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hhc
human health care

February 15, 2021

Doug Clark, Executive Director
Patented Medicine Prices Review Board (PMPRB)
Box L40|Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario, K1P 1C1

Re: Notice and Comment – On the change to the definition of Gap medicines and the timeline for compliance

Dear Mr. Clark:

On behalf of Eisai Limited (Eisai), we would like to take the opportunity to provide our input on the Patented Medicines Prices Review Board's (PMPRB) proposed changes to the definition of Gap medicines and the timeline for compliance.

Eisai is the Canadian subsidiary of Eisai Co. Ltd., a human health care (hhc) company seeking innovative solutions in disease prevention, treatment and care for the health and well-being of people in Canada and around the world. Our company's hhc philosophy is based on a clear understanding that patients as well as their caregivers are the key players in healthcare, and at Eisai, we strive to develop new drug therapies that meet the needs of these patients and their caregivers while improving their quality of life.

Our company is in an exciting period of research, innovation and unprecedented scientific advances to improve patient outcomes. Since opening our doors in Canada in 2010, we have brought several important innovations to Canadian cancer and epilepsy patients, which have led to improved health outcomes for patients and significant long-term savings for payers and the healthcare system.

In this context, we remain deeply concerned by the changes to the Regulations Amending the *Patented Medicines Regulations* and the associated PMPRB guidelines. Despite significant feedback submitted by stakeholders during the PMPRB's consultations and the delay in implementation of the Regulations, many fundamental issues remain unaddressed in the recently published Guidelines. Our key concerns with the new federal pricing regime include the following:

1. Health Canada is taking efforts to accelerate patient access to new medicines. The new PMPRB Guidelines introduce unnecessary uncertainty which will delay or eliminate access to these needed medications.
2. Unclear and multi-layered pricing rules affect our ability to commercialize new medicines in Canada.
3. Price ceilings for already commercialized therapies should not be reassessed by the PMPRB.

While we agree that the PMPRB plays an important role in managing excessive pricing, we believe the new pharmaceutical pricing framework goes far beyond this mandate. It is our position that changing the Comparator Basket will meet all the stated goals of the PMPRB. Instead, the new Guidelines introduce unnecessary complexity and duplication. Ultimately, we need a clear framework that provides

a predictable pathway in order to commercialize our innovative medicines and to encourage health research investments in Canada. This business uncertainty will therefore make it extremely challenging for our global office to prioritize Canada in the commercialization of new medicines.

We recommend that the PMPRB revise and simplify its new pricing regime to address these outstanding concerns to ensure that Canadian patients can continue to access new medicines and vaccines in a timely manner, especially at this very critical time for Canadians and our health systems given the ongoing COVID-19 pandemic.

Notice and Comment Consultation

In response to the PMPRB's invitation for comments on the two proposed consequential amendments to the new PMPRB Guidelines in this Notice and Comment consultation, Eisai offers the recommendations below.

Definition of Gap Medicines:
Eisai agrees with the proposed definition of Gap medicines: "Gap medicines are medicines for which a DIN was assigned on or after August 21, 2019 and first sold in Canada prior to July 1, 2021". We agree with the extension of the date of first sale to the new coming-into force date of July 1, 2021.

Compliance Timelines for Grandfathered and Gap Medicines:
Eisai recommends the PMPRB, at the minimum, maintain the previously communicated approach of assessing compliance with the Maximum List Price (MLP) for Grandfathered and Gap medicines after two reporting periods. Reducing the compliance timelines to one reporting period is not operationally feasible.

In previous amendments to the Guidelines, PMPRB implemented a transitional period to allow patentees adequate time to comply with the new Guidelines. For example, as outlined in the PMPRB Bulletin Issue No. 12 of September 1993, the Guidelines were amended to include highest international price comparisons. The Board stated it would not commence formal proceedings if it was satisfied that appropriate action was being taken to ensure that the price would comply with the Guidelines by January 1, 1996, thus effectively providing patentees four reporting periods to come to compliance.

Health Canada's reasoning behind the recent delay in implementation of the Regulations Amending the *Patented Medicines Regulations* was to allow industry further time to familiarize themselves with the PMPRB's final Guidelines. It would also provide industry with additional time to prepare for the new reporting obligations.

Rather than allowing patentees adequate time to comply with the new guidelines, condensing the compliance timeline poses operational challenges that will place undue burden on the industry. The proposed timeline more than halves the operational time for patentees to come to compliance. Time from receiving the Compliance Status Reports to compliance deadline shortened from ~10 months to ~4 months. This condensed timeline will cause strain on all stakeholders involved including wholesalers, payers, and pharmacies.

Reducing the compliance timeline also places undue challenges on the PMPRB. Patentees seeking requests for MLP reconsiderations would submit requests by mid-October, and it could be challenging for PMPRB to complete assessments and communicate revised MLPs to patentees in time for stakeholders to implement price changes prior to December 2021.

Ultimately, reducing the previously stated time to come to compliance for Grandfathered and Gap medicines poses additional unpredictability and operational challenges for all stakeholders. It is unclear why the PMPRB is proposing to reduce the compliance timelines rather than maintaining its original approach, especially considering the PMPRB was willing to provide three reporting periods in the June 2020 draft Guidelines.

Since entering the Canadian market, Eisai has decided to commercialize medicines and made significant investment decisions in Canada based on the current, reasonably predictable pricing environment. However, uncertainties in the new pricing reforms (as mentioned as feedback to recent PMPRB consultations), and further reducing the previously stated timeline to come to compliance, introduce significant and unnecessary uncertainty in the Canadian market.

Conclusion

In summary, the changes to the *Patented Medicines Regulations* and the PMPRB's final Guidelines increase the uncertainty innovators already face in developing and commercializing new treatments in Canada. Eisai fully supports reforms that contributes to health system sustainability and better and more affordable access to medicines for patients. We recommend the PMPRB maintain the MLP compliance timeline of two reporting periods for Grandfathered and Gap medicines.

We encourage the PMPRB to take the necessary time to further engage with industry and other stakeholders to address outstanding concerns in the October 23, 2020 Guidelines, and ensure the Guidelines are operational and offer the predictability needed for our global office to prioritize Canada in the commercialization of new medicines. Importantly, we recommend the PMPRB to revise its new pricing regime to ensure Canadians can continue to access new treatments, thus resulting in better health outcomes, and, ultimately, reduced costs for the health system in the long run.

Sincerely,

Pat Forsythe
General Manager
Eisai Limited