October 28, 2016

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

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I am writing to provide the views of Bayer Inc. on the Patented Medicine Prices Review Board's (PMPRB's) Guidelines Modernization Discussion Paper regarding possible reforms to its Compendium of Policies, Guidelines and Procedures (the "Guidelines"). We appreciate the PMPRB's continued efforts to increase dialogue between the Board and its key stakeholders. **Bayer is fully aligned with the position taken by Innovative Medicines Canada (IMC), including the request that working groups be established early in the consultation process prior to the release of the draft Guidelines**[1]. Comprehensive stakeholder consultation and engagement will provide the PMPRB with multiple perspectives of this complex issue and enhance all of our understanding of the potential impact of Guideline changes before implementation. Only by working in concert, can we achieve our common goal of continuing to provide innovative medicines to Canadians.

This letter presents topics that were either not addressed in the IMC response, or were addressed but merit reinforcement.

Unknown Impact of Lowering Drug Prices

When the PMPRB was formed, its Regulatory mandate was to ensure that prices charged by patentees for patented medicines sold in Canada were not excessive. While the PMPRB, as stated in its discussion paper, may not have any "preconceptions about the specific changes that may result from this process", it is evident that this consultation contemplates revising the current Guidelines to lower patented drug prices. We understand Parliament's intent when creating the PMPRB was to provide adequate consumer protection from excessive drug pricing while ensuring adequate incentive for pharmaceutical innovation. It is this incentive for

drug innovation that has enabled innovative pharma companies such as Bayer to develop treatments that have added precious time to the lives of patients diagnosed with cancer, protected Canadians from devastating strokes due to blood clots, and allowed hemophilic children to truly experience their normal childhood with less constraint on physical activity. The questions that form the PMPRB's discussion paper appear to be directed to broadening its mandate to one of affordability, while removing the potential reward for innovation. Such a change could be detrimental to Canadian patients whereby their access to and choice of drugs could be curtailed due to an overriding, singular economic-based perspective.

We urge the PMPRB to continue its dialogue with its key stakeholders, including patentees, to fully understand the impact of any Guideline change before it is implemented. Therapeutic choices should be patient-centered and clinician-driven, not just solely determined by economics. While price decreases may fulfill a short term measure used by the PMPRB to gauge relevancy, any change recommended in the upcoming draft Guidelines should be carefully vetted to ensure that access to innovative medicines for Canadians is not compromised.

With the adoption of international price referencing by many countries worldwide, drug launches have become sequential, whereby higher priced countries launch prior to lower priced ones. Canada is typically able to launch relatively early along the timeline due to the use of list prices. The existence of confidential prices offered within product listing agreements (PLA's), which are available to both public and private payers, allow Canadians to access these drugs relatively early and at a cost that are often below the list price. Thus, Canadians gain timely access to new drugs through early drug launches, while PLA's support this access at discounted prices. The Fraser Group/Tristat Resources estimate that 98% of the Canadian population is covered by one or more public and/or private prescription drug coverage plan[2]. Mandated transparent list price decreases may result in pharmaceutical parent companies deprioritizing Canada, enabling international price referencing countries with higher list prices than Canada to launch earlier. This may serve to delay Canadian access to patented drugs, an area where Canada already lags in terms of time to listing for the reimbursement of new medicines[3].

At the extreme, the decision not to launch a product at all may even be made by manufacturers. Ms. Tanya Potashnik from the PMPRB in the Standing Committee on Health indicated that the price comparison of Canadian and New Zealand

generic drugs was difficult to conduct and may be potentially due to a lower supply of generic products in New Zealand[4]. Pricing models that do not adequately take into account the clinical benefits of medicines could result in poor treatment choices for Canadians. Constraints on patient choices in drug therapy could in turn lead to poor disease management and require expensive hospitalizations and professional care, imposing greater costs at the system level.

Various studies have suggested that there is a positive correlation between access to prescription drugs and patient outcomes. A recent study published by the Canadian Health Policy Institute on a sample of drugs showed that while 90% were approved for marketing in Canada, only 74% were available in New Zealand[5]. In addition, the analysis found that mortality and hospital discharge rates are higher in New Zealand than in Canada indicating that the lack of innovative drugs may increase hospitalization and indicates that there may be a correlation between restricted or lack of important medicines leading to poorer health outcomes. Should this be the case, costs could be transferred from one healthcare segment to another as savings on drugs for some Canadians would be offset with increased hospital drug costs coupled with potentially higher hospitalization and mortality rates. On the same topic of New Zealand, Durhane Wong-Rieger, President of the Canadian Organization for Rare Disorders, has said that, "Unfortunately it means that most of the patients [in New Zealand] don't get any access to even what we would consider standard medicines, and they are blocked out of any of the innovative medicines."[6]

A similar example can be seen in the United Kingdom, where survival rates for various cancers are lower due to the absence of cancer medicines versus other European countries[7]. Amongst all industrialized countries, the U.K. has ranked near the bottom when it comes to survival rates for the ten types of cancer examined. The five-year survival rates are 50% lower in the U.K. versus Canada for liver and lung cancer. There is clearly a correlation between prescription drug access and health outcomes. Any policy change that could affect access needs to be examined carefully to ensure that the lives of Canadians are not monetized.

Changing Drug Ecosystem

Although the PMPRB's Guidelines have not changed significantly since 1993, the pharmaceutical drug ecosystem within which the PMPRB operates has undergone significant changes over this same timespan. The formation of Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), advent of product listing agreements with provinces and private payers, the genesis of the pan-Canadian Pharmaceutical Alliance, the Generic Value Pricing Initiative, mandatory generic substitution, various health technology assessment activities adopted by private payers, and many other changes address affordability, cost effectiveness and excessive prices.

In addition, IMC members including Bayer have provided over $770M over the past four years in the form of free goods and compassionate product in Canada for those patients who do not qualify for government assistance[8]. This figure excludes co-pay assistance, patient support programs, bursaries, fellowships, grants and a myriad of other benefits that branded drug manufacturers provide that are not captured by the PMPRB in its reporting. Despite these programs, Bayer continues to be concerned that the uninsured or underinsured may have difficulty obtaining patented medicines. This is why Bayer advocates for differential pricing by providing lower costs to the most vulnerable in society – those covered by the public formularies and those patients who obtain their medications from hospitals. If Bayer were to redirect the resources it currently provides to the most vulnerable patients by lowering the price to all Canadians, the overall impact would be diluted, and there would be fewer resources directed to those in greatest need.

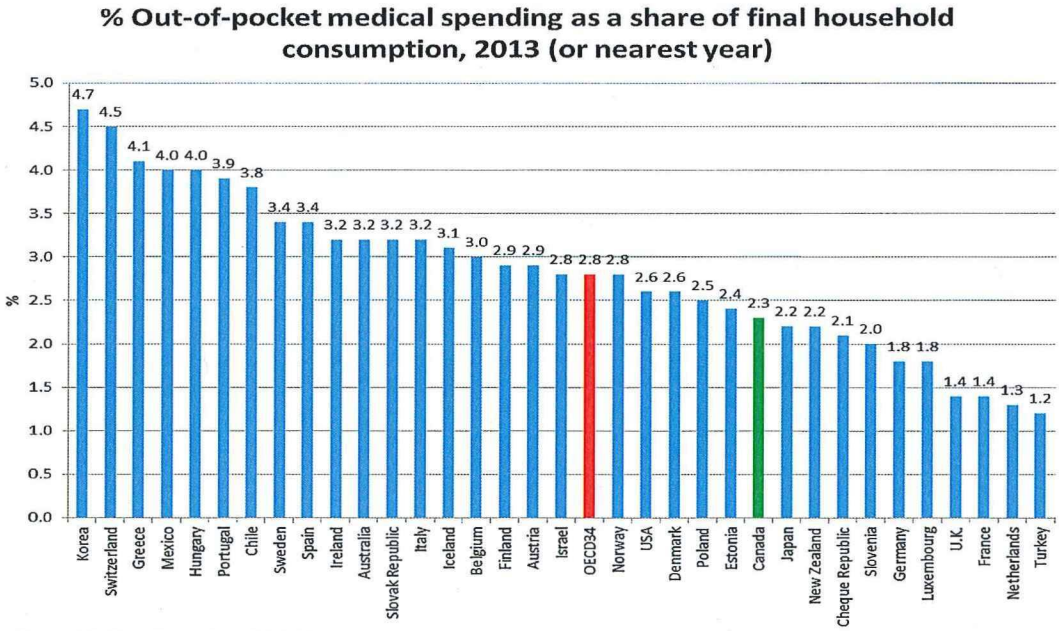
Affordability of Patented Drugs

It is clear from the Strategic Plan and Discussion Paper that the PMPRB intends to focus on the affordability of patented drugs. Affordability must also be well defined by Canadian consumers as they ultimately pay for medicines. The payers, be it the public, private or cash, are the ones who determine what is affordable according to their budget. The definition of affordability would differ between a province and a small corporation that provides benefits to its employees. Having a third party regulator determining a universal definition of affordability is an unreasonable

expectation that would likely have negative unintended consequences and also creates redundancy with the task already being performed by payers.

According to a 2012 Canadian Medical Association Journal (CMAJ) Study, one in 10 Canadians is unable to afford their prescription medication[9]. This closely correlates with the Analysis of the Commonwealth Fund 2007 International Health Policy Survey which indicated that 8% of the Canadian population did not fill a prescription or skipped a dose because of cost. However, countries such as Australia and New Zealand who generally have patented drug prices lower than Canada, had rates of 13.5% and 10.0%, respectively.[10] This is despite New Zealand having a comprehensive drug benefit program with low co-payments. Consequently, price reductions in Canada may not have the intended impact on patient access as influenced by "affordability". Guideline changes facilitating price decreases based on payer affordability would still not make a drug affordable to many of those who are under- or uninsured and yet could have significant negative effects on the majority of the population who have insurance coverage. Making patented drugs affordable to all Canadian patients is a complex issue that will require discussions with all the players in the drug ecosystem and cannot be achieved solely through a change in the PMPRB Mandate and subsequent Guideline changes.

The PMPRB has noted that Canada is the only developed country with a publicly funded health care system that does not include universal drug coverage[11]. Without a universal drug program it might be expected that Canadians are forced to devote a significant part of their household budgets to out-of-pocket spending for health. However, available evidence suggests the opposite. Out-of-pocket medical expenses in Canada as a proportion of total household consumption are relatively low and far below the OECD average[12]. The high number of Canadians covered by private and public insurers is the reason behind this low percentage in Canada. It should also be noted that, even though other countries may have universal public insurance plans, co-pays are often required to have access to these medications. The key takeaway is that a lower price in a particular country does not necessarily translate into increased affordability.



Source: http://www.keepeek.com/Digital-Asset-Management/oecd/social-issues-migration-health/health-at-a-glance-2015_health_glance-2015-en#page126

How high are Canadian Patented Drug Prices?

A study published by the Canadian Health Policy Institute (CHPI) concluded that spending on innovative medicines is small especially when compared to the growth and size of other healthcare costs. In 2014, total public and private health spending amounted to $215.7 billion, of which patented drugs accounted for only 6.4%. Patented drugs did not even make up the majority of drug spending. In 2014, private and public drug spending amounted to $33.8 billion, and patented drugs accounted for only 40% of that amount[13]. The increase in patented drugs costs have also been much slower than the spending on the rest of healthcare. Whereas per capita spending on all other health care (excluding patented drugs) grew by 13.1% from 2009 to 2014, per capita spending on patented drug costs grew by only 0.5%. CHPI estimates that only 3.5% of the $142.1Billion spent by governments on Healthcare in 2014 was on publicly covered patented drugs.

While the PMPRB has outlined that rising prices is one of the reasons for the consultation, the PMPRB has also acknowledged that, "the prices of patented

medicines in Canada remain at the median of international prices as defined by our comparator countries as per the *Patented Medicine Regulations*: France, Germany, Italy, Sweden, Switzerland, the U.K. and the U.S."[14] In its 2015 annual report, the PMPRB noted that Canadian patented prices were 18% below median international prices and that Canada was tied with Switzerland below German and U.S. prices in the PMPRB7[15,16]. As outlined by the PMPRB, international comparisons are difficult owing to the myriad of confidential agreements that are in place between patentees and payers. However, determining domestic prices are plagued by the same issues. Nevertheless, international price referencing should continue to be a key component of determining whether a patented drug is excessively priced or not in conjunction with the other factors outlined in the Patent Act. No one measure should be used in isolation given the limitations of the data available to both the patentee and the PMPRB.

On this point, a study commissioned by the IMC and conducted by a third party utilizing the same data provided to the PMPRB by patentees discovered that Canadian patented drug prices that have market exclusivity are actually 43% below the PMPRB7 median prices, putting it third lowest ahead of France and Italy and below the U.S., Germany, Switzerland, the U.K. and Sweden[17]. Although utilizing international list prices (and domestic prices) are 'flawed' due to confidential rebates aberrating the true costs of the patented drug, the sheer magnitude of the difference between Canadian list prices and the PMPRB7 median should provide sufficient evidence that Canadian prices are in-line with or lower than what we see internationally for market exclusive patented drugs.

Excessive Pricing Should Consider All Costs along the Distribution Chain

The PMPRB was originally developed to provide consumer protection from excessive drug prices, creating a counter balance to pharmaceutical patent protection. The PMPRB, however, does not have jurisdiction over other costs that a prescription drug accumulates as it moves down the distribution chain[18]. If co-pays and cash payers are the primary concern of the PMPRB, the entire value chain needs to be evaluated in conjunction with any change contemplated with the Guidelines regulating patented drug prices.

Frequency of Review (Re-Benchmarking)

Although not perfect, the current Guidelines provide a significant degree of predictability once the patented drug has been evaluated by the Human Drug Advisory Panel (HDAP) and PMPRB Staff. Aside from foreign price changes and exchange rate variations, patentees can predict their compliance with the Guidelines with a high degree of accuracy. Knowing that the price ceiling does not fluctuate allows patentees to direct maximum savings towards pCPA and PLA negotiations with public and private payers. If the price ceilings were to fall unpredictably, manufacturers would be forced to maintain a buffer to cushion any future price concessions they need to make as a result of re-benchmarking and potentially even forego opportunities to expand indications of the drug with Health Canada.

It should also be noted that re-benchmarking is already being achieved through the pCPA process with each successive Health Canada approved indication and with each PLA contract renewal. As with affordability, PMPRB will be duplicating the efforts of other agencies. In Rethinking the Guidelines, the PMPRB has to be cognizant of the roles of all other government agencies already fulfil in managing drug affordability, and determine how it can best deliver value in an efficient manner with the least amount of duplication.

Conclusion

Bayer is aligned with the positions taken by the IMC in its 'Rethinking the Guidelines' letter it has submitted to the PMPRB. It is clear that changes in the PMPRB Guidelines could potentially have a resounding and detrimental effect on Canadians. A truly sustainable healthcare system is one that can optimize patient access to life-saving and life-altering medications while incentivizing innovative drug companies to continue to invest in R&D and launch medicines in a timely manner for Canadian patients. We ask that the PMPRB consults closely with pharmaceutical manufacturers early in the process to fully understand the implications of new Guideline changes to ensure that the impact to patients is minimized.

Bayer would like to thank the PMPRB for allowing us to express our thoughts during this consultation process. We support the PMPRB's commitment to a framework that is relevant, sustainable, and appropriate as long as the consumer is protected

and the benefits of patented medicines are recognized and the risk of unintended consequences is minimized. We see a role for the PMPRB to complement the other government agencies to facilitate access of innovative medicines to Canadian patients. We look forward to continuing to work with the Board on refining the PMPRB's Guidelines.

Yours sincerely,

Dale Toki

Director, Pricing and Contracts
Bayer Inc.

ENDNOTES

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[1] http://innovativemedicines.ca/wp-content/uploads/2016/10/20161024_PMPRB_Submission_Final.pdf
[2] http://www.parl.gc.ca/content/sen/committee/372/soci/rep/repoct02vol6part3-e.htm
[3] http://innovativemedicines.ca/wp-content/uploads/2016/05/20160524_Access_to_Medicines_Report_EN_Web.pdf
[4] Standing Committee on Health, Number 006; 1st session; 42nd Parliament
[5] Rawson, N.S.B., How might the choice of prescription drugs in provincial pubic 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
[6] http://healthydebate.ca/2015/03/topic/pharmacare-2
[7] http://www.iedm.org/files/note0715_en.pdf
[8] KPMG, R&D Spending and Investments by IMC Members - Product donations to patients through compassionate use and special access programs
[9] http://www.cmaj.ca/site/misc/pr/16jan12_pr.xhtml
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[13] http://www.marketwired.com/press-release/cost-is-phony-excuse-regulate-prices-ration-access-new-drugs-canadian-health-policy-2099147.htm
[14] http://www.pmprb-cepmb.gc.ca/about-us/frequently-asked-questions#1404
[15] PMPRB7 is comprised of the U.S., U.K., Germany, France, Sweden, Italy, and Switzerland
[16] PMPRB Annual Report 2015
[17] IMC Analysis based on Form 2 Block 5 data submitted to the PMPRB, July-December 2015
[18] http://www.pmprb-cepmb.gc.ca/about-us/frequently-asked-questions#1398