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human health care

November 6, 2020

Standing Committee on Health
Sixth Floor, 131 Queen Street
House of Commons
Ottawa ON K1A 0A6
Canada

Dear Committee Members:

Re: Patented Medicine Prices Review Board (PMPRB) Study

On behalf of Eisai Limited (Eisai), thank you for undertaking this important study on the Patented Medicine Prices Review Board (PMPRB) reforms, and for the opportunity to provide our input.

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 are deeply concerned by the recent changes to the *Patented Medicines Regulations* and the associated PMPRB 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, the new pricing reforms introduce significant and unnecessary uncertainty in the Canadian market.

While we agree that the PMPRB has a role to play in managing excessive pricing, we believe the new pharmaceutical pricing framework goes far beyond this mandate and introduces unnecessary hurdles that inhibit efforts to bring new treatments to Canadians. We have highlighted in this submission our key concerns with the new federal pricing regime.

Concern #1: Health Canada's efforts to accelerate patient access to new medicines will be hampered by the new PMPRB's guidelines which introduce unnecessary uncertainty

There have been recent efforts at the national and global level to promote collaboration among international regulators in order to provide patients with earlier access to potentially life-changing medications. The new pricing guidelines adds additional and unnecessary complexity to an already onerous process. These reforms are jeopardizing efforts made by Health Canada and other international regulators to bring needed treatments to patients sooner.

Concern #2: Price ceilings for already commercialized therapies should not be reassessed by the PMPRB

Medicines that are already on the market should not be subject to the new PMPRB rules given that business decisions were made based on the current pricing regime, and at a time when the scope and impact of the new rules could not have reasonably been foreseen by pharmaceutical companies, such as Eisai.

For instance, our medicine Fycompa (Perampanel), which treats patients with epileptic seizures, was authorized for sale in Canada in 2014. It has already been extensively assessed by the PMPRB and has always remained in compliance with the agency's current rules. In addition, this product was evaluated by the Canadian Agency for Drugs and Technologies in Health (CADTH) and negotiated through the pan Canadian Pharmaceutical Alliance (pCPA). As Fycompa has been on the market for over 5 years and has already been deemed to be cost-effective and affordable by payers, it would be unnecessary and unreasonable to further reduce its price based on the new PMPRB rules. This would unduly penalize Eisai, which has been a good partner and corporate citizen with all our stakeholders, including all payers and the PMPRB.

Concern #3: Unclear pricing rules affect our ability to commercialize new medicines in Canada

It would not be appropriate for the federal government to implement the new pricing regime when there is still so much uncertainty on how prices will be determined by the new guidelines. This uncertainty affects our ability to determine prices for new product launches. A few examples of this include the application of economic factors, no guidance on reference price sources, and lack of clarity on market size thresholds.

Eisai Canada works with its global affiliates to make launch decisions based on the predictability of pricing decisions. Launching a pharmaceutical product in Canada requires a business case that shows the feasibility of a launch. The price uncertainty and the possibility of having to lower drug prices makes it difficult to create a business case for Canada.

Eisai agrees that the PMPRB has a role to play in managing excessive pricing. That is in the interest of all Canadians. However, it is our position that PMPRB has created an unintended consequence in introducing these new guidelines. The PMPRB's goal of reducing medication prices in Canada is based on an inaccurate assessment of the actual prices due to the fact that actual rebated prices are much lower and were not considered in their assessment. All provinces in Canada negotiate substantial volume discounts from manufacturers through the pan Canadian Pricing Alliance (pCPA) process. Not only is price negotiated, but there are specific criteria defining which patients can receive these drugs and when. The PMRRB does NOT include these confidential prices in their analyses and therefore vastly overstates the prices of Canadian drugs. This has significant impact and we believe goes beyond the stated intent of the PMPRB. Further price reductions mandated by the new guidelines are punitive and will unfairly impact companies who have agreed to rebates in good faith with the provinces. This introduces significant business uncertainty and sends the wrong signal to companies looking to continue to invest in the life sciences sector.

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. We need to be able to determine expected revenues before deciding whether and when to commercialize a medicine in

Canada and the current PMPRB regime simply does not allow us to do so. This business uncertainty will therefore make it extremely challenging for our global office to prioritize Canada in the commercialization of new medicines.

Conclusion

In sum, 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. However, we do not believe that the new pricing system will make a positive contribution to these objectives. Importantly, the new rules will make it much more difficult for Canadians to get access to new treatments, leading to worse health outcomes, and, ultimately, more costs for the health system in the long run.

We recommend that the federal government revise its new pricing regime to address 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.

We thank you again for undertaking this study and hope our feedback will help advance your deliberations and inform your recommendations to the federal government on this important issue.

Sincerely,

Pat Forsythe
General Manager
Eisai Limited