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human health care

August 21, 2023

Thomas J. Digby, Chairperson
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Re: Notice and Comment - Amendment to the Interim Guidance re: New Medicines (June 2023)

Dear Mr. Digby:

Eisai Limited ("Eisai") welcomes the opportunity to provide the PMPRB with our perspective on the June 2023 "Notice and Comment" with respect to the Board's Interim Guidance for New Medicines.

At the outset, we would emphasise that this document builds on and fully endorses the submission of our industry association BIOTECanada.

As background, Eisai Limited is the Canadian affiliate of Eisai Co Ltd., a leading Japan-based global multinational innovative pharmaceutical company. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, Eisai strives to create and deliver innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology. Our commitment to the health and well being of people worldwide is embodied in our corporate *human health care (hhc)* mission to put patients and their families at the heart of everything we do.

Overall, Eisai would encourage the PMPRB to provide greater clarity and stability to the Canadian market with respect to future price compliance obligations for both new and existing medicines. We recognize that, in the absence of revised Guidelines, the Board is seeking to reduce uncertainty by amending certain aspects of the Interim Guidance in the current Notice and Comment. However, there are a number of challenging aspects with the approach for reconsideration and revision. Adequate longer-term compliance stability can only be achieved by advancing clear, predictable and enforceable revised Guidelines for patentees and Board staff alike grounded in fulsome consultation.

Eisai would highlight and emphasise two specific areas of concern for reconsideration under any Interim Guidance.

First, the application of international median **price tests**, even for the temporary purposes of narrowing the pool of new medicines as either "reviewed" or "under review," would set a misplaced precedent for applying a universal ceiling using the median of international comparators for future Guidelines. In fact, the impact and utility of being deemed "reviewed" has not been elaborated as a concept, raising additional questions for patentees regarding compliance predictability. The lack of clarity on whether "reviewed" medicines would be subject to reassessment impairs the business case for Canada as an early launch destination for medicines during the interim period.

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Consistent with the PMPRB's legislative and regulatory framework as well as the stated policy direction from the Government of Canada, Eisai recommends that price compliance for new medicines should be assessed with reference to the entire basket of international comparators. As recent jurisprudence has established, it can be understood from the factors set out in the *Patent Act* that an excessive price is one that may exceed the price of international comparators. The rationale for the proposed approach to median price referencing under the "Notice and Comment" has not been provided, making it difficult for patentees to understand the objective and justification of this aspect including its longer-term implications.

Secondly, the proposed approach to **price increases** as stated in the "Notice and Comment," specifically with reference to the prior August 2022 policy, raises a number of concerns. Combined with a lack of explanation and context, anchoring Interim Period price levels to a static, fixed previous period of time (in this case, the first filing period of 2022) appears to omit the important reality of changing prices in the wider economy as measured by the Consumer Price Index (CPI). CPI is a mandatory legislated factor in the *Patent Act* for the purposes of determining non-excessive prices.

In the August 2022 policy document, the PMPRB provided the following commitment: "If it is necessary to extend the Interim Period beyond that date because the Guidelines are not yet in place, the PMPRB will revisit this issue" [of using the 2022 NEAP as the ceiling moving forward]. Not revisiting its decision to use the 2022 NEAP throughout the interim period is an unreasonable limitation on patentees and is inconsistent with the legislative framework.

Looking ahead, Eisai recognizes a much larger requirement for clear and meaningful stakeholder consultation by the PMPRB. We acknowledge that there has been a great deal of change and developments in recent years related to PMPRB reform. Despite this, Eisai and other patentees have sought to remain in compliance while ensuring Canada remains a destination of choice for new medicine launches at the global level.

We believe both patentees and the PMPRB have a shared interest in clarifying policy objectives and intent while promoting administrative feasibility and efficiency. Greater compliance certainty and predictability for all sides, including for PMPRB Board members and staff, should encourage a more efficient use of resources in the interests of improving and sustaining access to new medicines for Canadians in support of better health outcomes.

Sincerely,

Pat Forsythe
VP & General Manager
Eisai Limited

cc: Hon. Mark Holland, P.C., M.P.,
Hon. Francois-Phillipe Champagne, P.C., M.P.