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Mr. Douglas Clark
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Submitted electronically: ***PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca***

December 5, 2022

RE: SANOFI Canada Feedback on PMPRB Draft Guidelines (October 2022)

Dear Mr. Clark:

On behalf of SANOFI Canada ("SANOFI"), I am providing comments in respect of the PMPRB's draft Guidelines released for stakeholder comment in October 2022. This submission is provided further to SANOFI's past record of submissions to PMPRB on its Guidelines.

Our submission is complementary to and fully supportive of the submissions provided by our trade associations on this consultation, notably Innovative Medicines Canada and BIOTECanada.

On a positive note, SANOFI welcomes the proposed treatment of patented vaccines, biosimilars and over-the-counter products on a complaints-only basis for the purposes of commencing PMPRB investigations. This is a sensible approach given Canada's collected efforts to emerge from the recent COVID-19 pandemic and promote greater public health resiliency, as well as the nature of the reimbursement systems and related risks of non-excessive pricing for those product categories.

But on balance, the overall content and policy intent of the draft Guidelines are of significant concern. The draft Guidelines were received with disappointment and concern within our organization.

We see three principal areas of concern:

1. **The draft Guidelines are an unworkable and unwarranted shift towards discretionary and situational compliance rather than transparent, predictable and stable operations.**
2. **The draft Guidelines far exceed the Board's clearly defined legislative mandate and role in regulating non-excessive prices of patented medicines by instead seeking to actively manage and reduce prices.**
3. **The draft Guidelines are inconsistent with the public policy direction of the Government of Canada, including ongoing work with respect to increasing the accessibility of medicines, advancing a Biomanufacturing and Life Sciences Strategy, and a Strategy for Drugs for Rare Diseases.**

The draft Guidelines represent a massive course change for the Board from both a policy and an operational perspective. Compounding the sense of uncertainty, the PMPRB has not disclosed either the policy objectives of the draft Guidelines or their anticipated impacts, health-related or otherwise.

A potential January 1st implementation of these draft Guidelines is not advisable given the highly problematic nature of the proposed approach. We strongly echo and reiterate the call for Board staff to set aside the current draft and take the required time to design clear Guidelines supported by a proper impact assessment, all firmly anchored in the PMPRB's established mandate.

1. Discretionary Compliance Is Unworkable

Taken as an overall package, the draft Guidelines would represent a remarkable departure from the Board's established and demonstrably successful practice of promoting voluntary patentee compliance through the availability and consistent application of clear, so-called "bright-line" Guidelines. In stark contrast, the draft Guidelines instead set out a highly subjective, discretionary compliance model centered on PMPRB staff as a major new source of uncertainty and instability.

All reference or consideration of innovation has been removed – another major departure from past practice. In fact, the proposed approach disincentivizes innovation with a significant shift in how class comparisons may be conducted, with major unanswered questions around how appropriate product comparators will be determined, and the possible role and weighting in compliance decision-making to be played by generic products within a given class, if applicable. This shift would disproportionately negatively impact the feasibility of many future launches of new medicines, particularly for the most innovative therapies and therapies with small patient populations.

Recent regulatory changes solely address the membership of the basket of comparator countries for the purposes of international price referencing. We are unaware of any Government instruction to the PMPRB to abandon its historic approach to up-front, voluntary compliance based on clearly stated and applied operational price tests and calculations. This dramatic and consequential shift in operational philosophy was not subject to any prior public consultation over the past number of years and is being advanced without justification at a relatively late juncture, in October 2022, ahead of potential implementation in January 2023. This is highly disruptive and problematic for many stakeholders and merits complete reconsideration.

2. Non-Excessive Price Regulation, Not Price Reduction

Recent jurisprudence has strongly reaffirmed the Board's established mandate in the *Patent Act*. The PMPRB's operations must remain consistent with the standard of regulating non-excessive prices. In no manner does the PMPRB's mandate include assessments or regulation of "affordable" or "reasonable" pricing, nor does it extend to price management or price negotiation, which are properly the purview of other agencies and budget-holders.

It is therefore difficult to reconcile how and why the Board's proposed "Investigation Criteria" would set price limits related to the median of foreign comparator prices or lower. Under the draft PMPRB guidelines, any Canadian patented medicine exclusively launched in Canada or launched with a price which falls between the median and highest international prices, are to be automatically subject to an investigation. This appears both impractical and inconsistent with a non-excessive price standard. Moreover, it is unclear if other patented medicine prices would be deliberately excluded from the calculation of the domestic therapeutic class, leaving only other non-patented medicines available for comparison.

There does not appear to have been any rationale provided for this significant change in approach. It not only serves as a disincentive to new innovative therapies, but there has also been no explanation offered as to how this price management approach could remain consistent with the Board's regulatory mandate.

3. Need For Public Policy Alignment

The Government of Canada has completed or undertaken a range of public policy initiatives to strengthen the life sciences sector. These include initiatives to coordinate national efforts to recover from the COVID-19 pandemic, to advance and fund a first-ever Biomanufacturing and Life Sciences strategy at the federal level, to promote greater accessibility of medicines in general, to advance regulatory modernization and agility measures including for therapeutic products, and to advance a National Strategy for Drugs for Rare Diseases.

SANOFI has welcomed these initiatives and continues to work with Governments at all levels in support of common goals. Most notably, SANOFI has been very pleased to have secured major global investments in our Canadian facilities despite the pandemic and ongoing public policy challenges. More collaboration is required, and SANOFI looks forward to contributing to those efforts.

Against this ambitious policy context, the draft PMPRB Guidelines stand out as unaligned and directionally inconsistent with these other policy efforts. The PMPRB should revisit its approach and ensure far greater consistency and alignment with these other Government of Canada initiatives. Setting clear objectives and advancing a stable, predictable, and well-supported set of Guidelines will require far more care and consideration. A world-class price regulation system, for example, cannot depend on the subjective or arbitrary decision-making of Board staff but rather clear policies disclosed in advanced which are feasible from a compliance standpoint and consistent with Canada's overall public policy goals for patented medicines.

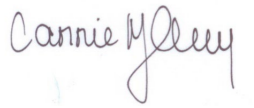
For global organizations such as SANOFI making product launch and investment decisions, Canada's relative market attractiveness and regulatory stability are a key consideration. Other aspects of the Canadian medicine review and reimbursement system are already complicated and subject to evolving public policies. Further uncertainty only detracts from Canada's overall standing and value proposition on the global stage. It is not apparent whether the Board will consider offering advance ruling certificates to patentees to assist in launch decision-making.

Recommendation

Considering the substantial problems contained in the current draft Guidelines, SANOFI recommends that the PMPRB restarts its Guidelines modernization process. Far greater care must be exercised to simplify the approach and provide greater predictability and stability to all stakeholders consistent with the PMPRB's established and recently reaffirmed legal mandate.

We are hopeful that the PMPRB will reflect carefully on the range of stakeholder submissions to this consultation and fundamentally reconsider the approach proposed in the current draft Guidelines.

Sincerely,



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