

August 4, 2020

Dr. Mitchell Levine
Chairperson, Patented Medicine Prices Review Board (PMPRB)
333 Laurier Avenue West
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Ottawa, Ontario
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Subject: June 2020 PMPRB Draft Guideline Consultation

Doctor Levine:

We are writing to you on behalf of BIOQuébec, Québec International, and Montréal InVivo, three organizations that, combined, represent virtually all the life sciences and health technologies sector stakeholders in the province of Quebec.

Thank you for the opportunity to share our comments about the interim guidelines published in June 2020 with you.

We would like to begin by stating that Quebec's life sciences and health technologies sector consists of more than 660 companies and represents over 32,000 high-quality jobs in the province, with an average salary above \$70,000.¹ This industry is one of the most important pillars of Quebec's economy, and it alone invests several billion dollars in research and development in the province. Quebec also attracts a large share of Canadian head offices of companies that operate in this sector. In fact, the Quebec government is relying on this sector of activity, including its research ecosystem component, to stimulate the province's economic recovery during the current COVID-19 pandemic.

¹ Study completed by Deloitte on behalf of BIOQuébec, Study on Public Policy Requirements and Financing Needs for the Life Sciences and Biotechnology Applied to Human and Animal Health Industry, 2019: https://static1.squarespace.com/static/57c496ac6b8f5bb965c464d3/t/5dbaef8698044146cbee3c5b/1572532107031/BIOQuebec_EtudePolitiquesPubliquesEtFinancement_SOMMAIRE+EXECUTIF+FINAL.pdf. The quoted data was obtained from Quebec's Ministry of Economy and Innovation website, Recensement des entreprises des sciences de la vie 2018: <https://www.economie.gouv.qc.ca/bibliothèques/secteurs/sciences-de-la-vie/recensement-des-entreprises-2018/> and from Montréal InVivo's data from 2014, Compétitivité des sciences de la vie et des technologies de la santé du Québec – Rapport synthèse, Étude diagnostique et comparative des sciences de la vie, 2016. See also: <https://www.montreal-invivo.com/secteurs/portrait-sectoriel/>

Given the importance of the life sciences sector to Quebec, we are very concerned by the PMPRB's new proposed tariff regime and the impact it will have on Quebec patients, our healthcare system, investments in health research, and our economy.

The considerable uncertainty created by the revised guidelines could delay and limit Quebecers' access to the most innovative drugs and curb investments in health, including investments in clinical and pre-clinical research, which is very worrisome to us. The new guidelines make it almost impossible for biopharmaceutical companies to determine what price they will be able to get for their products before they are launched on the Canadian market. As a result, it will be very challenging for biopharmaceutical companies to present a convincing business case to their world headquarters that, when launching new drugs and vaccines, priority should be given to the Quebec and Canadian markets.

What our three organizations are seeing in the field, and what is confirmed by recent data, is that the new measures being proposed have already begun to significantly reduce both the number of new drug launches in Canada² and clinical trial activity.³ In particular, IQVIA, a world leader in healthcare data analysis, completed a study that showed a marked decline in new drug launches in Canada in 2019 (see Appendix A for more details).

Moreover, this will weaken the biopharmaceutical sector, which is a key component of the health sciences innovation chain. As a result, a negative impact on Quebec's entire health sciences innovation chain, which includes research institutes, research hospitals, contract research organizations, and clinical trial centres, is to be expected.

We are especially concerned that this reform comes at a critical stage for the healthcare system and for Quebec's economy, which are currently affected by the health crisis. At a time when we need new vaccines and drugs to fight COVID-19, we cannot afford to implement new measures that may impact and compromise Quebecers' health. Furthermore, the new proposed measures create unnecessary additional uncertainty for the industry's research institutes and companies, which are already struggling with issues caused by the COVID-19 pandemic.

² Research conducted by IQVIA, New Medicine Launches: Canada in a Global Context, June 2020: https://lifesciencesontario.ca/wp-content/uploads/2020/06/FR_LSO_Global-Launch-Benchmarking_Webinar-June22-20_Final.pdf

³ Rawson N., Clinical Trials in Canada Decrease: A Sign of Uncertainty Regarding Changes to the PMPRB, Canadian Health Policy, April 2020: https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada-decrease--a-sign-of-uncertainty-regarding-changes-to-the-pmprb-.html?buy_type=

Quebec has already implemented effective processes to control its drug spending, which include an assessment body (the Institut national d'excellence en santé et en services sociaux). The province also generates substantial savings by negotiating directly with manufacturers, notably through the pan-Canadian Pharmaceutical Alliance. These negotiated agreements⁴ allowed Quebec to save more than \$400 million in 2019. They provide the flexibility needed to meet the province's and its patients' specific needs.

The new federal measures also run counter to the goal of growing Quebec's economy by making it a destination of choice for global investment. They threaten the objective of the Quebec Life Sciences Strategy, which is to make Quebec one of the five North American life sciences hubs by 2027.⁵

We are not the only ones apprehensive about the effects of this federal reform. Several other Quebec stakeholders⁶ have expressed concerns about the new measures, including the Quebec government,⁷ patient groups such as the Alliance des patients pour la santé and the Quebec Cancer Coalition, and research organizations such as CATALIS and Q-CROC, to name a few. Mélanie Bourassa Forcier, a Quebec health policy expert who is now Vice-Chairperson of the PMPRB, also supported an informed discussion on this issue, noting that "...these issues alone justify that the PMPRB reform be done in a broader, more transparent, better-documented context and, most importantly, that our provincial representatives have a greater say in the matter."⁸

With this in mind, we request that the PMPRB review its approach to better address the sector's concerns. We are arguing for a more balanced approach which is developed in collaboration with the industry's stakeholders, so that Quebec patients can benefit from quick access to innovative medicines and that our research ecosystem can continue to grow and contribute to the province's prosperity and health in the post-pandemic world.

⁴ RAMQ, 2018-2019 annual management report:

<http://www.ramq.gouv.qc.ca/SiteCollectionDocuments/citoyens/fr/rapports/rappann1819.pdf> (in French only); and Ministry of Health and Social Services 2018-2019 annual report: https://cdn-contenu.quebec.ca/cdn-contenu/adm/min/sante-services-sociaux/publications-adm/rapport-annuel-de-gestion/RA_19-102-01W_MSSS.pdf (in French only)

⁵ Quebec Life Sciences Strategy: <https://www.quebec.ca/gouv/ministere/economie/publications/strategie-quebecoise-des-sciences-de-la-vie-2017-2027/>

⁶ See: <http://www.pdci.ca/sharing-responses/>; also see the PMPRB draft guideline consultation:

<https://www.canada.ca/fr/examen-prix-medicaments-brevetes/services/consultations/lignes-directrices-provisoires/lignes-directrices-provisoires-2019.html>

⁷ Global News, Ontario and Quebec argued against federal plan to reduce drug prices, documents show, July 30, 2019: <https://globalnews.ca/news/5703652/federal-drug-price-regulations-provinces/>

⁸ Mélanie Bourassa Forcier, Conseil d'examen du prix des médicaments brevetés – Un organisme d'une efficacité discutabile, La Presse, February 2018: https://plus.lapresse.ca/screens/18c4fb77-a728-43c7-b821-a1d3519dd703_7C_0.html

Sincerely,



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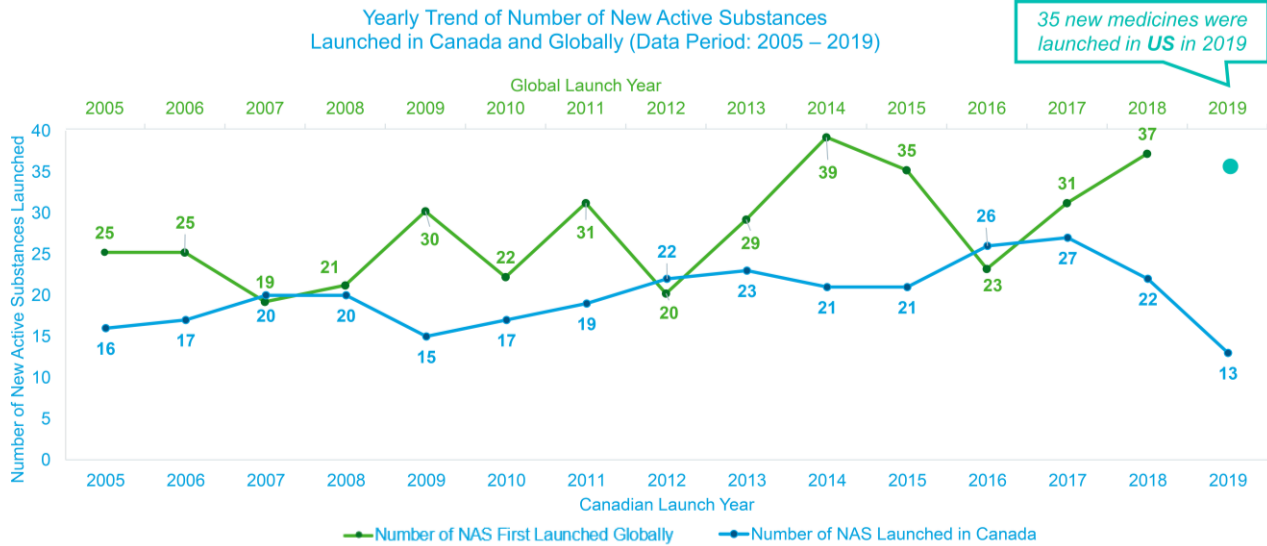


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cc. The Honourable Navdeep Bains, Minister of Innovation, Science and Industry
The Honourable Patty Hajdu, Minister of Health
The Honourable Pablo Rodriguez, Leader of the Government in the House of Commons and
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The Honourable Pierre Fitzgibbon, Minister of Economy and Innovation
The Honourable Christian Dubé, Minister of Health and Social Services

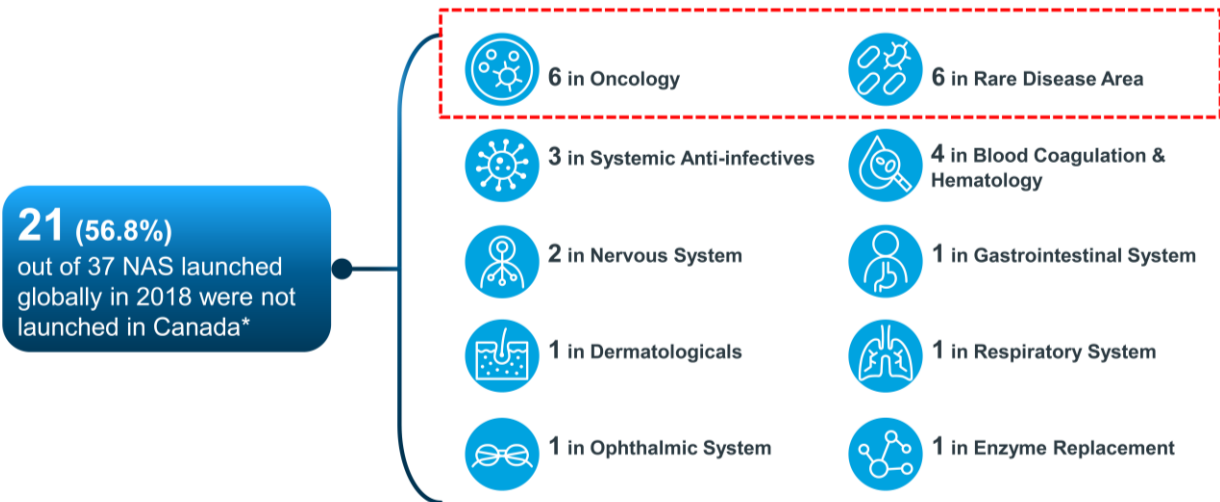
Appendix A: Study on the Launch of Medicines in Canada⁹

Globally, we see a different trend, with global launches on the rise



IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

Among 37 new medicines launched globally in 2018, over half of them were not launched in Canada, the majority of those were in oncology and rare diseases



* NAS from all therapeutic areas were grouped into the "Rare Disease Area" group according to FDA news release. Therefore, NAS in rare disease area were double counted in the "Rare Disease Area" group as well as corresponding therapeutic areas.

1 NAS was grouped into "Others" and not listed here.

IQVIA MIDAS® Database, all new launches within Jan 1, 2000 – Dec 31, 2019 (Data extracted on Mar 13, 2020). Top 25 countries based on 2019 sales. Austria and Sweden were excluded due to launch data quality. NAS: New active substance

⁹ Research conducted by IQVIA, Launch of New Medicines: Canada in a Global Context, June 2020, pp. 14-15: https://lifesciencesontario.ca/wp-content/uploads/2020/06/EN_LSO_Global-Launch-Benchmarking_Webinar-June22-20_Final.pdf