Danish Life Sciences Forum

Feedback on the proposed update to the Patented Medicine Prices Review Board Guidelines published October 6, 2022

The Danish Life Sciences Forum (DLSF) was formalized in 2018 as a way for Danish life sciences companies to collaborate around shared opportunities and challenges in the Canadian market, for the benefit of patients everywhere. With the support of the Danish Trade Council acting as the forum secretariat, the group consists of Novo Nordisk Canada Inc., LEO Pharma Canada Inc., Lundbeck Canada Inc. and ALK-Abelló Pharmaceuticals Inc. – all foundation-owned companies with a long-term mission to find cures in their therapeutic areas. Our mission is to leverage Danish and Canadian life sciences best practices to advance health, innovation, and the Canadian economy.

November 30, 2022

Dear Professor Bourassa Forcier,

Thank you for the opportunity to comment on the proposed update to the Patented Medicine Prices Review Board (PMPRB) Guidelines following the recent publication of the amendments to the *Patent Medicines Regulations*. This submission builds on our previous submissions throughout this process and is intended to be complementary to the input of Innovative Medicines Canada, of which we are members.

As Danish foundation-owned companies, we operate on a mandate to deliver wide-ranging health and socioeconomic benefits to society at large. We believe that a lot of good can be achieved through better and more affordable access to treatments for patients, and we fully support health system reform that leads to improved patient health outcomes or addresses healthcare sustainability in a holistic and collaborative way. It is within this perspective that the following comments are framed. We trust that these suggestions will help enable business continuity while still ensuring prices of medicines in Canada are appropriate within the mandate of the PMPRB.

After careful review of the proposed Guidelines, we believe that the PMPRB has failed to create Guidelines that are more streamlined, pragmatic and less prescriptive. Despite a singular change to the *Patent Medicines Regulations* (i.e. a new basket of comparator countries), the PMPRB has put forward a substantially different approach to assessing potential excessive prices related to the abuse of patents with no justification for why such a radical change in approach is warranted.

It appears as though the Board is moving from a compliance-based approach to one focused on investigations and hearings. In the history of the PMPRB, the pharmaceutical industry has been consistently compliant with previous Guidelines, resulting in relatively few hearings since its inception. Therefore, it is unclear why the proposed Guidelines focus on investigations, rather than giving more clear direction as to what constitutes 'excessive pricing', which is the mandate of the PMPRB. This uncertainty will most certainly result in more hearings and more delays in the availability of innovative medicines for Canadian patients as the industry grapples with the uncertainty inherent in the proposed Guidelines.

The proposed Guidelines are inconsistent with the mandate of the PMPRB to regulate excessive pricing and abuse of patents

The use of both the Median International Price and domestic Therapeutic Class Comparison (which may include generic prices) as co-triggers for an investigation may result in future medicines being assessed as excessively priced even if their price is below international norms. In creating rules under which a price that falls below the highest international price could still be considered 'excessive', the PMPRB is trying to expand its mandate in a manner that is not permitted by law.

Furthermore, the proposed Guidelines fail to tie the proposed pricing levels to abuse of patents through excessive pricing. Going forward, it is important that the new Guidelines be grounded in the mandate of the PMPRB, which is to ensure that prices are non-excessive in the context of patent abuse, as confirmed by recent court decisions (see e.g., *Innovative Medicines Canada v Canada (AG)*, 2020 FC 725, appeal under reserve in Court File No. A-215-20.).

The proposed guidelines are unclear and create ongoing uncertainty and lack of predictability

The proposed Guidelines do not provide predictable guidance. This will create significant challenges for a company looking to launch a new medicine in Canada, both in terms of understanding what price will be considered 'non-excessive' at launch and what prices will be acceptable throughout the life cycle of the product. Yearly re-benching to the international

median and the requirement to remain below a domestic Therapeutic Class Comparison (dTCC) that is assessed at launch, are unsustainable for the lifecycle of a medicine.

In addition, once an investigation has been opened, the proposed Guidelines give Board staff the discretion to create and apply new rules based on their 'perception' that a drug may be at high risk for excessive pricing, and to recommend a hearing if the investigation raises "new" or "unique" questions. These broad, open-ended powers that permit Board staff to trigger investigations and recommend hearings based on their own perceptions do not provide a sufficient level of clarity to allow companies to perform the robust pricing analysis that is required before launching a medicine in Canada. In essence, this discretion allows Board staff to set prices, which goes beyond their jurisdiction to ensure prices are non-excessive.

The ongoing business uncertainty created by the proposed Guidelines, including the potential for more disputes with undefined timelines for hearings and appeals, come at a particularly difficult time, as Canada and the rest of the world continue to battle the economic and health effects of the COVID-19 pandemic and a potential recession. It is therefore important to ensure that the Guidelines are designed to minimize uncertainty now and into the future.

Despite the PMRPB being regulated by the *Patent Act*, the proposed Guidelines undermine the value of patents and do not support innovation

Companies price medicines based on the value they bring to patients and the healthcare system while supporting appropriate access. The concept of value is not reflected in the proposed Guidelines which focus solely on price setting. As validated by the courts, price setting is not within the mandate of the PMPRB, and in addition, there are several unintended consequences of the proposed approach within the Guidelines, which may not be apparent to Board staff:

1. Future medicines not launching in Canada will decrease competition in a given therapeutic class. Public and private payers routinely negotiate prices below the levels set by the PMPRB, and there is more price pressure in a category with multiple medicines. Creating a market where only one or two medicines are available in a class limits competition and the ability of payers to negotiate the best price. As is seen in many other sectors of the Canadian economy (e.g., telecommunications), less competition can be expected to yield higher net prices for payers over time relative to other jurisdictions. In addition, lowering list prices will limit the ability of the industry to offer the types of discounts they are currently able to offer to the vulnerable patient populations covered by public payers. Not only will the proposed Guidelines decrease

competition in a given therapeutic class, but they will also create savings for the private insurance industry at the expense of public healthcare systems.

2. The proposed Guidelines have stated that Board staff will focus on medicines at the 'highest risk' for excessive pricing, which staff have historically identified as high-cost medicines. The staff's discretion to focus on high-cost medicines will adversely impact the ability of companies to bring rare disease medicines to Canada, impacting the many Canadian patients who could benefit from these treatments and undermining broader Government objectives, such as a national rare disease strategy.

3. The proposed Guidelines undermine the whole-of-government approach to the development of the Canadian biopharmaceutical industry. We have learned through the recent pandemic the value of strong government and industry collaboration. Global investment in the Canadian biopharmaceutical industry can only occur if innovative medicines can be sold in Canada at sustainable prices. In addition, clinical trials are an important investment in Canada and these proposed Guidelines will result in trials being more difficult to conduct here as the standard of care may not be available if fewer medicines launch in the future. This not only limits investments in Canada but means that the most vulnerable Canadians will be unable to access the newest treatments through clinical trials.

Innovation and the life sciences sector are key drivers of economic growth, improved health outcomes, and long-term health system sustainability. By introducing new and significant uncertainty through these proposed Guidelines, the R&D ecosystem in Canada will continue to erode, diminishing the health and economic benefits that result from it.

Methodologies for CPI adjustment and price sources

CPI-adjustment methodology: In paragraph 33 of the Draft Guidelines 2022, the PMPRB stipulates that a list price increasing by more than the changes in the Consumer Price Index (CPI) may trigger an investigation.[1] However, the PMPRB does not specify how the CPI adjustment will be applied. We propose adding the same description for CPI-adjustment methodology as in Schedule 9 of the previous Compendium of Policies, Guidelines and Procedures (updated February 2017).

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[1] Patented Medicine Prices Review Board. (2022). *PMPRB Draft Guidelines 2022* (p. 11, para. 33). Retrieved from: Draft-Guidelines-2022.pdf (canada.ca)

Price sources methodology: In the Draft Guidelines 2022, the PMPRB does not specify the methodology that will be used to determine prices for both domestic and international prices. During its Public Webinar on November 3, 2022, the PMPRB Staff expressed its intent to allow for "apple-to-apples" price comparisons with domestic and international list prices. Some medicines sold in Canada are only reimbursed by private insurers and do not have a published list price that is publicly verifiable. As such, to allow for "apples-to-apples" price comparisons, we believe that the PMPRB should accept ex-factory prices from other markets even though they are not publicly listed.

Recommendations

The proposed Guidelines will undermine the efforts of the federal government to move forward on the PMPRB file and, by design, will result in many more hearings and court challenges. We strongly recommend that the Board retract the proposed Guidelines and move forward in a constructive and collaborative way, aligned with the Government's objectives for the biopharmaceutical industry.

Past leadership of the PMPRB has supported a more collaborative approach to Guideline reform and we urge the current leadership to adopt that same approach for Canadians to continue to receive the latest innovative medicines and to help foster sustainable healthcare systems across the country.

Conclusions

We believe that by adopting our proposed approach, the federal government will achieve its mission (via Innovation, Science and Economic Development Canada) to foster a growing, competitive, and knowledge-based Canadian economy and its mission (via Health Canada) to help Canadians maintain and improve their health.

We have all learned the importance of this sector to Canada and the world over the past two years, and the Danish Life Sciences Forum companies are ready to support the federal government to achieve its important objectives.

We thank you for considering our input on this issue.

Sincerely,

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