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human health care

December 5, 2022

Doug Clark
Executive Director
Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario K1P 1C1

Submitted electronically via: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/2022-proposed-updates-guidelines.html

RE: October 2022 PMPRB Draft Guidelines Consultation

Dear Mr. Clark:

In response to the current PMPRB consultation on draft Guidelines, Eisai Limited ("Eisai") would like to highlight our company's perspective on the Board's proposed approach. This submission builds on and fully endorses the concurrent submission of our industry association partner BIOTECanada.

Eisai Limited is the Canadian affiliate of Eisai Co Ltd., a leading global Japan-based multinational pharmaceutical company. Eisai's 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.

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. With operations in Canada since 2011, Eisai is proud to provide five (5) medicines in Neurology and Oncology. We have worked diligently as an organization to secure and maintain full compliance with all PMPRB Guidelines as consistent with our corporate mandate and best global practices.

After careful reflection and assessment against our in-market and pipeline products, Eisai agrees with the recommendation of BIOTECanada that the proposed changes to the Guidelines should not proceed at this time. A much more considered and extensive consultation is required to ensure that the Board can effectively implement its mandate in a manner fully aligned with its mandate and Canada's public policy goals, while assuring sufficient compliance predictability for patentees and Board staff alike. The current draft Guidelines fall well short of those critical imperatives.

Our perspective as a company is informed from our accumulated experience to date in achieving PMPRB compliance for our marketed products, but also with consideration of our late-stage pipeline assets. In particular, we see a number of highly promising innovations emerging from clinical trials in key areas of healthcare system need (and current high disease burden and cost) such as Alzheimer's disease, where there is currently a complete absence of disease-modifying therapies on the market.

As a Canadian affiliate competing with multiple jurisdictions for global prioritization and company resources, our intention is to promote a compelling business case for Canada as an early launch destination for future medicines. The PMPRB regime is highly consequential for product launch sequencing. Whether non-excessive pricing is knowable in advance, and at what comparative level to other jurisdictions, is highly consequential to launch determination.

The draft Guidelines would represent a major departure in practice (and impact) for pricing compliance in Canada. Rather than a relatively predictable, structured approach based on voluntary compliance as in the past, the draft Guidelines would introduce a much more unpredictable, negotiated case-by-case approach dependent on Board staff sentiment. The proposed "Investigation Criteria" appear to depart from the non-excessive price standard into a very different landscape of "median" or much lower price comparisons. Compounding the concern for patentees, no analysis, rationale or explanation is being offered to better explain the Board's intentions or objectives with these Guidelines.

Further downstream, Canada's overall system for the review and negotiation of new medicines is already highly complex and challenging for global manufacturers such as Eisai. This type of variable, price-management approach from the PMPRB may not be workable or appropriate to the types of products that will be brought forward in the coming years, especially as they appear to disproportionately scrutinize first-in-class, early-launch products.

Accordingly, we see significant implications for Eisai's ability to launch future products in Canada should these draft Guidelines proceed. This prospective regime would generate new and entirely unhelpful compliance uncertainty for Eisai at the global level, negatively impacting Canada's ability to secure early product launches, investments, and other key drivers of our business.

Simply put, for Canada's relative market size and other market options, our country value proposition would be greatly impaired, and our affiliate likely deprioritized within the global company. We believe this is counter-productive from a patient care perspective and disconnected from the ongoing work elsewhere by Canadian governments to improve patient access to therapies, strengthen our healthcare system, and foster a world-class life sciences sector as a foundational basis of economic and social resilience.

There is an urgency to step back from this destabilizing approach. Companies cannot delay global decisions indefinitely or take unnecessary launch risks where future compliance obligations are in question. A major rethinking is required here to restore certainty and clarity as to the Board's intentions and expectations of patentees in a much more rigorous manner.

Sincerely,

Pat Forsythe
General Manager

cc: Hon. Jean-Yves Duclos, P.C., M.P.,
Hon. Francois-Phillipe Champagne, P.C., M.P.