Comments on the proposed amendments to the Patented Medicines Regulations

Executive Summary:

Affordability:

- *In our mixed-payer system, the mandate of the PMRPB does not and should not include an assessment of affordability.*
  - *Affordability can only be determined by the budget holders*
  - *Proposed factors are already being utilized by other agencies in the reimbursement system and would result in duplication of effort*
- *Proposals will not significantly contribute to public healthcare sustainability and affordability.*
  - *Savings will preferentially favour the private insurance industry with no ability of the government to ensure savings will be passed onto patients or the healthcare system*

Access:

- *Proposals may have the unintended consequence of decreasing access to innovative medicines for Canadians*
  - *Proposed additions to the comparator countries have less access to new medicines than Canada*

Innovation:

- *This initiative is not aligned with the federal and provincial governments' Life Sciences Innovation and Economic Development Agendas; it will inhibit life sciences investment and the ability of smaller companies to develop within Canada*
- *Concepts in the proposed regulations contravene the Patent Act, which is designed to reward innovation. Applying increased regulatory scrutiny to the most efficacious medicines will discourage making the most innovative medicines available in Canada.*

Clarity*:*

- *There is a lack of clarity as to how and why many of the proposals will be implemented, leaving it difficult for stakeholders to understand their impact, either negative or positive.*

Innovative medicines should be viewed as an investment in health, not as a cost to the system. All stakeholders need to collaborate to determine the best way to pay for innovation as an investment in the future health of Canadians

First Principles

Canadians value our high-quality healthcare system, and we are admired around the world for our drive and desire to provide equal access to healthcare for all of our citizens. We understand the interconnectedness and positive impact a healthy population has on productivity, economic stability and success. Therefore, all health policies in Canada, including pharmaceutical pricing regulations, need to start with the principle of ensuring optimal healthcare for all Canadians.

Canada needs to remain a country where innovative high-quality treatments are available to all citizens. It must be recognized that innovative medicines deliver important patient outcomes and reduced healthcare resource utilization while consuming only 6.4% of the overall healthcare spending in Canada.[i]

It is befitting a country with the global stature of Canada to promote and maintain economic and health regulations that encourage and support the development and utilization of innovative treatments. The current government's Innovation Agenda is designed to support this concept, as does the *Patent Act*, which governs the mandate and activities of the PMPRB.

Any changes to the PMPRB regulations or guidelines need to start with these principles.

It is Janssen's concern that the proposed changes to the Pricing Regulations could work against the goal of maintaining a world-class healthcare system and optimal health for Canadians.

Current Environment

The PMPRB was established at the time when patent protection was improved for medicines, and was designed to ensure that the prices of patented medicines are not excessive. The policy goal was to ensure that *on average*, the prices of medicines in Canada do not exceed the international median of an appropriate basket of comparator countries, and indeed, the PMRPB has been very successful in meeting this policy objective. For example, in the most recent Annual report, the PMPRB clearly shows that prices in Canada are 18% below the international median and year-over-year, prices have not increased significantly for over 20 years.[ii]

However, the pricing and reimbursement environment for medicines in Canada has changed significantly since 1987 in several ways:

- Use of Health Technology Assessments to determine value-for-money for public payers
- Negotiation of agreements with provincial drug plans through the pan Canadian Pharmaceutical Alliance to address specific provincial access and affordability concerns
- Negotiation of agreements with private drug plans and cost containment programs such as ManuLife's DrugWatch to address specific employer-based access and affordability concerns
- Greater focus by many manufacturers on transformational medicines that meet significant unmet needs in smaller populations
- Increasing healthcare funding pressures with aging populations and years of challenging economic growth

Given the significant role that payers themselves have developed to determine a price that meets their access and affordability needs, it makes sense for the PMPRB to assess their role and impact in this new ecosystem.

A major concern of payers appears to be the increase in the number of 'high-cost' drugs, compared to the more broadly-used lower cost-per-patient medicines common in the past. The consultation paper proposes a 'Risk-Based' approach to pricing regulation to manage this concern. However, the changes presented in the consultation paper do not clearly explain how the PMPRB will define a 'risky' medicine from a pricing perspective nor how the proposed amendments will be applied differently to different types of medicines to manage risk. In the absence of this description, the reader is left to assume that all factors can and will be used by the PMPRB to assess price for all medicines. In fact, the courts have clearly stated that all factors in the regulations need to be considered when determining excessive pricing. The Board cannot use one factor to the exclusion of others.[iii] Therefore, if it is truly Health Canada's goal to more tightly regulate only 'high risk' medicines, a clear definition of what constitutes a 'high-risk' medicine, as well as a detailed description of how new factors will be applied to this category needs to be included in the regulations.

This discrepancy provides only one example of the issues that arise when applying broad regulatory changes to a narrow issue with no clear direction as to how these changes are intended to achieve policy goals. Interestingly, none of the proposals in the consultation paper address the cost of the majority (80%) of medicines prescribed by physicians in Canada, namely, generic medicines as discussed by Minister Philpott on The Fifth Estate.[iv] In contrast, Health Canada's proposals appear to be designed to penalize the most innovative medicines that have the most promise to address the unmet medical needs of Canadians.

The proposed regulatory amendments put forward by Health Canada are based on an underlying assumption that lowering list prices for innovative medicines will result in:

- More medicines becoming available to more patients
- More resources becoming available for other areas of healthcare
- Less financial burdens for patients

It is our position that not only will these goals not be met by the proposed regulatory changes, but that these changes result in unintended consequences for patient access to medications, patient outcomes, health system sustainability and innovation in Canada. **It is our strong recommendation that Health Canada postpone further action on the proposed amendments and work in collaboration with the pharmaceutical industry, payers and patients, and other federal Ministries, most notably Innovation, Science and Economic Development, International Trade, Finance and Treasury Board to develop a collective solution that addresses the needs of not only payers, but more importantly, Canadian patients.**

We recognize the inherent conflict between innovation and affordability, particularly in a publicly-funded healthcare system. However, the promise of current and future innovation is stronger than ever and should be incorporated in the development of new healthcare policies to ensure optimal health outcomes now and in the years to come as opposed to establishing short-sighted policies based on a few exceptional cases.

The remainder of this paper outlines why the federal government's goals will not be met with the proposed regulatory amendments and offers suggestions for the development of a collaborative and holistic approach to pricing and reimbursement of medicines in Canada for the benefit of all Canadians. The Appendix includes specific comments on the five proposals for the Minister's consideration.

Affordability

Approach outlined in the Health Canada consultation is unlikely to achieve the stated goals of improved affordability for all Canadians

The federal government has no ability to ensure that any savings achieved with these regulatory changes will result in savings for specific consumers or increased investment in healthcare. While there may be some savings for the Canadians who pay for medicines themselves, the proposals ***will not increase the number of Canadians with adequate drug coverage***. The vast majority of savings from these proposals will be directed to the private payers, where the government has no ability to determine how these savings will be applied by private payers or the employers they service.

Lowering list prices will not increase savings to the public healthcare system. As public payers have already developed processes to address affordability issues specific to their populations and healthcare needs through direct negotiation with manufacturers, they will continue to pay the same net price regardless of changes to the PMRPB Regulations. In fact, in some cases they may be forced to pay higher net prices, with the additional savings being applied to the private market.

Private payers in Canada have been surprisingly slow to invest in the infrastructure to negotiate and manage product listing agreements. Still today several insurers have chosen not to invest in the required infrastructure. There is an element of the private insurance business model where lower drug costs result in less revenue to the insurers. Janssen has encouraged insurers to explore product listing agreements and has pioneered such agreements to lower the cost of biologic treatments. The agreements have been operationalized at Janssen's expense and with some insurers Janssen has co-invested in the infrastructure to enable product listing agreements.

Therefore, lowering list prices will preferentially pass savings on to the private insurance industry, enabling these companies to market the perceived savings to Canadian employers. The reductions in list prices enabled by the PMPRB on behalf of the private insurers may not be realized by Canadians in whole or in part due to the liberal retail and wholesale mark ups allowed by the private insurers. As well the administration costs and "insurance rates" charged by private insurers to Canadians lacks clarity. Studies have reported significant increases in private insurance administration costs over the past decade.[v] There is a significant delta between the IMS Brogan / Innovative Medicines annual private insurance drug forecast and report annual "rate" increases to private drug plans.[vi] Due to these issues, there is no guarantee that this will result in a significant increase in affordability for employers, nor increase access to innovative drugs for patients

Recommendations: *If Regulatory changes are to be made, proactively obtain information from the private insurance industry on how they will expand access to patients and decrease costs to employers, tied to specific metrics and penalties for failure to meet targets. Ensure savings for public payers are returned to the drug budget or broader health system funding.*

The PMPRB cannot and should not assess affordability

'Affordable' is a relative term, which encompasses not only price, but other factors such as:

- the value a payer or consumer places on a medicine;
- the patient populations in each jurisdiction (public or private)
- the payer's/consumer's healthcare or benefits budget;
- the overall budget of which the healthcare or benefits budget is a part;
- the benefit levels of private insurance plans;
- additional costs such as markups, dispensing fees and plan administration costs, none of which PMRPB has any ability to regulate

The language in the consultation document discusses the concept of "protecting Canadian consumers from ***excessive*** prices". PMPRB does not have the mandate or ability to determine one ***affordable*** price for all Canadian consumers. The affordable price for a single consumer will be different than that of a province and different than that of a private payer customer. Therefore, the concept of setting one 'affordable' price for all consumers by a federal body is not possible in our mixed-payer system. The mandate of the PMPRB is to determine 'excessive' pricing, which does not include or incorporate the willingness- or ability-to-pay of an individual consumer.

Because the assessment and prioritization of these factors vary greatly for each payer/consumer, what is considered affordable to one payer or consumer may not be affordable to another. For this reason, the PMPRB's efforts to equate *affordable* with *non-excessive* are not well- founded.

The provinces are constitutionally responsible for managing their own healthcare budgets. As budget holders, they are best placed to determine what is affordable within their own system. They make the determination of an affordable overall drug budget based on their own eligibility requirements. For each plan, the rationale for coverage, the economic and fiscal environment, population and health needs are different, therefore, the value each province places on an individual drug may differ substantially.

This is the key role for the pan-Canadian Pharmaceutical Alliance (pCPA); negotiating affordability based on the budgetary needs of the public payers. Individual drug plans choose whether to join a negotiation for a medicine based on the needs of their population, and they then choose whether they value and can afford the negotiated price. The provincial drug plans, not the PMPRB, are best suited to work collaboratively with industry to determine affordability.

In addition, public and private payers services vastly different patient demographics and therefore assess value and affordability very differently. Private payers mainly cover working-age Canadians and their dependents, and are interested in metrics such as productivity and absenteeism, and decreasing short- or long-term disability. They also have a multitude of different drug plan designs that impact the cost of medications, regardless of the list price. Public payers on the other hand mainly cover older or non-working Canadians and, as they are part of the government-funded healthcare system, value overall health of the population and metrics such as decreased healthcare resource utilization. Again, for the above reasons, it is not appropriate for a federal regulatory agency to determine one affordable price for each payer.

The PMPRB states that international best practices include tools such as cost-effectiveness and market size. However, they fail to point out that the pricing decision for medications in such countries is made by the same body making the reimbursement decision i.e. the price is tied to affordability, reimbursement criteria, etc by the agency who holds the budget. ***The proposed tools are already being used in Canada by appropriate decision-makers; the public and private payers themselves.*** As payers are already using these tools, it

does not make sense for PMRPB to duplicate their work, particularly when a federal agency is unable to assess affordability in our mixed-payer system.

***Recommendation**: Continue to allow payers to assess affordability, as appropriate, to meet their population's needs. Affordability should not be considered in determining non-excessive price. Therefore, pharmacoeconomic evaluation, market size and GDP should not be added as factors to the PMPRB regulations.*

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Access

Approach outlined in the Regulatory consultation will decrease access to the most innovative medicines for Canadians

Health Canada and the PMPRB have indicated that the target price for medicines is now the OECD median. If this is the case, ***Canadians will have to accept levels of access to innovative medicines similar to that of the OECD median.*** According to the PMPRB, of new medicines launched between 2009 and 2014, 61% were available in Canada as of 2015. In contrast, the OECD median for availability of these new medicines was 45%. Several of the proposed countries' access to innovative medications fall even lower than the OECD median (South Korea 33%, Netherlands 36%, Japan 38%).[vii]

Some will argue that the half- to two-thirds of medicines that are not available in those countries are not innovative and therefore not important to patients. While not all medicines are important to all patients, patients respond differently to different medicines, even those in the same class, therefore it is important to ensure the right medicine gets to the right patient at the right time. For example, countries such as South Korea, Australia and New Zealand have poor coverage of oncology and other classes of medicines, and worse outcomes for patients.[viii] [ix] As a recent study by the Canadian Cancer Society projected that half of all Canadians will get cancer in their lifetimes,[x] it is more important than ever that we continue to improve access to innovative medicines in this country.

The PMPRB has clearly stated that they wish to apply the greatest regulatory scrutiny on those drugs that are the most efficacious.[xi] Therefore, it is likely that these regulatory proposals will disproportionately disadvantage the best medicines, which is counterintuitive to the desire to drive innovation. While there may be a belief that the OECD median represents appropriate access to 'me-too' medicines, it is important to acknowledge that ***the idea of penalizing the best medicines will result in decreased access to the best innovation for Canadian patients***. Lower prices signal that the best innovation is not valued in Canada, and manufacturers will be reluctant to accept this approach, thereby delaying or denying new launches in our country.

***Recommendation:** To better inform regulatory reform, hold direct in-depth consultations with patient groups to determine the optimal level of access. Are patients willing to give up choice of the most innovative medicines in exchange for lower prices on other drugs?*

Importantly, setting prices and access to innovation to the OECD median signals to the world that ***Canada is unable or unwilling to provide a level of healthcare equal to our global economic standing.*** In Budget 2017 and to global investors, Minister Morneau stated that Canada has the strongest growing economy in the G7.[xii] Why then are we comparing ourselves to a level of healthcare and access to medicines in countries like Turkey and Greece (e.g. the OECD median)? Is this the position we want to present to the world and will Canadians find this acceptable? Will other G7 countries find it acceptable for Canada to demand the status and privileges of an economic leader while only paying the prices of countries with declining economies?

***Recommendation:** Criteria based on Canada's level of healthcare spending and economic standing in the world should be used to select comparator countries. The G7 is a good example of healthcare systems and economies to which we should strive to compare ourselves.*

Utilizing confidential rebates to assess excessive price will result in decreased ability of manufacturers and payers to develop innovative access agreements, thereby resulting in decreased access

It is stated in the consultation document that PMPRB "is left to set its domestic price ceilings on the basis of information that only includes list prices and does not reflect the actual prices paid in the market". However, it is unclear why the PMPRB needs to know net prices to determine if an average price is *excessive*, given that any rebate would be, by definition, below a non-excessive price. The Consultation Document states that information about indirect price reduction/rebates would be treated as privileged under the *Act*. However, it also says that this information "would be taken into consideration by PMPRB when determining whether a patentee is compliant with ceilings set to determine price excessivity." If a patentee is required to reduce a drug's price after Board Staff 'considers' this information, it may be possible for third parties to deduce the product's confidential pricing. A confidential price with one payer cannot be used to assess the price with another payer, nor to set the excessive price for a competitor.

Furthermore, the risk of loss of confidentiality will discourage manufacturers from entering agreements with payers, and thereby may impede the launch of an innovative product in Canada. Importantly, adding elements to the Regulations that have the effect of discouraging new medicines from launching is not consistent with purpose of the *Patent Act n*or the current Innovation Agenda of the federal government. In addition, it is contrary to competition policy to encourage and facilitate the sharing of competitively sensitive pricing information. Over time, an unintended consequence of sharing competitively sensitive pricing information is that it could lead to less price competition because there is less uncertainty in the marketplace as to how a competitor will price its products. In some contexts, this has the effect of stabilizing industry pricing rather than promoting vigorous pricing competition.

The PMPRB has no authority to request information that is not necessary to determine if a patentee's <u>average</u> price is excessive. The entire scheme of the *Patent Act* is based upon average pricing, and must be so, as it is clear that the PMPRB cannot set retail prices nor otherwise interfere with contractual arrangements involving patentees and entities beyond the "factory-gate" of the drug distribution chain.[xiii] Requiring the reporting of rebates goes beyond the mandate of PMPRB and, using this information to establish a price ceiling would mean that PMPRB is effectively setting the retail price of the drug.

Currently, the system allows for manufacturers to negotiate different contracts with different customers, and to provide different benefits to customers, which is standard for most industries. The federal courts have upheld the concept that differential pricing is an attribute of the current legislative regime and have not allowed an interpretation or implementation of regulations that discourages manufacturers from providing benefits to customers. Forcing one price for all customers will actively discourage benefits to customers generally, and in some cases, will have the unintended consequence of a higher net price for some customers who may have been receiving larger benefits, despite a lower list price overall. This is not aligned with the intent of Parliament, nor with direction from the Courts. **This will result in decreased access and affordability for public payers**.

Overall, the constitutional basis – patents – that gives the PMPRB its jurisdiction requires the federal Government to behave in a way that does not penalize the pharmaceutical industry on subjective grounds for the existence of a patent and otherwise harm patient treatment over the medium and longer term.

We need to be thinking about differential pricing in innovative ways. The PMPRB cannot put in place regulations that discourage an innovative approach to listing agreements, both for public and private payers. For example, medicines for rare diseases are often expensive, and often have supporting data that is less robust because of the difficulty in doing large clinical trials in these patient populations. There is currently an opportunity for manufacturers and payers to work together to find a way to fund these types of medicines at an agreed-upon price in conjunction with real-world data collection or other innovative approaches. Price and coverage can then be re-assessed once the data collection is complete. In this scenario, the PMPRB is not able to negotiate or impose such an agreement. Significant reductions in list price imposed by the PMRPB will not allow these innovative approaches to occur, thereby limiting access to this important category of medicines for Canadians

There are many other examples of innovative approaches to listing agreements and contracts designed to address specific needs of public and private payers, hospitals and Purchasing Organizations. While negotiations usually include an element of price reduction, they often also address elements that are not under the purview of the PMPRB, such as data collection, administration of the medicine to patients, supply-chain considerations, etc. As the PMPRB has no ability to address or contemplate these factors, this again highlights the need for the PMPRB to work holistically with all other stakeholders and agencies within the reimbursement system when designing regulation and guideline changes.

Recommendation: *PMPRB should continue to assess excessive price based on average ex-factory price and not require reporting of third-party rebates. Confidential rebates cannot be used to set transparent list prices, so it is unclear how the PMRPB plans on using this information.*

Access and Affordability Conclusions:

The PMPRB needs to look closely at any regulatory changes it considers, and how they fit into the larger reimbursement ecosystem. There are significant issues with the way medicines are assessed for reimbursement in Canada, partly because the development of agencies such as PMRPB, CADTH, and pCPA has happened in a reactive and piecemeal way. Going forward, to optimize the system, all agencies and stakeholders need to work together to develop more holistic and innovative approaches to access so that innovative treatments can reach Canadians in a timely manner. We commend the Minister on her approach to alignment of the timing of Health Canada and CADTH reviews of new medicines, as this will decrease the time to access for public patients. However, changes made to the Patented Medicine Regulations made separately from collaboration with other parts of the reimbursement ecosystem are unlikely to have the desired effect of increasing affordability and access for Canadians.

Innovation

Proposed regulatory changes will impede the federal and provincial governments' Life Sciences Innovation and Economic Development Agendas

The great gains made in healthcare outcomes over the past century would not have been possible without innovation in the life sciences sector. To continue to grow the overall health, well-being and wealth of our country, the federal government has recognized healthcare as one of six key sectors in the Budget 2017 Skills and Innovation Plan. Canada possesses the key fundamentals needed in life sciences to build a sustainable and prosperous healthcare system for the future: strong clinical research; leading hospitals and universities; emerging innovation clusters that bring together universities, entrepreneurs, researchers and capital; and a renowned public healthcare system. In addition, several provincial governments, such as Quebec and Alberta have recently focussed significant resources towards ensuring robust Life Sciences ecosystems, including small and large business investments, academic research and commercialization.

However, these fundamentals need to be supported by innovative and forward-thinking procurement models in healthcare, as opposed to the current cost-containment mindset which is being supported by Ministry of Health initiatives such as the proposed drug pricing regulatory reform.

A key example of the promise of life sciences leadership and collaboration is JLABS@Toronto. an innovation incubator collaboration between Johnson & Johnson, academic institutions such as University of Toronto, hospitals and the Ontario government. This entrepreneurial approach is designed to harness and amplify the best of Canadian health science to the benefit of all Canadians. However, without federal government leadership to establish a 'whole of government' approach to the life sciences sector across departments and between levels of government, health and innovation policies will not be successful in rewarding outcomes and results, and supporting Canadian companies to the benefit of all Canadians.

In addition to impeding the federal government's Innovation Agenda, the proposed changes will impact provincial efforts regarding **provincial Life Sciences innovation**, including the recently announced **Life Sciences Strategy in Quebec**, the aspiration of provinces like **Alberta in healthcare innovation and**

investment and the recent progress made in **data accessibility and analysis** in provinces like Alberta, Quebec, Manitoba and Newfoundland.

The result of the proposed Regulation reform will be less motivation and ability of multinational companies to invest in life sciences in Canada and therefore less innovation being accessible to Canadians. Longer term these changes will also inhibit the ability of Canadian researchers and bio-science entrepreneurs by making it more difficult to commercialize their innovations at home.

***Recommendation**: Hold specific consultations, in collaboration with the Ministry of Innovation, Science and Economic Development and Provincial counterparts to develop innovation-based procurement processes that support and value innovation, in alignment with whole-government priorities and the Patent Act.*

Patent Act is designed to support innovation; changes to PMPRB Regulations cannot contravene the legislation

The intent of Parliament in creating the PMPRB was not to drive down prices, but to support and encourage innovation through the *Patent Act*, while ensuring that prices for patented medicines are not excessive. The Regulatory proposals contravene that Parliamentary intent by disregarding the plain and ordinary meaning of the word 'excessive', and instead, substituting the concept of 'affordability'.

The PMPRB is regulated by the *Patent Act* which inherently supports innovation whereas the proposed regulatory changes emphasize the consumer protection aspect of the PMPRB. It is important to recognize that consumer protection is not only about price. The role of the PMPRB in the context of the *Patent Act* is to protect consumers in two ways: (1) By rewarding pharmaceutical patentees for innovation, thus encouraging development of further life-saving and life-improving medicines for the benefit of all Canadians; and (2) By ensuring that prices of patented medicines are not excessive. This two-fold consumer protection role is entirely consistent with the PMPRB's place in the patent laws of Canada. Proposals such as penalizing medicines that represent the greatest levels of innovation are directly contrary to the fundamental context of the PMPRB, which is to encourage and not stifle innovation.

Summary and Conclusions

Health Canada's consultation paper outlines proposals based on the assumption that prices of patented medicines are too high and need to be decreased. This viewpoint is based on selective data, and highlights a lack of focus on actual policy issues that require more attention such as the issue of Canadians with no or inadequate drug coverage. Health Canada has missed an opportunity to be a true partner in the goal of healthcare sustainability by recognizing the value that medicines bring to patients and the healthcare system. Health Canada has the unique opportunity to be an agent of change to support and encourage innovative approaches to funding of new treatments, particularly for the more vulnerable patient populations in Canada and to support the federal government's Innovation Agenda.

We recognize that the pricing and reimbursement environment has changed significantly since the establishment of the PMPRB, and that payers are concerned about innovative treatments that cost more per patient than in the past. Now may be the time to rethink the way these types medicines are paid for in Canada, but a top-down regulatory price control approach by the federal government will not achieve the goals of increased access and affordability for all Canadians. As a shared goal, we should be working towards ensuring improved access to innovative medicines for Canadians. To accomplish this goal, there needs to be a true collaboration between all parts of the healthcare ecosystem, including payers, patients, healthcare professionals, innovation research and the pharmaceutical industry to ensure continued access to the best care for Canadians. We encourage Health Canada to work across silos to ensure we are successful in creating a world-class sustainable healthcare system.

Janssen believes that all stakeholders should be working together to address a set of policy priorities that is different than those highlighted in the consultation document:

- What is the best way to fund innovation today that also enables the development and delivery of future innovation?
- How do we ensure all Canadians have access to the high-quality innovative medicines they need for optimal health?
- How do we better align the reimbursement system to allow for optimal access to medicines at prices that reflect the true value to patients and the healthcare system?

Only once these questions are addressed, will the PMRPB be able to clearly define its role in the new reality of pharmaceutical reimbursement in Canada.

Appendix: Additional Comments on Specific Proposed Amendments:

Note: for additional technical information regarding these proposals, please reference the submissions from Innovative Medicines Canada and BIOTECanada

Proposal #1: Introducing new factors to help determine whether a price is excessive.
Proposal #4: Modernizing reporting requirements for patentees

- As described above, the proposed factors and tools are already used by both public and private payers in determining appropriate net price based on their own values and budgets. The PMPRB does not need to replicate this work unless the goal is to eliminate CADTH, INESSS, pCPA and private payer drug assessments. **New regulations need to ensure that they are not causing replication in government activities.**
- As opposed to the current factors, cost-effectiveness and market size/budget impact are highly assumption-based, and therefore, are inefficient in setting ceiling prices. For example, the consultation paper states that if the market size increases significantly than assumed at launch, then the price is excessive and needs to be reduced. Is the opposite true: if a medicine fails to achieve the anticipated market size, should the price be increased?
    - ***Ongoing assessment of assumption-based net prices is currently accomplished by the payers themselves, it is unnecessary for PMPRB to duplicate this work***
- Cost-effectiveness models used by CADTH do not apply to all consumers in Canada. Value-for-money is very different for public and private payers and individual patients and CADTH models do not apply to the latter consumers.
    - Contrary to the consultation document, which clearly states a desire to reduce regulatory burden on patentees, providing cost-effectiveness and budget impact models for all consumers will add significant regulatory burden
- **As the legislation already allows the Board to look at additional factors when an excessive price cannot be established, we recommend that these factors be used in the context of an Alternative Dispute Mechanism on a complaints-basis if a non-excessive price cannot be established, not added to the Regulations in the proposed manner**
- If the intent is to only apply these factors to a certain category of 'high-risk' medicines, more clarity needs to be provided in the Regulations by the Minister in this regard and how any new factors will be applied to ensure they are effective in meeting the intended objective, as the PMPRB staff in the future may interpret the changes differently than what was intended by lawmakers

Proposal #2: Amending the list of countries used for international price comparisons

- In addition to the commentary provided above regarding the economic and health standards of Canada compared to the OECD, the new specific countries chosen to represent the OECD do not meet the standards outlined in the consultation paper
    - economic measures beyond GDP should be considered
    - the new countries have different pharmaceutical market characteristics e.g. significantly different populations (both in numbers and age/ethnicities), pharmaceutical utilization, revenues and market entry of new products[xiv]
- As described above, Health Canada should consider comparing Canadian medicines to those available in a comparable set of economies, such as the G7
- It is also important to note that while some of these jurisdictions may have "national pricing containment measures" relating to drug pricing, the authority in those jurisdictions for such measures is not granted by their nation's patent protection legislation. **Any "measures" adopted under the Patented Medicine Regulations must respect purpose of the Act, and respect Canada's international obligations.**
- Additional challenges include the impact of fluctuations in exchange rates and the differences in medical practice, approved indications and the reimbursement policies in the proposed countries
- Five additional comparator countries will significantly increase the regulatory burden for patentees and workload for PMPRB staff, again contradicting the stated goal of decreased regulatory burden

- Given that the majority of additional countries have fewer new medicines launched than Canada, there will be many circumstances whereby a price comparison cannot be made because a medicine may never be available in that comparator country. Tracking launches in 12 countries over several years is a significant commitment for PMRPB staff.

Proposal #3: Reducing regulatory burden for generic drugs with a patent

- "Risk-Based Approach": While more regulatory control is outlined through the addition of new factors and adding additional reporting requirements regarding international prices, no decrease in regulatory burden on less 'risky' categories of medicines is outlined, beyond a category which is already in existence and is currently only assessed on a complaints-basis [xv]
- If Health Canada truly wants to move to a Risk-Based approach to regulatory control, the following categories of medicines should be included in Proposal #4, as these are categories where various market forces are successful in setting market prices
  - Innovative products once they have generic competition
  - Innovative products with one or more competitors with the same mechanism of action
  - Vaccines and blood products
    - All of these categories have limited power to price beyond market forces

Proposal #5: Providing information related to third party rebates

- The proposed amendments do not explain why confidential rebates to third-party payers are needed by the PMPRB and what they will be used for. Rebates to third-party payers are highly confidential, not only to the manufacturer, but also to the payer. More clarity needs to be provided regarding the intended use of this information and specifically how having this information will help the PMRPB increase affordability and access to medicines for Canadians.
- As described above, the level of uncertainty regarding intent, and business-critical nature of this information may force some companies to decline to negotiate agreements with payers, thereby limiting access to innovative medicines for Canadians

References

[i] Skinner BJ (2016). Spending on patented drugs in Canada 1990 to 2014. Canadian Health Policy, Toronto. Canadian Health Policy Institute.

[ii] Patented Medicine Prices Review Board Annual Report 2015. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1273

[iii] Capaxone Decision http://www.smart-biggar.ca/en/articles_print.cfm?news_id=743

[iv] http://www.cbc.ca/fifth/episodes/2016-2017/the-high-cost-of-phamaceuticals-canadas-drug-problem

[v] The increasing inefficiency of private health insurance in Canada, Michael R. Law, et. al. CMAJ. 2014,186(12): E470.

[vi] The 2016 IMC/IMS Brogan private drug plan forecast (2017). Data on file, Innovative Medicines Canada.

[vii] Patented Medicine Prices Review Board Meds Entry Watch 2015. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1307&lang=en

[viii] Rawson NSB (2016). How might the choice of prescription drugs in provincial public insurance plans be impacted if a cost-control system like New Zealand's was adopted in Canada? Canadian Health Policy, September 26, 2016. Toronto: Canadian Health Policy Institute. www.canadianhealthpolicy.com

[ix] Lorier & Rawson. Lessons for a national pharmaceuticals strategy in Canada from Australia and New Zealand. Can. J. Cardiol. 2007; 23:711.

[x] http://www.cancer.ca/~/media/cancer.ca/CW/cancer%20information/cancer%20101/Canadian%20cancer%20statistics/Canadian-Cancer-Statistics-2017-EN.pdf?la=en

[xi] Patented Medicine Prices Review Board. Guidelines modernization discussion paper. http://www.pmprb-cepmb.gc.ca/CMFiles/Consultations/DiscussionPaper/PMPRB_DiscussionPaper_June2016_E.pdf

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

[xiii] See *Pfizer*, Paragraph [11]

[xiv] Patented Medicine Prices Review Board Meds Entry Watch 2015. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1307&lang=en

[xv] PMRPB Quarterly Newsletter February 2017. http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1292&lang=en#a5