



**Submission to the Patented Medicines Pricing Review Board
Notice and Comment on the Change to the Definition of
Gap Medicines and the Timeline for Compliance
from
The Mississauga Board of Trade
February 15, 2021**

Introduction

Since being established in 1961, the Mississauga Board of Trade (MBOT) has played an important leadership role serving and representing the interests of business of all sizes and sectors in our community. Mississauga is Canada's sixth largest city and third largest in Ontario – with a population of over 700,000 residents and over 50,000 businesses employing over 440,000 people, including 60 Fortune 500 Canadian headquarters. Mississauga is where successful companies choose to do business.

MBOT's large, diverse and active membership has made us one of the most vibrant business associations in Canada. As the "Voice of Business" we advocate on policy issues that impact local business at all levels of government and are influential in helping to shape policy decisions.

MBOT also offers a wide variety of valuable business services and professional development programs, networking events and marketing opportunities, to help business grow, prosper, and get connected.

Comments on the PMPRB Guidelines Consequential Amendments

Canada's life sciences sector – which has a considerable footprint in the City of Mississauga - has been at the forefront of Canada's response to the COVID-19 pandemic. The sector has been working hard to contribute to global efforts to develop vaccines, treatments, tests and other solutions needed to stem the tide of this crisis.

Moving forward, the life sciences sector also has an important role in driving our country's economic recovery and building up our resilience in the face of future health challenges.

However, the current path that the PMPRB has taken is not only putting the health of Canadians and our economy in jeopardy, but also stifling our sector's efforts to respond to the COVID-19 crisis.

MBOT is concerned about the impact of the PMPRB proposal to halve the transition period for companies to comply with the new Maximum List Price requirements for Grandfathered and Gap medicines. This will clearly divert companies' attention and resources away from the COVID crisis.

The original purpose of the *Patent Act* and the regulations was to strike a balance between the ability of a drug manufacturer to establish a price for its medicine during the protection period and the interests of governments and consumers by ensuring that Canadians continue to have access to patented medicines at non-excessive prices.

This proposal would also undermine, and effectively negate, the Federal Government's efforts to support the sector's response to the crisis by delaying the coming into force date of the regulations in the first place.

MBOT believes that the draft regulations do not strike the right balance and sends a message to drug manufacturers that they will not be able to attain a pricing regime for the medicines that they produce that will allow them to recover the costs associated with research and development, manufacturing and distributing of new patented medicines.

The City of Mississauga is a hub for innovation and has dozens of life sciences and pharmaceutical companies generating millions of dollars and employing thousands of highly skilled workers in our community. The PMPRB changes will have a concerning impact on innovation in Mississauga's biopharmaceutical cluster.

MBOT is concerned that innovation, jobs, clinical trials and the timely launch of new medicines appear to be at risk as a result of the proposed changes. We are very worried about the possible exodus of companies and human capital to international competition which is very real in the biopharmaceutical sector.

The proposed guidelines will also send a signal to the life sciences sector to not invest in the development of new medicines which ultimately will affect patient health and actually cause greater costs to the public health system in Canada. There are many examples of new medicines that have been created in Canada that have had a significant impact on patient health and have resulted in less hospitalization, better health outcomes and longer life expectancy.

The Biopharmaceutical industry needs stability and predictability and the assurance that the regulatory system will be fair and transparent. These guidelines are an even more complex mixture of formulae, price floors, price ceilings and missing information than the previous version. There is no way to properly calculate what a potential price could be in Canada.

Conclusion

MBOT remains very concerned over the impact of the draft guidelines on a sector of Mississauga's economy that employs thousands of highly skilled workers and the investment of millions of dollars into the local economy.

We strongly urge the PMPRB to reconsider the proposed six month transition period and revert back to the twelve month period as originally proposed in the 2020 Guidelines.

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