*. 2007 Jun;19(3):483-95, <https://www.ncbi.nlm.nih.gov/pubmed/17391570>.

¹⁴ DiMasi JA, Grabowski HG, Hansen RA. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ*. 2016;47:20-33

¹⁵ <http://pm.gc.ca/eng/minister-innovation-science-and-economic-development-mandate-letter>

to both improve “access to necessary prescription medications” and “outcomes and quality of care for Canadians.”¹⁶

We would welcome the opportunity to meet with the Ministers to discuss specific AZC examples and further illustrate this issue.

GROSS DOMESTIC PRODUCT (GDP):

Like the new pricing factors suggested above, it is unclear how GDP considerations would help determine excessive pricing. GDP, market strength and purchasing power are already captured or referenced through international price comparisons. The PMPRB will not improve their ability to protect Canadians from excess pricing by selectively applying economic measures such as GDP and GDP per capita. Neither measure accounts for the variations in value or ability to pay between different countries. If anything, a current GDP comparison could justify higher relative prices in Canada. A recent presentation by the Government of Canada highlighted that Canada’s GDP had the fastest growth among G7 countries and that our net debt-to-GDP ratio was the lowest.¹⁷ This positioning by the Government of Canada points to a strong economy that should be able to reward innovation and deliver innovative medicines to Canadians sooner. But to be clear: AZC does not agree that GDP per capita is a suitable proxy for ability to pay, and it should not be used by the PMPRB in its pricing analysis.

In sum, it is not evident that any of these new factors will aid the PMPRB in determining what constitutes “excessive price,” and are therefore outside the PMPRB’s mandate. They will also not improve Canadians’ access to innovative medicines. In fact, the above factors would delay or prevent the future launch of new medicines and new indications. Furthermore, the introduction of pharmacoeconomic evaluations and fixed cost-per-QALY thresholds will unduly increase regulatory burden and duplicate the functions of CADTH and the pCPA in determining the value of innovative biopharmaceutical products. Affordability assessments need to be made at the payer level based on the patient population being served. In our opinion, the excess regulatory burden cannot be justified for these measures.

Proposal #2 – Amending the Basket of Countries Used for International Price Comparisons

We are concerned by the lack of clear objectives stated to justify amending the basket of countries as proposed by PMPRB in the consultation document. We also remain unclear on the rationale used in selecting the proposed PMPRB12 basket. It appears that the new PMPRB12 basket has been proposed to achieve two objectives: 1) match the median price ratio of the Organization for Economic Coordination and Development (OECD) countries, and 2) remove the United States from the basket.

There was no analysis or discussion presented about how the new countries were selected or why the United States was removed, and it makes no sense to exclude it based on the rationale in PMPRB’s consultation paper. If the concern is about addressing the pricing of certain outlier products, we argue that the PMPRB already has the tools it needs to address those issues.

¹⁶ <http://pm.gc.ca/eng/minister-health-mandate-letter>

¹⁷ http://www.international.gc.ca/investors-investisseurs/assets/pdfs/download/The_Canadian_Opportunity.pdf

The selective nature of the proposed PMPRB basket changes prompt some fundamental questions: What do we expect of our Canadian healthcare system and innovation economy in the 21st century? Do we aspire to be a world-class or second-tier healthcare system? Canada cannot be a world leader in health and innovation via middle-of-the-pack pharmaceutical policies. We reiterate that all seven of the new countries in the proposed PMPRB12 basket have delayed market entry for new products relative to Canada.¹⁸ Moving in this direction is simply not beneficial for Canadian patients.

We strongly support the language in the IMC submission that calls into question the validity of removing the United States and attempting to move toward the OECD median price level.

The OECD median price ratio is 22% less than the Canadian drug price ratio. The positioning of this statistic in statements made by the Minister of Health and the PMPRB consultation document suggest that the aim is to reduce Canadian drug prices by more than 20% overall. Changes of this magnitude proposed by the Government would result in a significant impact to the highly skilled Canadians who work across the healthcare ecosystem, as well as a reduction in both clinical trial and health sciences R&D in Canada. Most importantly, Canadian patients would be negatively affected because it would result in both the delayed launch of future innovative medicines and fewer new medicines entering the Canadian market.

We disagree with the statement that Canadians pay the highest drug prices outside the United States. Analysis shows that when single-source – i.e. patented, innovative – medicines are considered alone, Canada ranks 3rd lowest for prices among the PMPRB7.¹⁹

While the Government's proposed changes appear to focus only on future products, the lack of clarity on policies related to current in-market products is of great concern. Any changes should only be applied prospectively, and to new medicines.

RESEARCH & DEVELOPMENT (R&D) FOOTPRINT

In 2016, AZC invested \$82.4M in research and development (R&D) initiatives in Canada, according to the OECD criteria for measuring research investments. That's more than 10% of the gross revenues for our single-source – i.e. innovative – products, and nearly double what is captured through PMPRB's current R&D reporting criteria. We have long called for the Government of Canada to adopt the OECD criteria for capturing research investments, as these criteria are more reflective of the types of investments we make today including multinational clinical trials, Real World Evidence, epidemiology, health economic and outcomes research. These are areas not captured by the 30-year-old Scientific Research and Experimental Development (SR&ED) credit definition which PMPRB relies on. We believe that Canada is significantly out-of-step with the OECD in how it measures R&D and that adopting its updated criteria would enable Canadians and the Government of Canada to see the full extent of our industry's considerable research impact.

¹⁸ National Prescription Drug Utilization Information System (NPDUIS) Database http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/NPDUIS_MedsEntryWatch_2015_e.pdf

¹⁹ Source: Form 2 Block 5 data submitted to PMPRB, July-December 2015, Innovative Medicines Canada members.

Our business models have changed but what remains the same is our drive to help Canadians live longer, healthier lives. And this is borne out by the facts: Hepatitis C is now curable, HIV is now a chronic disease, and life expectancy and five-year cancer survival rates have made huge gains – all thanks to innovative medicines.

In summary, Health Canada and the PMPRB must clearly identify what problem they are trying to solve before changes are made to the basket of reference countries. AstraZeneca Canada is ready and willing to help identify real, sustainable solutions. We believe that the Government's proposals as set out would have negative unintended consequences for the health of Canadians, as well as the innovative biopharmaceutical industry and health science institutions across the country. Further, changing the basket will not improve the R&D to revenue ratio. To accurately capture the true impact and value of Canadian health sciences research investments, we must modernize the way we measure innovative biopharmaceutical investments in Canada – an area we are presently out-of-step with the OECD.

We believe that regulations which would have a significant impact on access to medicines for Canadians and the entire biopharmaceutical industry should undergo appropriate discussion and consultation, to ensure that the intended and unintended consequences of these changes are well understood. A six-week consultation period is an extremely short amount of time to get this right. AstraZeneca Canada applauds the Federal government for their recognition of the importance of improving patient access to medications and innovation broadly, as well as for proposed changes to align the drug approval and review processes of Health Canada and CADTH. However, these proposed PMPRB changes would negatively impact patient access to medications, prohibit innovation in Canada and would be a detriment to supporting a thriving innovation economy.

Proposal #3 – Reducing Regulatory Burden for Generics with a Patent

The proposal to embark on a risk-based approach to regulation is worth further exploration. We agree with the proposal as stated, and would support its expansion. Firstly, branded medicines that have been genericized should also benefit from this proposal. Further, we encourage the PMPRB to evaluate whether a risk-based approach to all pharmaceuticals could ease the burden on more common or established products and product classes while ensuring appropriate oversight and resources are directed to other products.

A risk-based approach could work better for manufacturers and the PMPRB if it ensures the appropriate level of oversight and regulatory burden is applied to pharmaceutical pricing in Canada. It could also bolster Canadians' confidence that the PMPRB is achieving its objectives.

In sum, AZC supports a risk-based approach for multisource products – both brand and generic – and other low-risk products such as vaccines which undergo tendering. We agree that starting with multisource products, including the original branded product, is an important first step to demonstrate a risk-based approach to regulating excessive pricing can work.

Proposal #5 – Providing Information Related to 3rd Party Rebates

We are not supportive of this proposal as it is unclear how rebate data would be used by PMPRB or provide any additional benefit to payers or patients.

The rebate data requested are outside the scope of PMPRB's current and proposed mandate. It is not clear to us how providing the details of confidential, negotiated agreements between a company and insurers – including both public and private payers – has any bearing on determining an excessive price. These confidential agreements are negotiated to assist insurers in serving the needs of their specific patient populations, which is a value offering added beyond the list price. If the list price is deemed not to be excessive, then it follows that any further value-add or discount only improves the value of the offering.

In sum, we view this proposal as adding regulatory burden with no benefit to payers or patients. It would penalize innovative biopharmaceutical companies for offering value-added agreements to payers. We would be open to sharing confidential rebate information if there was a specific question of excessive pricing related to one of our products.

CONCLUSIONS and NEXT STEPS

An aging population, the growing prevalence of chronic disease and slower economic growth are putting pressures on healthcare budgets – often driving increasing public scrutiny on drug pricing as a way to ensure a sustainable health-care system for the long term. AstraZeneca Canada believes that solving this issue of healthcare system sustainability is complex and far from one-dimensional.

It is important that we understand the great value that innovative medicines bring – and how their appropriate use can have a powerful impact, including reducing other healthcare costs like hospitalization, emergency room visits and surgery. It is also important that we anchor to the facts when it comes to what is driving increased healthcare costs in Canada.

We believe that the biopharmaceutical industry can do more to support and address the matter of health care sustainability, while ensuring that we do not render Canada an unattractive market for important global research investments and new product launches. It is important that regulations strike the right balance in achieving fair and globally competitive prices in Canada, while ensuring that the biopharmaceutical market retains its ability to launch new medicines and ensure Canadians benefit from early access to these innovations. We are seeking to remain a healthy and competitive knowledge-based industry which supports innovation and economic growth in Canada. Most importantly, we want to ensure that Canada can deliver a first-class healthcare system.

Canadians deserve to get the best medical treatments that will help them. That's why we strive every day to deliver life changing medicines to Canadian patients.

We believe we have an important obligation to share thoughtful feedback on the Government's proposals, including what we deem to be the unintended and negative impact from these proposed changes. The proposals will negatively affect Canadian patients and weaken our health care system. They will also negatively impact the entire biopharmaceutical ecosystem in Canada – companies, universities, research institutions and the knowledge-based workforce within these organizations. We highlight the shortcomings in the proposals in the hope that government will do the right thing and consult more broadly with Canadians in a process led jointly by the Ministers of Health, Finance and Innovation, Science and Economic Development to truly identify what problems need to be fixed and how.

Lowering prices at the PMPRB level will not inherently improve patient care. If implemented in the manner proposed, these changes will reduce Canadians' access to new innovative medicines, and impact highly skilled jobs and research partnerships.

We need to make Canadian pharmaceutical policy based on Canadian values and needs in healthcare. Fundamentally the Government of Canada must ask: what aspirations do we have for our healthcare system and our innovation economy? Simply driving to lower prices and effectively turning the biopharmaceutical industry into a lowest-cost commodity market will not achieve better health outcomes or economic growth. Spending on innovative medicines represents 6.5% of total health spending and is subject to rigorous evaluation. As we've argued above, any perceived savings through these proposed PMPRB changes are not proportional to or worth the negative impact to patient care, knowledge-based jobs, local clinical trial and research investments, and Canada's overall innovation economy.

AstraZeneca Canada firmly believes we must work in partnership to develop policies that will serve the needs of Canadians now and in the future.

Therefore, we recommend:

- 1) That the Ministers of Health, Finance, and Innovation, Science and Economic Development embark on a broader consultation with Canadians about the gaps in Canadian pharmaceutical policy that must be addressed and how we should address them, together, in partnership with patients and industry;**
- 2) That the Ministers conduct bi-lateral meetings with industry CEOs to discuss specific impacts and the opportunity for developing a new pharmaceutical policy framework before any changes are made to PMPRB's mandate;**
- 3) That Proposals #1, #2, #4, #5 not be implemented as written and that further discussion is needed to identify the goals and appropriate levers to improve Canadians' access to medicines and encourage an attractive life sciences economy in Canada;**

- 4) That Proposal #3 be further explored and expanded to include all multisource products, including branded and generic products.**

We appreciate your time in reviewing this document. We look forward to meeting with you to discuss further.

Sincerely,



Ed Dybka
President
AstraZeneca Canada

