4 October 2016

To the Patented Medicine Prices Review Board,

Thank you very much for inviting input on your Guidelines modernization process.

I am a family physician and researcher in Toronto. My views are informed by my experience providing care for people who cannot afford medicines including life-saving medicines and my experience conducting a clinical trial of providing people with free access to essential medicines.

Please find my answers to your questions below.

I would be happy to provide additional input in writing and I would be happy to meet with you. Thank you very much for considering my views.

Sincerely,

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1. **What does the word "excessive" mean to you when you think about drug pricing in Canada today?**

   A price is excessive when Canadians cannot afford the medicine or do not use it as intended because of the price. A definition of excessive pricing that is based on whether Canadians can and do use the medicine is consistent with the role of the PMPRB:

   "The Supreme Court further found that the PMPRB, in interpreting its consumer protection mandate, must take into paramount account its responsibility for ensuring that patentees do not abuse their statutory monopolies 'to the financial detriment of Canadian patients and their insurers.'"

   "…it acts as one half of that balance by serving as a counterweight to and reasonable check on the exclusive rights afforded to pharmaceutical patentees."

   If the PMPRB is protecting consumers, then its interventions should be directed by the effects or prices on consumers.

   In principle, a medicine could be excessively priced regardless of the price of medicines with the same benefit (e.g. in the same therapeutic class) or the prices paid in other jurisdictions. In practice, these factors should be taken into consideration as they will usually help identify medicines that Canadians cannot afford.

   The PMPRB should collect and review Canadian data about cost-related non-adherence (not taking medications as directed because of the cost) in order to determine if medicines prices are excessive.

2. **Given that it is standard industry practice worldwide to insist that public prices not reflect discounts and rebates, should the PMPRB generally place less weight on international public list prices when determining the non-excessive price ceiling for a drug?**

   Yes, these public list prices are misleading. They are also not closely related to whether or not Canadians can actually afford medcines.

3. **In your view, given today's pharmaceutical operating environment, is there a particular s. 85 factor that the Guidelines should prioritize or weigh more heavily in examining whether a drug is potentially excessively priced?**

   The actual price in the relevant market is most important. That amount should be compared to what Canadians can actually pay.

4. **Should the PMPRB set its excessive price ceilings at the low, medium or high end of the PMPRB7 countries (i.e., the US, the UK, Sweden, Switzerland, Germany, France and Italy)?**

   The ceiling should be based on what Canadians can actually afford to pay. It could be based on actual income levels, minimum wage, living wage, rates of cost-related non-adherence or other Canadian figures.

   Information from other countries can help inform the ceiling, but they should be secondary considerations. The selection of countries should be based on the similarities to Canada with respect to income and inequity.

5. **Does the amount of research and development that the pharmaceutical industry conducts in Canada relative to these other countries impact your answer to the above question and if so, why?**

   No, industry research and development is totally irrelevant to discussions about prices. Prices should not be raised in some vague hope that it will encourage research in Canada; we know that has not happened in the past. Prices should be set based on what Canadians can pay.

6. **What alternatives to the current approach to categorizing new patented medicines (based on degree of therapeutic benefit) could be used to apply the statutory factors from the outset and address questions of high relative prices, market dynamics and affordability?**

Consider whether the medicine is “essential”. The World Health Organization has promulgated the concept of essential medicines since the 1970s and there is literature about how the concept has been implemented in low, medium and high income countries. Each medicine on a list of essential medicines is needed because it serves a purpose not served by the others. Essential medicines should be affordable. The price ceilings should be lower and reflect what a low income Canadian can afford (with or without government assistance including “catastrophic” drug coverage).

7. **Should the PMPRB consider different levels of regulatory oversight for patented drugs based on indicators of risk of potential for excessive pricing?**

The level of oversight should be based on the importance of the medicine, not the likelihood of excessive pricing. Essential medicines should be subject to greater oversight.

8. **Should the price ceiling of a patented drug be revised with the passage of time and, if so, how often, in what circumstances and how much?**

Price ceiling should regularly be reviewed with short intervals (e.g. quarterly or every six months). Prices ceilings should increase only in exceptional circumstances; generally price ceilings should decrease over time.

9. **Should price discrimination between provinces/territories and payer types be considered a form of excessive pricing and, if so, in what circumstances?**

Large price discrimination between jurisdictions should alert the PMPRB to potential excessive pricing since, in practice, it may well indicate that prices are excessive in at least some jurisdictions. But price discrimination does not necessarily indicate excessive pricing because, in principle, all of the prices could be reasonable.

10. **Are there other aspects of the Guidelines not mentioned in this paper that warrant reform in light of changes in the PMPRB's operating environment?**

Members of the public who are free of potential conflicts of interest should be involved in committees and decision making. These people should reflect the diversity of Canada.

The actual performance of medicines in Canada should be considered. Effectiveness in real-world settings should help to determine prices after introduction. See my response to question #8 about prices usually declining over time but, in exceptional circumstances, increasing. If a medicine works better than expected, the price ceiling might increase while if it does not work as well as expected (e.g. not as well as expected based on clinical trial results) the price ceiling should drop.

11. **Should the changes that are made to the Guidelines as a result of this consultation process apply to all patented drugs or just ones that are introduced subsequent to the changes?**

The changes should apply to all medicines that Canadians need today regardless of when they were introduced.

12. **Should one or more of the issues identified in this paper also or alternatively be addressed through change at the level of regulation or legislation?**

Two concepts could be added to the regulations: cost-related nonadherence (whether Canadians can actually afford a medicine) and essential medicines.