Janssen Inc.

19 Green Belt Drive
Toronto, ON M3C 1L9
1.800.387.8781 toll free
416.449.9444 tel
416.449.2658 fax

www.janssen.ca

October 21, 2016

Douglas Clark
Executive Director
Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Mr. Clark:

On behalf of Janssen Inc., I am pleased to provide our submission to the Patented Medicine Prices Review Board (PMPRB) in response to the content of the Guidelines Modernization Discussion Paper dated June 2016.

The PMPRB has been undergoing an extensive assessment of its role in the Canadian reimbursement environment, as outlined in the three-year Strategic Plan. As noted in that Strategic Plan and in the Discussion Paper, there have been significant changes in the reimbursement environment since 1987 with both government and private payers developing processes and agencies designed to ensure that new medicines are clinically-effective, cost-effective and affordable. Therefore, we agree it is an important exercise to re-evaluate the role of the PMPRB in today's dynamic environment. To date, the PMRPB has remained separate from our public and private reimbursement processes, as the arbiter of the 'non-excessive' price. However, in the Strategic Plan and Discussion Paper, the PMPRB contemplates moving away from this mandate and positioning itself as an agency that will determine 'affordable' prices. We believe this is a significant departure from the original purpose for which the PMPRB was established and requires meaningful discussion and debate among all stakeholders.

We recognize that provincial, federal and private payers are concerned about managing health budgets. Canadians are extremely proud of our publicly-funded healthcare system and view it as one of our most important and distinguishing features when compared to other countries around the world. Canadians want a system that enables optimal health for current and future generations. However, Janssen believes that while the changes suggested in the PMPRB Discussion Paper may decrease the *price* for some medicines, they will have no impact on other factors driving the *cost* of medicines and may have unintended consequences, including limiting access to the most innovative medicines. This seems counterintuitive when the original mandate of the PMPRB evolved from our country's desire to encourage more innovation in Canada.

We are at a critical junction in the evolution of our health care system where we must decide if we are committed to finding multi-dimensional and innovative solutions for maintaining the high quality of health care we expect in Canada, or if we will let the issue of affordability hijack the need for a more comprehensive discussion about the complex challenges we face, resulting in changes that may not allow for future sustainability or success. If we limit ourselves and focus only on prices, we will miss out on the grander opportunities that the promise of science and innovation offer for a healthier, happier and more productive nation. We are ready and willing to work with Canadian governments and health plan providers to build a health care system that not only values innovation but is innovative itself and provides a leading example to the world on how the current challenges can be overcome with a collective and collaborative approach.

Janssen is aligned with the input provided by Innovative Medicines Canada with regards to this matter. In addition, please note that the Innovative Medicines Canada submission provides greater detail on many of the topics raised in this submission.

Attached is our analysis of the ideas put forward in the Discussion Paper. Given the important nature of this review, we have endeavored to provide thoughtful and meaningful feedback beyond the questions posed in the Guidelines Modernization Discussion Paper. We also welcome the opportunity to bring together the key players in our healthcare system to have a more fulsome discussion on how to build solutions that work, are not duplicative and do not create unintended consequences.

Sincerely,

Chris Halyk
President

cc: Carole Watson, Director, Strategic Pricing, Janssen Inc.
Dr Mitchell Levine, Vice-Chairperson, Patented Medicine Prices Review Board
Normand Tremblay, Member, Patented Medicine Prices Review Board
Carolyn Kobernick, Member, Patented Medicine Prices Review Board

Comments on: PMPRB Guidelines Modernization Discussion Paper
Released: June 2016

The PMPRB Guidelines Modernization Discussion Paper presents a viewpoint supporting the need for significant change in the approach to setting a ceiling price for medicines in Canada. We agree that the reimbursement environment has changed significantly since the inception of the PMPRB and it is an appropriate time for the PMPRB to assess its mandate, effectiveness and relevance. However, the concepts discussed in the Paper, if implemented in isolation of the roles and functions of other bodies in the entire reimbursement process, will not achieve the goal that government should be focused on, namely, optimal access to medicines for all Canadians.

Key Points:

- *Amendments suggested in the Discussion Paper will not significantly contribute to healthcare sustainability and may have the unintended consequence of decreasing access to innovative medicines for Canadians*
- *The mandate of the PMRPB does not and should not include an assessment of affordability*
- *Innovative medicines provide significant positive impact to Canadians and our health care system; therefore, therapeutic value must be included in any pricing assessment*
- *Amendments suggested in the Discussion Paper cannot and should not be considered unless the legislative mandate of the PMPRB is fully debated and changed by Parliament*
- *All stakeholders need to collaborate in order 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 health care for all of our citizens. We understand the interconnectedness and positive impact a healthy population has on quality of life, productivity and 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 is befitting a country with the global stature of Canada to promote and maintain regulatory, economic and health policies 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 PMPRB.

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

Our goal is to ensure that any guidelines modernization is done in a way that allows Canada to continue to be a premier country for new medicines, which benefit patients, the health system and the economy. The system should ensure that Canadians have the ability to choose the best therapeutic options.

It is Janssen's concern that some of the ideas put forward in the Discussion Paper could work against the goal of maintaining a world-class healthcare system and optimal health for Canadians.

Determining an Appropriate Price Must Necessarily Incorporate Therapeutic Value

Recent public discourse about the price of medicines has lost focus on the value and positive impact a drug has on individual patients, caregivers, the healthcare system and society. The PMPRB has suggested that therapeutic value assessments be eliminated from the price tests and be replaced by a focus on potential for monopoly power and an assessment of affordability. Therapeutic value must continue to be considered as an important factor when assessing excessive price for the simple fact that the price of any product is determined, at least in part, based on the benefits it brings to the consumer. For this reason, Section 85 of the *Patent Act* clearly states that therapeutic class is a factor that must be considered by the PMPRB in its assessment of excessive pricing.

The PMPRB is regulated by the *Patent Act* which inherently supports innovation. Janssen fundamentally disagrees with the statement on page 14 of the Discussion Paper that the PMRPB regime can be divorced from the context of its enabling statute and from that *Act*'s goal of encouraging innovation for the benefit of consumers. 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 dispensing with therapeutic benefit and even 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. The suggested changes are undervaluing the concept of patents.

Innovative medicines provide significant value to the healthcare system. Several studies have clearly demonstrated that use of innovative medicines consistently results in not only improved outcomes for individual patients, but decreased costs in other parts of the system and greater societal benefits.[1][2][3][4][5][6] This inherently makes sense; if a patient can be cured of Hepatitis C, they will no longer need ongoing treatment, and they will not require a costly liver transplant. If a patient with schizophrenia can be maintained in the community with appropriate medicines, they will not incur costly hospital stays and will have an opportunity to be a contributing member of society. To assess the price of a medicine without incorporating some assessment of its therapeutic value displays an inherent lack of understanding of the significant positive impact medicines have made on the overall health of Canadians and the healthcare system. We know of no other international pricing regime that focuses on economic factors and excludes therapeutic factors.

In the Discussion Paper, the PMPRB suggests that products with the greatest therapeutic advantage should be subject to the greatest regulatory oversight. Again, this is counterintuitive to the mandate of the PMPRB and its enabling statute. Fundamental to pharmaceutical pricing regimes around the world is the concept of rewarding innovation. It is concerning that several ideas in the Discussion

---

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

[2] Lichtenberg FR. Pharmaceutical innovation and longevity growth in 30 developing and high-income countries, 2000-2009. National Bureau of Economic Research (NBER), Working Paper n. 18235, July 2012.

[3] Lichtenberg FR, The impact of pharmaceutical innovation on premature cancer mortality in Canada, 2000-2011. Int J Health

[4] Hermus et al. Reducing the health care and societal cost of disease. The role of pharmaceuticals. The Conference Board of Canada, 2012.

[5] Lichtenberg FR. Benefits and costs of newer drugs: An Update. National Bureau of Economic Research (NBER), Working Paper no. 8996, 2002.

[6] 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. URL: www.canadianhealthpolicy.com

Paper appear to penalize the most innovative medicines that are likely to have the greatest impact for patients.

Assessing price without incorporating therapeutic value would disconnect the PMRPB from the rest of the reimbursement processes in Canada, and would make it an outlier in the way price regulation is approached internationally. The PMPRB needs to look closely at any guideline or legislative 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. Any changes to the PMPRB Guidelines made separately from collaboration with other parts of the reimbursement ecosystem are unlikely to have the desired effect of increasing access or improving the overall sustainability of our healthcare system.

Recommendations:

- *Review the current system of incorporating therapeutic value into price assessments with the goal of appropriately encouraging innovation*
- *Ensure any proposed changes are not penalizing innovation*
- *Work in collaboration with all stakeholders to address healthcare sustainability concerns*

Guideline changes proposed in the Discussion Paper require legislative amendment

The Discussion Paper raises the concept of 'affordable', as opposed to 'excessive', when determining a ceiling price. However, it is our view that the PMRPB does not have the mandate to assess affordability.

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 ideas in the Discussion Paper contravene that Parliamentary intent by disregarding the plain and ordinary meaning of the word 'excessive', and instead, substituting the concept of 'affordability'. The *Patent Act* clearly outlines the factors that need to be considered by the PMPRB when determining if a price is excessive. In general they are; the price in Canadian markets, international prices, the prices of other products in the same therapeutic class and the Consumer Price Index. Nowhere in these factors is the concept of regulating pricing based on affordability.

The Discussion Paper is correct in that there have been many changes in the reimbursement environment in Canada since 1987, including:

- greater budgetary pressures on healthcare;
- the advent of Health Technology Assessment, with CADTH and INESSS determining the relative cost-effectiveness of new products and indications;
- the introduction of confidential Product Listing Agreements and the pan-Canadian Pharmaceutical Alliance allowing public payers to assess and address affordability based on their own budgetary priorities and population requirements;
- new and innovative tools used by private payers to manage costs (e.g. managed formularies, listing agreements, case management systems, etc);
- a change in the types of drugs developed by pharmaceutical manufacturers – drugs that treat smaller, more specialized patient populations at sometimes a higher cost per patient.

All of this has led the PMPRB to question its relevance in the face of this unprecedented level of assessment of pharmaceuticals in Canada. However, what has not changed since 1987 is the mandate of the PMPRB as determined by Parliament and set out in sections 79 to 103 of the *Patent Act* and its associated Regulations. On page 10 of the Discussion Paper, it is stated that the legal framework of the PMPRB has to be brought in line with today's pharmaceutical environment and international best practices and that "Guidelines modernization is a necessary first step toward" achieving that goal. It is Janssen's position that the proposals raised by the PMPRB in the Discussion Paper go well beyond the mandate of the PMRPB and contravene Parliament's intent. Therefore, any changes to the Guidelines should follow amendments by Parliament to the PMPRB's legal framework, not the other way around.

Parliamentary review of these amendments is particularly necessary in light of the significant and substantive nature of the changes described in the Discussion Paper. These include:

- changes to the usual meaning of the word "excessive", equating 'affordable' and 'non-excessive' when these two concepts are very different;
- discarding the use of therapeutic benefit as a starting point for pricing analysis despite inclusion of this factor in subsection 85(1) of the Patent Act;
- unilaterally deciding to give more weight to certain factors outlined in subsection 85(1) over others, despite Parliament's intent and the Courts' clear direction otherwise;
- contradicting the intent of the Governor in Council in choosing the seven reference countries;
- eliminating the concept of price averaging, despite direction from the *Patent Act*, the *Regulations* and the Federal Court requiring the PMPRB to do otherwise.

Therefore, we are of the view that legislative amendments are required for all proposals set out in the Discussion Paper, including any substitution of 'excessive' with 'affordable'.

Recommendations:

- *In collaboration with all stakeholders, determine key policy issues the government proposes to address, beyond the rhetoric of "drug prices are too high"*
- *Debate the mandate of the PMPRB in Parliament and whether it needs to be changed, in order to develop sound policy and the political will to address any concerns*

The PMPRB does not have the ability to 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 a given 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;
- many other factors that the PMRPB is not privy to and cannot assess.

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* seems illogical. Therefore asking the question "What does excessive mean to you?" is simplistic and leading.

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 pCPA; negotiating affordability based on the budgetary needs of the public payers. Individual drug plans choose whether or not to join a negotiation for a particular medicine, based on the needs of their population, and they then choose whether or not 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.

The same is true for employers and private insurance plans. Health benefits are offered to employees for a wide variety of reasons and the goals of these benefits are very different than those of the provincial drug plans. For example, a private payer will likely prioritize treatments that enable productive work and decreased disability. Private payers have developed a wide variety of tools to address affordability, while still providing the benefits requested by their employer customers.

Therefore, due to the wide variety of payers in Canada, in contrast to other international pricing regimes it is impossible for one single agency to assess one 'affordable' price for everyone.

Recommendation:

- *Continue to allow budget holders for both public and private insurance plans to assess and determine the affordability for medicines based on their respective patient populations, higher level budgetary prioritization and values*

Differential and innovative pricing agreements bring more value to payers and enable access

A key focus discussed by the PMPRB is how to regulate the price of high cost drugs, particularly those breakthrough products for which there is little or no competition. As a first principle, all stakeholders should recognize that in general, these medicines are treating patients with diseases for which there was previously no treatment and can be life-saving or life-altering. We need to work together to find a way to fund these innovative treatments to save lives today, and as an investment in future innovations.

Currently, the system allows for manufacturers to negotiate different contracts with different customers, and to provide different benefits to customers. 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.

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 the medicine at an agreed-upon price in conjunction with real-world data collection or other innovative approaches. Price and coverage is then re-assessed once the data collection is complete. In this scenario, the PMPRB is not in a position to negotiate or impose such an agreement.

If the PMPRB puts into place regulations that significantly impact the initial price of the medicine, this takes away the ability of the manufacturer to even contemplate developing innovative coverage with evidence development or other types of agreements. The end result is less innovation available to patients.

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 GPOs. 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 Guideline changes.

Recommendation:

- *Closely analyze any proposed Guideline changes to ensure there are no negative consequences with respect to:*
  - *The ability of manufacturers to provide benefits to customers*
  - *The ability of payers to collaborate with manufacturers to develop innovative approaches to providing affordable coverage*

Changes to the Guidelines cannot be chosen simply for the purpose of decreasing prices.

The mandate of the PMPRB is not to drive down prices; it is to ensure that prices are not excessive. Therefore any changes to the Guidelines must be considered with this mandate top of mind. Concepts such as scheduled post-launch price decreases, new price reviews with new indications or changes in market dynamics, changing the basket of international comparators, and many other ideas in the Discussion Paper do not address the issue of excessive pricing; they are merely attempts to lower prices.

There is also no clear analysis or data to support the idea that these changes will have a positive impact on healthcare sustainability. In addition, many of these concepts are already utilized by the public and private payers through tools such as updated HTA assessments with new indications, renegotiation of pricing agreements, and tiering. Therefore, a multi-stakeholder comprehensive approach to finding innovative solutions to our healthcare sustainability issues is necessary, not a unilateral proposal for price reductions by the PMPRB. The PMPRB does not need to duplicate work already being done at the private and provincial levels by those who control their budgets.

Recommendations:

- *Ensure that the intent and outcome of any proposed Guideline changes are aligned with the legislative mandate of the PMPRB.*
- *Ensure that any proposed Guideline changes do not replicate processes already underway by other agencies.*

Competition principles and market forces must be considered in this process to ensure long-term investment in innovation.

When looking at pharmaceutical pricing regulation from a purely economic perspective, as long as the private sector is relied upon to provide effective drug treatments to improve public health, market forces and economic incentives must remain at the centre of any national pharmaceutical pricing regime. The main reason is that the high risks taken to develop lifesaving and life-altering drugs must be appropriately rewarded; otherwise, no one will assume these risks for the benefit of public health.

The complexity of pricing dynamics is acknowledged in virtually every economic and regulatory realm. Determining 'excessive prices' for medicines is no exception. The more intervention and manipulation of pricing, the greater the risk for unintended consequences that harm consumers and distort or disrupt market factors that incentivize product development, production and supply that serve consumers in the medium and long term. This is why competition laws and authorities have largely stayed away from the area of price enforcement. It is important to note that the drug industry is marked by the presence of large buyers, including governments, who have and do exercise countervailing buyer power and as such, market forces are already in place to regulate pricing, outside of federal regulations.

The intent and effect of price regulation does not lend itself to properly reward risk taking behavior or superior innovation. In an industry that requires taking big risks to develop lifesaving medicines and improving public health outcomes, the risks of excessive intervention on pricing are also high. The market and product offerings cannot be viewed as a static single event, but rather as a continuum of events that must continue to be able to support the research and development of the next big cures. One of the most important public health priorities must be to ensure new drugs are developed and available to Canadians over the medium and long-term.

Excessive attempts to manipulate prices and downplay or remove therapeutic value from any related assessment undermine the intent of the *Patent Act* and the integrity of the patent system, and do not serve the best interests of Canadians. Moving forward, we must increase collaboration between all stakeholders to facilitate better budget and healthcare priority planning, as a shared responsibility, to ensure proper medium and long-term market functioning to develop, produce and make available new drugs of high therapeutic value to Canadians.

Recommendations:

- *Recognize the high-risk nature of pharmaceutical innovation*
- *Develop regulations that enable, rather than hinder, the development of new innovative treatments to the benefit of Canadians now and in the future*

Guideline changes must work in alignment with other steps in the reimbursement process, not duplicate or replace work done by other agencies

The PMRPB is well aware of the governmental agencies and processes that operate in Canada to assess and determine reimbursement for drugs in Canada. No other part of the healthcare system is subject to as much bureaucratic scrutiny as the price of innovative medicines, particularly when those medicines represent only 6.4% of health spending.[7] If the PMPRB is determining affordability, this could significantly alter the mandate of other agencies such as CADTH/INESSS and pCPA, or at very

[7] Canadian Health Policy Institute, Spending on Patented Drugs in Canada 1990-2014, February 23, 2016

least result in the duplication of their work.

The PMPRB is correct in its assertion that cost-effectiveness is the mandate of the HTA organizations and is using this fact to justify removing therapeutic value from its price assessments. However, HTA reviews are designed to determine if a medicine is cost-effective at a *given price*, not to *determine a price*. This is an example of why the Board needs to recognize that the PMPRB does not operate in isolation from the other parts of the reimbursement ecosystem. In the past, the PMPRB has operated separately from HTA organizations and pCPA but is now proposing steps to duplicate efforts of those agencies. Providing stronger price data analytics for payers when they are undergoing their own affordability assessments is an example of how the PMRPB can provide greater value to the reimbursement system. We encourage the PMRPB to take further steps to holistically assess its role in the broader reimbursement ecosystem to determine how all governments, agencies, manufacturers and other stakeholders can collaborate to achieve our common goals – including access to innovative medicines for all Canadians. Creating regulatory activities that duplicate the work of other agencies is not a cost-effective approach to pricing regulation.

Recommendations:

- *Ensure that any proposed guideline changes do not duplicate the work of other government agencies*
- *Lead a collaboration with all Stakeholders to determine a better, more efficient, more innovative approach to reimbursement of medicines in Canada*

Summary and Conclusions

The Discussion Paper outlines a number of questions based on the PMPRB's 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. The PMPRB 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. The PMPRB has the 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.

Janssen believes that all stakeholders, including the PMRPB, should be working together to address a different set of questions than those listed in the Discussion Paper:

- What is the best way to fund innovation now 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 re-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.