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human health care

March 19, 2025

Anie Perrault, Acting Chairperson
Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Re: Feedback to PMPRB March 2025 Draft Guidelines Consultation

Dear Ms. Perrault,

Eisai Limited ("Eisai") welcomes the opportunity to provide the PMPRB with our perspective on the proposed December 2024 Guidelines.

At the outset, we would emphasise that this document builds on and fully endorses the submissions of our industry associations BIOTECanada and Innovative Medicines Canada (IMC).

As background, Eisai Limited is the Canadian affiliate of Eisai Co Ltd., a *human health care (hhc)* company with the mission to put patients and their families at the heart of everything we do. Since opening our doors in Canada in 2010, we have created and delivered innovative solutions to Canadian patients in areas of high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to develop new drug therapies that meet the needs of patients and their care partners, while improving their quality of life.

Eisai acknowledges the PMPRB's commitment to stakeholder engagement and efforts in taking the time to conduct thorough consultations. However, despite the positive direction, many uncertainties remain unaddressed in the recently published Guidelines.

Existing Medicines

Eisai made drug launch decisions and significant investments in Canada under the previous Guidelines. Our current portfolio of products has been thoroughly reviewed by the PMPRB. It is not appropriate for the PMPRB to re-review pricing of medicines that have already been deemed compliant and therefore non-excessive. Eisai recommends Existing Medicines should only trigger an In-Depth review if price increases are beyond allowable CPI adjustments or a complaint is raised. Grandfathering maintains predictability and ensures patients continue to have access to the medications they need.

For instance, Lenvima (lenvatinib) received its notice of compliance (NOC) for radioactive iodine-refractory differentiated thyroid cancer (RAIR-DTC) in December 2015. Following this, Lenvima obtained positive recommendations from both Canada's Drug Agency (CDA) and the Institut national d'excellence en santé et en services sociaux (INESSS). It successfully negotiated pricing and reimbursement criteria that were considered affordable by provincial drug programs, leading to its funding across the country for four indications: differentiated thyroid cancer, hepatocellular carcinoma, endometrial carcinoma,

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and renal cell carcinoma. The listing of Lenvima by pan-Canadian payers underscores its recognized value to the healthcare of Canadians. The PMPRB's proposal to re-review the price of Lenvima overlooks the well-established federal and provincial processes already in place.

Transition Period

The proposed Guidelines state Annual Review for Existing medicines will start one year from the date the Guidelines go into effect. As noted above, Eisai recommends grandfathering of Existing Medicines. For New Medicines launched during the Interim Period (July 1, 2022 to implementation of the new Guidelines), Eisai recommends that the transition period for the implementation of the new Guidelines be extended to at least two years.

In the recent Discussion Guide, the PMPRB considered three options ranging from one year to three years. In previous amendments to the Guidelines, PMPRB implemented a transition period to allow patentees adequate time to comply with the new Guidelines. A two-year transition would be appropriate, and would allow pharmaceutical companies adequate time to adjust their pricing strategies without disrupting the supply of essential medicines to patients.

Initial and Annual Review

Eisai agrees with adopting the highest international price (HIP) of the PMPRB11 basket of comparator countries and recommends the HIP is maintained in the final Guidelines. Especially for smaller manufacturers like Eisai, who do not have the support of large and specialized teams to manage fluctuating pricing dynamics such as ever-changing foreign market or regulatory conditions. Predictability and stability over time in pricing is crucial for developing and commercializing new innovative treatments in Canada, and therefore, Eisai recommends that once the price of a medicine is considered reviewed and acceptable at the Initial Review, subsequent Annual Reviews should only review against the allowable CPI increase.

Overall, Eisai recognizes the PMPRB's ongoing effort to engage with stakeholders and the collaborative approach to foster constructive dialogue. We believe that the proposed Guidelines, with the suggested adjustments above, will continue to move the Guidelines in a positive direction. Thank you for your consideration of our submission, we look forward to continued collaboration towards our shared interest of better health outcomes for Canadian patients and care partners.

Sincerely,

Pat Forsythe
VP & General Manager
Eisai Limited