Response to the PMPRB Phase 2 Consultations *on* New Guidelines

July 25, 2024

Thank you for the opportunity to contribute to the consultation on the new PMPRB Guidelines. I taught health policy from 2001 to 2016 at York University and worked as an emergency physician from 1982 to 2022 so I approach these Guidelines from the perspective of both an academic and a clinician.

Overall, I have concerns about the amount of evidence that the PMPRB has presented for some of the changes that it is discussing making and also for the overall tone of the document which is biased towards the interests of the pharmaceutical industry.

1. **Section 5.1:** The PMPRB proposes to rely initially on the International Price Comparison (IPC) in determining whether drugs need a more in-depth review. If the IPC falls within the boundaries that the PMPRB sets, then the PMPRB will not proceed to use the Therapeutic Class Comparison. However, the PMPRB has not presented any information about how often the IPC fails to predict when a price might be excessive.
2. **Section 5.2:** The PMPRB proposes not to do an in-depth review if the IPC cannot be conducted, e.g., if Canada is the first launch country. This proposal means that the drug will not be subject to any initial price review and therefore the PMPRB will not have any way of knowing if the price is excessive. It is not known how often this situation may arise since the Board does not present any information about how often in the past Canada has been the first launch country in the PMPRB11.
3. A Therapeutic Class Comparison will only be done for drugs subject to an in-depth review. Therefore, most of the drugs will not have a TCC. While the purpose of the PMPRB is not to evaluate the additional therapeutic benefit of new patented medicines, it has been doing this type of analysis since its inception and this information has proven to be very valuable for clinicians and researchers. The PMPRB is now proposing to effectively eliminate this resource to the detriment of clinicians providing treatment and patients receiving treatment.
4. **Section 5.4:** The PMPRB is concerned that the balancing methodology used to assign weights to various factors is fair to Rights Holders, however the proposed Guidelines do not say that the weights should be fair to payers – public, private or people who pay out of pocket.
5. **Section 6.l.l:** The PMPRB has identified three IPC criteria, but it has not considered a fourth which would be the midpoint between the Lowest International Price and the MIP, nor has the PMPRB brought forth any reason why this option was not considered.
6. **Section 6.2.1:** If the PMPRB opts for Options 1 or 2 in terms of who to allow to make complaints, that would be unfair to those who have to pay out of pocket for their medications since no one would be representing their interests.
7. **Section 6.3:** How is the PMPRB defining the term “therapeutic class”? The definition will determine which products are comparators. The determination of therapeutic class requires a

determination that the benefit to harm profile of the drugs in the class is comparable and that is a scientific judgement not a pricing judgement. Moreover, when the PMPRB talks about its scientific staff it does not say whether the staff has clinical expertise which is necessary to be able to properly evaluate whether two (or more) drugs are clinically comparable.

8. **Section 6.3:** One of the sources of information that the PMPRB proposes using in its scientific evaluation of a new patented medicine is comments from Rights Holders without recognizing that there is strong evidence that Rights Holders overstate the benefits of their products and understate their safety risks.
9. **Section 6.3.1:** A single level of similarity would only be appropriate if all the drugs were in the same 4th level in the Anatomic-Therapeutic-Chemical classification. Any publications, meta-analyses, clinical practice guidelines, etc. that are used to establish similarity should not be funded by the Rights Holder and the first/senior author should not have any financial conflict-of-interest with the company making the drug. There is strong evidence that when there is a financial conflict-of-interest that studies are more likely to yield positive results and conclusions compared to when studies are funded by any other source.
10. **Section 6.3.1:** The argument for abandoning the evaluation of therapeutic improvement is non-existent if it is not also going to be accompanied by disallowing pricing at the HIP. If pricing to the HIP is allowed, in effect, the PMPRB would be saying that even though it cannot determine how much additional therapeutic value a new patented medicine represents it is going to allow that medicine to be priced as though it were the most therapeutically valuable member of that class. Furthermore, if industry is arguing that innovation should be recognized (see Section 4 of the Guidelines), it should be the type of innovation that matters most to clinicians and patients which is therapeutic gain beyond what is currently available. Other definitions of innovation are not important to those two groups.
    In addition, the PMPRB has advanced a very convoluted interpretation of section 85 (1) of the Patent Act. The section makes it clear that the new patented medicine must be compared with RELEVANT markets. If the PMPRB is unable to assess the therapeutic level of new drugs, how can it assess if the market is relevant or not? Is the market for velocipedes relevant for the market of F1 racing cars? Both can travel in the street and move forward? How can we judge if the market is relevant? Should we price velocipedes based on previous prices of F1 cars? In a nutshell, by eliminating the assessment of therapeutic level for new drugs, the PMPRB eliminates the meaning of the word RELEVANCE in section 85(1).
11. **Section 6.3.2:** If the Board is arguing that its scientific review staff have the necessary expertise to provide recommendations about comparators then the Board should provide information about the academic and clinical training of that portion of its staff. Based on the points that I previously made about defining a therapeutic class and determining appropriate comparators, the PMPRB should not be diminishing the role of the Human Drug Advisory Panel. Moreover, should the PMPRB need to contract with outside experts those people should be ones who do not have financial conflict-of-interest.

Should the PMPRB wish to contact me about this brief, I can be reached at either jlexchin@yorku.ca or by phone at 416-209-4885.

Sincerely

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