

**Submission to the Patented Medicines Pricing Review Board  
Draft PMPRB Guidelines  
from  
The Mississauga Board of Trade  
July 30, 2020**

**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 Draft PMPRB Guidelines**

MBOT is concerned about the impact of the proposed draft PMPRB guidelines on the very businesses that are investing millions of dollars every year in research and development of new medicines to the benefit of all Canadians.

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.

These Guidelines, which are issued pursuant to subsection 96(4) of the Act, are intended to provide transparency and predictability to patentees regarding the process typically engaged in by public servant employees of the PMPRB in assessing whether a patented medicine appears to be priced excessively in any market in Canada. The Guidelines also provide an overview of the processes that patentees should be aware of regarding their filing obligations under the *Patented Medicines Regulations*.

MBOT believes that the draft regulations do not strike this balance and send 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 latest draft 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.

Although not directly related to the draft PMPRB guidelines, we would also like to comment on the Scientific Research & Experimental Design (SR&ED) program as it is very much intertwined with patented medicines approvals. MBOT has called upon the Federal Government to simplify and modernize this program so it better reflects the reality of research and development investments being made by the biopharmaceutical companies in Canada and properly reflects the true levels of investment being made.

It would be helpful for the Board to consider the impact of this program in its regulatory review.

## **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 respectfully ask that the PMPRB delay the implementation of the new guidelines in January 2021 and go back to the drawing board by including industry representatives in further consultations and changes to the draft guidelines.

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