



August 4, 2020

Patented Medicine Prices Review Board

Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
K1P 1C1

Delivered via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Comments on June 2020 Draft Guidelines

Otsuka Canada Pharmaceutical Inc (OCPI) thanks you for the opportunity to provide input to the revised draft Guidelines. We are members of Innovative Medicines Canada and are fully aligned with their submission on the revised draft Guidelines, but also wish to bring separate concerns affecting OCPI and our associated partners to your attention.

First, we'd like to recognize the Board's revisions to the 2019 draft Guidelines. We recognize that some changes have been incorporated, and we do believe some progress was made versus the first iteration of the guidelines on aspects like product grandfathering. However, we believe there are still a number of significant issues with the proposed Guidelines that we would like to bring forward.

Working with partners: certainty in pricing and process

As we had originally noted, a key consideration for our parent company to invest in Canada was Canada's well-established pharmaceutical environment, with its clear rules of engagement providing market partners with certainty and security. This certainty has been a key component of our ability to bring treatments to the Canadian market – whether in marketing treatments from our Japanese parent company or developing external partnerships with international companies to bring innovative medicines to Canadians.

As an example of the latter, OCPI recently succeeded in bringing two treatments to the Canadian market through a Canada-specific licensing agreement with Vifor Pharma. Both have been approved by Health Canada and provide additional therapeutic choices for Canadians.

Otsuka Canada Pharmaceutical Inc.

2250 Alfred Nobel Boulevard, Suite 301 • Saint-Laurent, Québec H4S 2C9 Canada • Phone: 514-332-3001 • Fax: 514-332-3107

These investments were facilitated by the perception of a stable and predictable regulatory environment in Canada.

Leveraging international partnerships represents a significant opportunity for both OCPI and Canadians as we are able to provide a broader range of choices and new treatments for patients. OCPI has grown in large part due to these partnerships. We believe that the most recent Guidelines still fail to provide companies with the certainty and security required to build an acceptable business case to bring treatments to Canada. Simply put – if we cannot provide a clear and sensible process as part of our discussions, the Canadian market’s appeal within a global context should be expected to become weaker.

In a departure from the PMPRB’s stated mandate to protect Canadians from excessive pricing, the proposed price review process instead creates an environment which can decrease prices in Canada based on external factors (e.g. fluctuations in currency exchange rates) in foreign countries. What is troubling is that while the proposed guidelines have a mechanism to reduce prices in Canada in response to decreasing prices in one or more jurisdictions internationally, they do not provide fair balance to allow for increases should international prices return back to original levels, adding another threshold (i.e. “ if the prevailing MIP exceeds the MLP by more than 10%, the MLP may be adjusted based on the actual lagged change in the consumer price index (CPI)”). In this sense, this proposed mechanism acts to decrease prices in Canada based on external factors over the lifecycle of a medication, adding to uncertainty when planning for the Canadian market.

Ensuring Canada remains a priority

Concerns around certainty also extend to Otsuka’s own products. As a Canadian affiliate of a company based in Japan, we often engage in discussions with our parent company and other affiliates to ensure R&D investments are made in partnership with Canadian sites, as well as discussing the sequential launch trajectory of drug products. Like any pharma, our parent company looks at a wide variety of factors in choosing the geographical order by which these drugs will be commercialized– including certainty and process. Without a clear understanding of how a treatment may be priced in accordance with the proposed Guidelines, Canada may no longer be a priority for product launches and lose its first-tier status in that regard, ultimately limiting options for Canadians.

Concluding Remarks

As we mentioned in our first submission, a key objective of our company is continued growth and investment in Canada to be able to continue to bring innovative medicines to Canada.

Predictability and fair regulatory environment are not only key to our ability to bring innovation to Canadian patients but also critical to achieve a sustainable health system. We appreciate that the federal government is seeking that objective, but believe that the Guidelines fail to strike a balance between market and patient access and a sustainable health system.

A handwritten signature in blue ink that reads "Michael Laranjo". The signature is written in a cursive, flowing style.

Michael Laranjo, CPA CA
President and General Manager
Otsuka Canada Pharmaceutical Inc.