6755 Mississauga Road
Suite 600
Mississauga, ON
L5N 7Y2

October 31, 2016

Mr. Douglas Clark
Executive Director
Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, ON
K1P 1C1
Submitted via Email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca;
douglas.clark@pmprb-cepmb.gc.ca

Dear Mr. Clark,

RE: Celgene Inc Response to PMPRB Guidelines Discussion Paper

Thank you for the opportunity to comment on the PMPRB's Guidelines Discussion paper.

Celgene is a global biopharmaceutical company focused on the discovery, development and commercialization of innovative therapies for unmet medical needs in cancer and immune-inflammatory diseases. Since opening our operations in Canada in 2006, Celgene Inc has commercialized treatments to address some of the toughest health challenges faced by Canadians.

Celgene has a rich pipeline of investigational compounds in preclinical and clinical development, with 24 compounds in a later stage of development. Our pipeline, including recent acquisitions and external collaborations, has the potential to support introduction of multiple new drugs for the treatment of patients with hematological malignancies and solid tumor cancers and for inflammatory and immunological disorders.

Celgene investments in research and development exceed $3.69 billion annually (2015). Canadian patients directly benefit from these investments in innovation and we conduct many clinical trials in Canada. The local economy benefits from our investment in Canadian biotechnology companies. Many of these investments and benefits are not captured in the R&D methodology that the PMPRB must currently follow under law and regulation. PMPRB-reported R&D is not reflective of our full value and commitment to Canada.

Celgene is a member of BIOTECanada and fully supports the submission of our association. We would also like to take this opportunity to raise and reiterate some key points for the PMPRB's consideration.

Our submission is organized as follows:

- Principles to Guide PMPRB Guidelines Reform
- PMPRB Mandate
- Challenges with the Vagueness of Current Consultation Process
- Therapeutic Assessment
- International Comparisons
- CPI and Cost Control Over time
- Private Market Gaps
- Key Messages and Next Steps

Principles to Guide for PMPRB Reform

It is useful to ground our positions on PMPRB reform on some core key principles that we hope all stakeholders will recognize. These were developed with consideration to the PMPRB's strong regulatory history, the need to engage in a sound public policy development process, and with respect to our role in bringing life-savings therapies to Canadians at prices that reflect their value to society. We feel that PMPRB Guidelines reform must:

1. **Be based on evidence and high quality analysis:** Any policy changes should be rooted on solid information and analysis of pharmaceutical trends and any specific challenges posed by the existing rules.
2. **Support and maintain predictability:** Any changes should offer incremental improvements to the existing Guidelines. Drastic changes to the pricing system for patented medicines could have unintended impacts and produce uncertainty for manufacturers and patients.
3. **Recognize value and therapeutic improvements:** The PMPRB and the Human Drug Advisory panel (HDAP) have considerable history and expertise in assessing therapeutic value. It is not clear if the PMPRB could function without employing some assessment of the incremental value that a new therapy brings to the health system.
4. **Respect the roles of various players within the health and pharmaceutical regulatory system:** The PMPRB safeguards against excessive-pricing. Public and private drug plans have responsibility to ensure their plans are affordable and sustainable. They leverage various tools including HTA assessments and negotiations with manufacturers to ensure this. These distinct roles must be maintained.
5. **Reduce complexity:** Regulatory burden can be reduced without adding new sources of complexity as part of competition-style regulations.
6. **Protect consumers from excessive pricing though price ceilings. Reform must not change the fundamental role of the PMPRB so that it actively distorts the pharmaceutical market**: The PMPRB was intended as, and has always functioned as a safeguard or backstop against excessive pricing. It has never actively attempted to shape or influence overall pharmaceutical expenditures, distort the market, or actively influence prices in one direction or another. The PMPRB does not have experience in budget impact or drug-plan affordability nor is it Canada's competition regulator. The PMPRB should remain as a backstop or safeguard against excessive pricing.

PMPRB Mandate

In keeping with the above principles we note that the PMPRB legislated mandate is to prevent excessive pricing. As raised in the consultation document, the Supreme Court of Canada has noted that the legislative intent of the PMPRB's mandate to prevent excessive pricing was rooted in consumer protection.[1]

With this mandate so clearly articulated in law and judicial rulings, we are curious as to why the PMPRB is just now introducing the vague new concept of "affordability" and positioning it as part of its role despite a lack of clarity on what this may entail. The PMPRB has not provided a clear definition of affordability and we can find no reference in the relevant legislation or case law. Furthermore, in our view, nothing in the 2011 Supreme Court ruling in any way "conflicts" or otherwise undermines the role of the PMPRB to assess therapeutic benefit.

Affordability is an inherently comparative term in that it must relate to some other variable such as income, population dynamics, utilization rates or expenditure management practices. Given this complexity and implications for public policy, we find this to be an inherently flawed direction and respectfully recommend that the PMPRB focus on its legislated mandate.

In our view, excessive pricing should not be defined as a function of budget impact or other population dynamics related measure such as percentage of drug expenditure. Public and private payers have many tools at their disposal to secure value for their investments in innovative therapies. The PMPRB plays a distinct and important role in preventing non-excessive pricing and should continue to focus its efforts in this area.

Challenges with the Vagueness of Current Consultation Process

We recognize the PMPRB's desire to reassert its role in the health system and open this discussion to a diversity of stakeholders. PMPRB discussion paper and briefings for industry have identified several very broad areas and themes for potential reform. It has posed several open-ended questions that suggest *potential* directions that could drastically alter the pharmaceutical landscape in Canada.

Without specific details on proposed changes it is difficult to comment on many of these questions. However, we are concerned by the potential for drastic changes to PMPRB rules concerning a yet to be defined "competition" policy model based on potential for "exploitative pricing."

We would note that the PMPRB *already functions* to prevent excessive pricing where the existence of a patent inherently implies *potential* for abuse. The pharmaceutical industry is already subject to Canadian competition laws and so it is somewhat unclear what new provisions the PMPRB may have in mind.

[1] Celgene Corp. v Canada (Attorney General), 2011 SCC 1, [2011] 1 S.C.R

The current Guidelines revision process lacks clear direction, objectives, and specific policy proposals. As the Guidelines reform process progresses, we hope to see the emergence and explicit articulation of reform objectives and appropriate analysis to support any proposed reforms.

We remain keenly interested in working with the PMPRB on an incremental and predictable approach to reform. While the existing Guidelines are somewhat onerous and not perfect, we feel that current Guidelines framework should continue to serve as the general model going forward.

Therapeutic Assessment

The discussion paper touches on the issue of whether the PMPRB should continue to assess therapeutic benefits. Assessing degree of therapeutic improvement is an essential component of the PMPRB's role and should remain so.

The *Patent Act* specifies that the Board must consider the "prices at which other medicines in the same therapeutic class have been sold in the relevant market" in its determination of excessive price. It is hard to imagine a scenario where the PMPRB could consider this factor without differentiating between levels of therapeutic improvement:

- For example, if a new drug entered a therapeutic category dominated high-cost drugs the PMPRB would need an assessment of comparative therapeutic benefit so as not to automatically award a high price.
- Similarly, if a clinical breakthrough product entered a category dominated by old, cheaper generics it would not be sound policy to automatically force the price of the breakthrough drug to the generic pricing level.

Not differentiating between levels of therapeutic improvement could alter financial incentives for international companies to bring drugs to Canada.

The current therapeutic class comparison test (TCC) helps to assure general consistency of pricing when there are multiple patented drugs to treat the same condition.

PMPRB practice has always been to sensibly identify degree of therapeutic improvement to operationalize its statutory requirements. Breakthrough products can be priced at a premium over existing therapies within the same therapeutic class, typically at the median international price. This is appropriate and helps to recognize innovation.

Through the Human Drug Advisory Panel (HDAP), the PMPRB has considerable expertise and experience evaluating therapeutic benefits and we see this as an essential component of the PMPRB's work going forward.

This PMPRB work is complementary to, and not duplicative of, the cost-effectiveness work that Health Technology Assessment (HTA) bodies like CADTH do as part of the formulary review process.

International Comparisons

The PMPRB's 2015 Annual Report notes that international median prices are 18% above their respective Canadian prices.[2] In 2014 and 2015, Canadian prices actually declined relative to median international prices.[3] The evidence would not seem to support a conclusion that there is a major imbalance in Canadian prices relative to the PMPRB's regulatory comparators. To reiterate an important point, we believe policy changes in this area are not supported by available evidence.

CPI and Cost Control Over Time

According to CIHI, Canadian prescription pharmaceutical expenditures have been essentially flat in recent years and has not exceeded 1.7% growth in the past five years.[4] This reflects, in part, the PMPRB's ongoing success in holding price increases to inflation as measured by the consumer price index (CPI). While we see the current CPI policy measures as working well, Celgene is open to further discussing any challenges the PMPRB sees in this area and any specific measures that may be under consideration.

Private Market Gaps?

The PMPRB notes there is a "growing price gap between public payers, who are able to negotiate collectively through the pan-Canadian Pharmaceutical Alliance (pCPA), private payers, who may lack the flexibility to do so under competition laws and cash customers, who have no ability to negotiate."

The PMPRB has not supported this point with sufficient evidence. There is currently a dearth of information on net pricing gaps and potential insurance gaps in Canada.

There is considerable evidence available in the public domain that the private insurance sector does in fact negotiate agreements to drive value for private plan sponsors.[5] Furthermore, there are examples of multiple insurers participating in third party formulary management schemes.[6] Insurers are also pooling risk on high cost drug claims through the Canadian Drug Insurance Pooling Corporation (CDIPC).[7]

At the end of the day, most of the lives covered by the private insurance sector are concentrated with a handful of major insurers who are large sophisticated entities with considerable purchasing power and negotiation capacity. Their mechanisms "reduce financial exposure and...provide the best possible value proposition" to their clients.[8]

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[2] PMPRB 2015 Annual Report, p. 30-31.
[3] Ibid.
[4] Figures for 2014 and 2015 are CIHI forecasted. CIHI, National Health Expenditure Trends, 1975 to 2015, data tables, https://www.cihi.ca/sites/default/files/document/nhex_2015_datatables_en.zip
[5]" Sun Life has a new arrangement with Janssen Inc. to reduce costs on REMICADE®" https://goo.gl/pRq9zt "Preferred pricing for Remicade® is here" https://goo.gl/rYJ5rK; Update on Manulife DrugWatch: Repatha® and newest indication for Humira now listed on Manulife drug plans" https://goo.gl/B1upov
[6] http://www.reformulary.com/index_en.php?page=members
[7] http://cdipc-scmam.ca/about.html
[8] https://goo.gl/B1upov

Regarding potential out-of-pocket gaps, we note that more analysis is required. Nearly all provinces have catastrophic drug programs that engage when a reasonable percentage of a patient's income is spent on drugs. Others have universal coverage models (e.g. Quebec).

According to CIHI, out-of-pocket spending on prescribed drugs has actually *decreased* modestly in recent years: from $6.56 billion in 2010 to $6.38 billion (CIHI forecast) in 2015.[9]

Furthermore, companies often offset patient costs through patient support programs and essentially function as a payer of last resort in some cases.

As such, the extent of any potential pricing and insurance gaps in Canada is not known and requires further analysis. This theme of knowledge gaps in the private market has also emerged at the Parliamentary Heath Committee's ongoing study of pharmacare in Canada. Before any policy changes to the pharmaceutical system are made, we must collectively do a better job of identifying with hard data the extent to which any problems may exist. Polling or survey data is not sufficient for this task.

Key Messages and Next Steps

Celgene is committed to being a productive partner in the PMPRB's Guidelines reform process.

In our view, the function and impact of the PMPRB in the Canadian market has not drastically changed over time and the PMPRB has not demonstrated a pressing need for a radical overhaul of its regulatory model. Due in part to CPI controls, pharmaceutical prices remain remarkably stable in Canada. Pricing trends in Canada continue to closely reflect international median pricing of the PMPRB's regulatory basket. Public and private plans continue to drive value through listing agreements.

We welcome further discussion on these issues and look forward to future opportunities to meet with Board Staff and the full Board itself. In particular, we feel it would be helpful to discuss how we might work together to streamline processes or decrease regulatory burden in some areas.

Kind regards,

Kevin Leshuk,
Vice President and General Manager
Celgene Inc

[9] CIHI, National Health Expenditure Trends, 1975 to 2015, data tables, https://www.cihi.ca/sites/default/files/document/nhex_2015_datatables_en.zip