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hhc
human health care

August 31, 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, the references to the comparator countries and the international price tests for Grandfathered medicines and their line extensions

Dear Mr. Clark:

On behalf of Eisai Limited (Eisai), we would like to take the opportunity to provide input on the Patented Medicines Prices Review Board's (PMPRB) proposed changes to the definition of Gap medicines, the references to comparator countries, and the international price tests for Grandfathered medicines and their line extensions. We would also like to comment on compliance timelines and the issue of consistency in the recently published Guidelines.

Eisai's History in Canada

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. Since entering the Canadian market in 2010, Eisai has been a good partner working diligently to productively engage with all stakeholders, including physician and patient groups, payers and the PMPRB.

A Challenging and Unstable Pricing Environment

For most of the past decade, Eisai has commercialized medicines and made significant investment decisions in Canada based on a pricing environment we have found to be largely reasonable and predictable. We also understand that the Board has an important mandate to update its Guidelines to reflect changes to the global biopharmaceutical environment and in keeping with its statutory mandate to prevent the excessive pricing of patented medicines.

However, since the Board's launch of the reform process, Eisai has become increasingly concerned about the direction and speed of the proposed reforms – and about the significant impact of those reforms on a Canadian policy and business ecosystem. The numerous changes to the Guidelines throughout the PMPRB reform – including the most recent and unexpected proposed amendments – have created a pricing environment that is not only less stable but also less predictable for companies like Eisai who are working to bring innovative treatments and therapies to patients and their physicians across the country.

It is against this backdrop that we would like to highlight three overarching concerns with the PMPRB's most recent proposed changes to its Guidelines:

1. **Price ceilings for already commercialized therapies should not be reassessed by the PMPRB.** The prices of our products that are already commercialized in Canada were deemed to be compliant with the current PMPRB rules, have been thoroughly reviewed by CADTH, negotiated by the pan-Canadian Pharmaceutical Alliance (pCPA) and considered cost effective and affordable by public and private payers. We therefore do not believe it is appropriate for the PMPRB to reassess price ceilings for these medicines.

2. **Compliance timelines for Grandfathered and Gap medicines should remain consistent – as per the PMPRB's own previous proposals – and patentees should be allowed at least two filing periods to comply after the new amended regulations come into effect.** Condensing the compliance timelines poses operational challenges that will place undue burden on all stakeholders involved including wholesalers, payers, and pharmacies. Assuming the Board's new Regulations come into effect on January 1, 2022, the operative date for assessing compliance with the MLP should be January 1, 2023.

3. **With the Board's new amended Regulations due to come into effect in a few short months, the Board should also rescind its unexpected and unprecedented proposal for change in the international price test for already compliant Grandfathered medicines and their line extensions.** These changes create considerable uncertainty, especially given the ongoing disruption caused by the evolving COVID-19 pandemic.

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

- **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 prior to January 1, 2022 and first sold in Canada prior to January 1, 2022."* We also agree with the extension of the date of first sale to the new coming-into force date of January 1, 2022.

- **References to the Comparator Countries as "scheduled" countries:** Eisai urges the PMPRB to continue referring to the new basket of comparator countries as the "PMPRB11". Not only has this language already been used throughout the current reform process, but the term has the advantage of being simple, clear, consistent, and accurate.

- **International Price Tests for Grandfathered Medicines:** Eisai re-states its position that price ceilings for already commercialized therapies should not be reassessed by the PMPRB. Notwithstanding, by proposing changes to the previously communicated price tests for Grandfathered medicines and their line extensions only a few months prior to the coming into effect of the new amended regulations, the Board will add significant avoidable uncertainty.

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We recommend the PMPRB maintain the previously communicated price tests and to consider the following factors when evaluating operational challenges with the proposed amendments:

- **The PMPRB should work towards creating reasonably predictable Guidelines rather than generating additional uncertainty six months prior to new amended regulations coming into force**. This unexpected proposed change introduces additional operational uncertainty to the already complex new PMPRB Guidelines.

- **The highest PMPRB7 price test was directed at controlling patent abuse and remains pertinent and consistent with the excessive pricing provisions**. Being above the Median PMPRB7 price level but below the Highest PMPRB7 does not necessarily define excessive pricing nor patent abuse.

- **In situations where a new price rule is proposed, which represents a significant and unprecedented departure from the current Guidelines, there should be a reasonable rationale and explanation detailing any departures from the Guidelines**. In these circumstances, the amendments to the Guidelines should be accompanied with a transparent comprehensive inclusive evaluation process with detailed explanation of the analysis and assumptions. Without these, the amendments appear arbitrary and hinder productive engagements with stakeholders.

- **The impact of pricing reform should be progressive and consistent**. The rules for price increases and price decreases should be consistent in the new Guidelines. For instance, the PMPRB has proposed that MLP increases be adjusted based on the actual lagged change in the consumer price index (CPI). Therefore, Eisai recommends that MLP decreases also be transitioned year over year to a value percentage equivalent to the adjusted allowable increases based on CPI, in keeping with creating a sustainable business ecosystem

Our company is in an exciting period of research, innovation, and unprecedented scientific advances to improve patient outcomes. Unfortunately, the uncertainties of the new Guidelines and proposed amendments make it extremely challenging for our global office to prioritize Canada in the commercialization of new medicines.

Based on the relationship between a thriving and sustainable biopharmaceutical sector and patient and physician access to innovative medicines, Eisai strongly encourages the PMPRB to ensure its Guidelines offer the clarity, the stability, and the predictability all Canadians deserve.

Sincerely,

Pat Forsythe
General Manager
Eisai Limited