



Montreal, January 30, 2020

Dr. Mitchell Levine
Chair, Patented Medicine Prices Review Board (PMPRB)
By email
PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

SUBJECT: The FCCQ's Comments on PMPRB Interim Guidelines

Dear Dr. Levine,

Representing more than 50,000 businesses operating in all sectors of the economy across Quebec, the FCCQ is the largest network of businesspeople and companies in the province. Our mission is to defend the public policy interests of our members in order to promote an innovative and competitive business environment. To this end, we regularly participate in public debates and make recommendations on political, economic, and social issues.

In recent years, we have participated in a number of federal health-related debates, including the implementation of a national pharmacare program as well as amendments to the *Patented Medicines Regulations*, and the modernization of the Patented Medicine Prices Review Board (PMPRB). Our extensive network enables us to take a unique look at these issues not only from the perspective of employers, but also from a variety of sectors, such as generic and innovative medicines, and pharmacists.

From the outset, the FCCQ has applauded PMPRB's efforts to protect Canadians from excessive drug prices. In fact, we believe that the sustainability of private and public insurance plans is essential to ensure that Canadians have access to a wide range of drugs. We also believe that affordability is the key to sustainability.

However, we are concerned about the impact of significantly altering market conditions for patented drugs in Canada, especially for an industry that is highly competitive and international in nature. That impact is being felt on the ground. In fact, many of our members have already experienced layoffs, while others have delayed new product launches or put major investments on hold.

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In light of these findings, the FCCQ is concerned about reduced access to new innovative drugs in Canada, drugs that could improve the health of Canadians, reduce the number of hospitalizations, and increase productivity in the workplace.

The PMPRB Interim Guidelines, enabling the application of the new Patented Medicines Regulations, released on November 21, underscore our concerns.

A need for greater predictability

Rather than providing clarifications, the FCCQ considers that the new Interim Guidelines add a level of complexity and generate a lot of questions and uncertainty for the industry.

By way of example, in addition to the new regulatory pricing factors of pharmaco-economic value, market size, and Canada's GDP and GDP per capita, the Interim Guidelines provide "a re-evaluation procedure for drugs that may warrant a higher or lower ceiling due to changes in market conditions¹." Clearly, Category 1 patented drugs, the major source of innovation in this sector, could have their prices adjusted if their annual revenues exceed \$25 million. This practice seems highly unusual to us and creates a lack of predictability for companies that will continually have to adjust their business model or postpone certain investments. Not to mention that this is a major change that has not been fully analyzed and that at no time does the new *Patented Medicines Regulations* reference such a price adjustment.

The socio-economic footprint of Quebec's life sciences sector

The life sciences industry is a vitally important sector of the Quebec economy. According to the most recent data, the sector represents more than 660 businesses that provide 32,000 well-paying jobs in various regions of Québec². The average salary in the life sciences industry is close to \$70,000, almost 60% higher than the average salary for all sectors in the province³.

¹ CEPMB, consultation sur les Lignes directrices provisoires : https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-quidelines/document-information-lignes-directrices-provisoires-fr.pdf

² Ministère de l'Économie et de l'Innovation : https://www.economie.gouv.qc.ca/bibliotheques/secteurs/sciences-de-la-vie/recensement-des-entreprises-2018/

³ Valeur économique de la chaîne d'innovation en SVTS, Montréal InVivo, juillet 2015 : http://www.montreal-invivo.com/wp-content/uploads/2018/01/Recommandations-en-vue-du-budget-provincial-2017-2018.pdf





Indeed, it is a dynamic and job-generating sector with many players, including research centres, hospitals, and other related employers. Among other things, the sector has invested more than \$10 billion in state-of-the-art infrastructure, research centres, and health facilities in Quebec⁴.

Quebec also stands out as one of the few regions active in the three major life sciences subsectors: biopharmaceuticals, medical technologies, and natural health products⁵. With regard to the pharmaceutical industry in particular, close to half of the Canadian head offices of major pharmaceutical companies are located in Quebec⁶.

Given the importance of the life sciences industry to its economy, the Quebec government launched the Quebec Life Sciences Strategy in May 2017 with the goal of, among other things, attracting more than \$4 billion in private investment by 2022 and positioning the province among the five largest North American hubs in the sector by 2027⁷.

Like many other organizations with an economic focus or working in the life sciences sector, the FCCQ applauded the launch and implementation of the Quebec Life Sciences Strategy, especially because it promotes an innovative and forward-looking environment for the industry. Nevertheless, we are concerned that the changes to the PMPRB will undermine the efforts of the Government of Quebec and its capacity to implement the Quebec Life Sciences Strategy.

The FCCQ's recommendation

In light of the importance of life sciences to Quebec's economy, the FCCQ considers that the proposed reform is clearly precipitated and is worried about the consequences it will cause, in addition to those already apparent. Further, although consultations

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⁴ Montréal International : https://www.montrealinternational.com/fr/actualites/montreal-international-et-quebec-international-et-quebec-international-unissent-leurs-forces-pour-accroitre-linvestissement-direct-etranger-en-sciences-de-la-vie-et-technologies-de-la-sante/

Ministère de l'Économie et de l'Innovation : https://www.economie.gouv.qc.ca/objectifs/informer/par-secteur-dactivite/sciences-de-la-vie/

Médicaments novateurs Canada: http://innovativemedicines.ca/wp-content/uploads/2019/01/20191011 M%C3%A9moireMNC Quebec Janv2019 FINAL.pdf

⁷ Stratégie québécoise des sciences de la vie 2017-2027 : L'innovation prend vie : https://www.economie.gouv.gc.ca/fileadmin/contenu/publications/administratives/strategies/sciences_vie/strategie_sciences_vie.pdf





have taken place, the concerns of stakeholders such as the FCCQ have not been addressed to date.

We thus ask that there be a moratorium on the changes proposed in the PMPRB Interim Guidelines in order to better define the public policy issues that must be addressed and to find balanced, reasonable solutions that do not jeopardize the health of the life sciences ecosystem or access to new medicines.

We continue to be available to discuss this important question at your convenience.

Yours sincerely,

Charles Milliard, MBA President and CEO