



July 30, 2020

Patented Medicine Prices Review Board  
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On behalf of Purdue Pharma (Canada), we offer our response to the second draft of the PMPRB Guidelines consultation which was initiated on June 19, 2020. This letter is in addition to our detailed response submitted to PMPRB in February 2020.

To begin, we state our support and alignment with Innovative Medicines Canada (IMC) as well as concerns raised by other impacted organizations and patient groups over time.

In summary, while there have been some changes in the latest Guideline draft issued June 19, 2020, we are very concerned that these Guidelines remain overly complex, lack predictability and may create potential supply issues and increase the likelihood that patentees will encounter disincentives and uncertainty when trying to bring new medicines to Canada. Favourable access to existing and new medicines for Canadian patients had been a hallmark of the innovative pharmaceutical industry in Canada – many aspects of the new drafted Guidelines are not supportive of this concept.

The Guidelines as they now stand have the potential to negatively affect access to both existing and especially new medicines for Canadian patients. We are also extremely disappointed that, with the implementation date close at hand, the current consultation process does not seem directed to consider potential changes or answer operational questions based on concerns that have been raised.

We call for a major revision to the framework proposed by PMPRB and in closer consultation with the innovative industry. Industry has relevant expertise, experience and perspective with respect to issues such as global supply and new product development. Furthermore, industry has expressed its desire to work with PMPRB based on fairness and common objectives and to address the hurdles posed by the new drafted Guidelines. The current COVID-19 situation demonstrates the need to leverage expertise, demonstrate leadership and have long-term vision to best ensure that Canadians remain at the front of the line where access to medical treatments is concerned.

## I - Existing “grandfathered” medicines

Purdue Pharma (Canada) has three areas of concern with respect to patented medicines already on the market.

1. **Highest International Price (HIP) Test:** The change to HIP from MIP is more in line with the concept of “continuity” for existing medicines as stated in the Canada Gazette Part 2 – August 21, 2019. There are, however, operational problems that have not been addressed.
  - a. **Multiple strengths and illogical pricing:** For a medicine that has multiple strengths, it is possible that certain strengths may be sold in only a few countries and (based on HIP) have a maximum list price (MLP) that is significantly lower relative to the other strengths. This can result in illogical pricing across the available strengths – e.g. a higher strength having a price significantly below that of a lower strength.  
**Suggested solution:** Price per mg in Canada for any brand strength can be **based on the HIP per mg for any strength**. This will **eliminate the potential for illogical pricing maximums** for some strengths and reduce the risk of patentees having to face possible supply issues with certain strengths – or not being able to launch new strengths (e.g. for a pediatric or geriatric dosage).
  - b. **Limited reference basket - for one or multiple strengths:** Again, if prices are pushed too low, supply can be a real and ongoing potential issue.  
**Suggested solution:** The new Regulations identify 11 reference countries so, ideally, **pricing tests should be conducted against the full spectrum of reference countries**. At a minimum, the reference basket should comprise the majority of the 11 countries for the same medicine - and preferably all the 5 remaining from the original basket of 7 - so that **the HIP is not based on only 1 or 2 countries**, for example. It is counter-productive and not in the spirit of ensuring continuity if existing medicines are referenced only to a few, low-priced countries.
2. **Non-excessive Average Price (NEAP) to set Maximum List Price (MLP):** Use of NEAP in the manner proposed in the draft Guidelines to benchmark MLP is problematic and not consistent with the concept of continuity for existing medicines. There are many patented medicines for which there are multiple list prices in effect in Canada. In the case where the list prices have been aligned to increases in CPI over time, the use of NEAP will penalize patentees who have, for example, not maximized prices in all provinces because they have complied with provincial public plan pricing regulations that impacted list prices. The use of NEAP creates complexity where it is not needed.  
**Suggested solution:** Simply **reference the current maximum list prices** in effect in Canada as the national benchmark for list price ceilings with consideration to HIP as well. Allow for increases in CPI – see next point.

3. **The Consumer Price Index (CPI) and price changes:** The Regulations indicate that prices may increase with consideration to CPI. Over that last 30 years, price increases for patented medications increased on average less than the increases in CPI – i.e. price increases have generally been modest. Over the potential 20 years of patent life, there should be a provision for prices to keep pace with inflation – given that related production costs (raw materials, production wages, etc.) will undoubtedly increase. This will allow for manufacturers to better ensure continuity of supply.

**Suggested solution:** Allow maximum list prices to increase annually by the CPI factors in the same manner as in the past.

## II – New medicines

Our previous letter sent to PMPRB in February 2020 indicated that the November 2019 draft of the Guidelines included assessments for new medicines that were too complex, filled with uncertainty and had the potential to push prices below viable levels. The second draft of the Guidelines did not address these concerns and have added complexity to the assessment process. Purdue Pharma (Canada) is aligned to the stated position of IMC in that a new framework must be developed to immediately address these issues.

Key areas of focus include but are not limited to the following issues:

1. The Federal Court has ruled that consideration of confidential third-party rebates are not within the mandate of PMPRB. A significant portion of the Regulations and Guidelines need to be adjusted to exclude reference to such rebates.
2. The proposed Guidelines are complex and lack clarity that could result in new products not coming to Canada or being unnecessarily delayed.
3. The process used to assess both Category I and II drugs seems focussed at pushing prices lower at every turn and many of the benchmarks seem arbitrary. The potential price reductions of 50% or more does not seem to promote an environment for investment in new products and research and development in Canada.
4. The complexity for new product assessments may be beyond the capacity for some patentees with more limited resources and expertise in this area. Such companies may not have the personnel or financial ability to deal with the huge administrative burden anticipated with especially Category I assessments and proposed ongoing submissions.
5. Instead of employing complex assessments, simple solutions such as a focus on international price comparisons do not seem to be embraced in the drafted Guidelines.



### **III – Conclusion**

There is an immediate need to provide working groups of PMPRB officials and industry representatives with a mandate to generate an alternative Guidelines package consistent with core regulatory principles of feasibility, fairness, predictability and transparency. This is intended to support the health of Canada’s innovative medicines industry so that it can continue to contribute to the well-being of Canadians.

#### **About Purdue Pharma (Canada)**

Purdue Pharma (Canada) is a research-based pharmaceutical and consumer healthcare company which has operated in Canada for more than 60 years. Its employees are committed to improving the health and quality of life of Canadians. The company has a broad portfolio of prescription and non-prescription medications including: prescription treatments for pain, ADHD, chemotherapy-induced nausea and vomiting (CINV) and various ophthalmic conditions, as well as Consumer Health products. The company supports evidence-based education for the safe use of its products. Purdue Pharma (Canada) is independently associated with the worldwide Napp/Mundipharma network of companies.

We thank you for considering the observations and recommendations we have made.

Sincerely,

Melanie Milburn  
Vice President, Market Access