

November 6, 2020

Standing Committee on Health
131 Queen Street, 6th Floor
House of Commons
Ottawa, ON K1A 0A6
Canada

Members of the Committee:

Subject: Submission of BIOQuébec, Québec International and Montréal InVivo to the Standing Committee on Health for its study of the PMPRB

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

We welcome the Committee's interest in undertaking a study on reform of the Patented Medicine Prices Review Board (PMPRB), and we greatly appreciate the opportunity to share our views for this study.

First, we would like to point out that the life sciences and health technologies sector in Quebec includes more than 660 companies providing more than 32,000 high-quality jobs in Quebec, with an average salary of more than \$70,000.¹ This sector is one of the most important pillars of the Quebec economy, and it alone invests billions of dollars in research

¹ Deloitte study on public policy and funding requirements for the biotechnology industry (Étude sur les besoins en politiques publiques et en financement pour les industries de la biotechnologie et des ORC appliquées à la santé humaine et animale), carried out for BIOQuébec, 2019: https://static1.squarespace.com/static/57c496ac6b8f5bb965c464d3/t/5dbaef8698044146cbee3c5b/1572532107031/BI+OQuebec+EtudePolitiquesPubliquesEtFinancement_SOMMAIRE+EXECUTIF+FINAL.pdf. The data cited are from the 2018 census of life sciences firms conducted by the Quebec Department of Economy and Innovation, <https://www.economie.gouv.qc.ca/bibliotheques/secteurs/sciences-de-la-vie/recensement-des-entreprises-2018/>, and from Montréal InVivo's study on the competitiveness of Quebec's life sciences and health technologies (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) (2014 data). See also <https://www.montreal-invivo.com/secteurs/portrait-sectoriel/>.

and development in the province. Quebec also has a large share of the Canadian head offices of companies operating in this sector. In fact, the Quebec government is counting on this sector, including the research ecosystem, to drive the province's economic recovery following the COVID-19 pandemic.

We are very concerned about the PMPRB's new tariff regime and the impact it will have on Quebec patients, the health system, investments in health research, and our economy, in view of how important the life sciences sector is to Quebec.

In particular, the high level of uncertainty created by the reform of the PMPRB could delay and limit Quebecers' access to the most innovative drugs and hamper health investment, including investment in clinical and pre-clinical research, which is of great concern to us. It is virtually impossible for biopharmaceutical companies to predict what price they will be able to get for their products before they are launched on the Canadian market. As a result, it is very difficult for those companies to make a convincing business case at their international head office to give priority to the Quebec and Canadian markets for the launch of new drugs and vaccines.

What our three organizations are seeing on the ground and what is confirmed by recent data is that the new federal measures have already begun to significantly reduce the number of new drug launches in Canada² as well as clinical trial activity.³ In particular, IQVIA, a leader in health data analytics, has carried out a study that shows a marked decline in new drug launches in Canada in 2019 (see Appendix A of this document for more details).

Moreover, weakening the biopharmaceutical sector, which is a key link in the health sciences innovation chain, is expected to have adverse impacts on the entire chain in Quebec, including research institutes, teaching hospitals, contract research organizations, and clinical trial centres.

We are especially concerned that this reform comes at a critical time for the health care system and for the Quebec economy due to 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 have an uncertain impact and could compromise the health of Quebecers. In addition, the new federal measures create unnecessary additional uncertainty for industry and research institutes, which are already struggling with the COVID-19 crisis.

² Research study by IQVIA, New Medicine Launches: Canada in a Global Context, June 2020: https://lifesciencesontario.ca/wp-content/uploads/2020/06/EN_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>

Moreover, Quebec already has effective processes in place to control its drug budget, including an evaluation body, the Institut national d'excellence en santé et en services sociaux (INESSS). Quebec also achieves substantial savings by conducting negotiations directly with manufacturers, notably through the pan-Canadian Pharmaceutical Alliance. In 2019-2020, Quebec saved more than \$600 million with negotiated agreements.⁴ Those negotiations provide the flexibility to meet the specific needs of patients and the province.

In addition, the new federal measures work against the goal of making Quebec a destination of choice for global investment to grow its economy. They threaten the goal of the Québec Life Sciences Strategy, which is to make Quebec one of North America's top five life science hubs by 2027.⁵

We are not the only ones concerned about the effects of the federal reform. Several other stakeholders in Quebec⁶ have expressed concern about the new measures, including the Government of Quebec,⁷ patient groups such as the Alliance des patients pour la santé, the Coalition priorité cancer au Québec and the Regroupement québécois des maladies orphelines, and research organizations such as Catalis Recherche clinique Québec, Q-CROC and CQDM, to name only a few. Mélanie Bourassa Forcier, a Quebec health policy expert, now Vice-Chairperson of the PMPRB and Assistant Commissioner (Ethics and Regulation), Quebec Health and Welfare, also advocated an informed discussion on this issue, noting that “these questions alone are reason for ensuring that the reform of the PMPRB takes place in a

⁴ RAMQ, 2019-2020 annual management report, p. 137:

<https://www.ramq.gouv.qc.ca/sites/default/files/documents/rapport-annuel-2019-2020.pdf>; and Department of Health and Social Services, 2019-2020 annual management report, p. 74: https://cdn-contentu.quebec.ca/cdn-contentu/adm/min/sante-services-sociaux/publications-adm/rapport-annuel-de-gestion/RA_20-102-01W_MSSS.pdf?1601562204

⁵ Québec Life Sciences Strategy:

<https://www.quebec.ca/en/government/ministere/economie/publications/2017-2027-quebec-life-sciences-strategy/>

⁶ See <http://www.pdci.ca/sharing-responses/>; see also the consultations on the PMPRB's Draft Guidelines <https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines/draft-guidelines-2019.html> and <https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/draft-guidelines.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/>

broader, more transparent, better documented context, and most of all, it is important for our provincial representatives to have a greater say in this matter” [translation].⁸

With this in mind, we would like the federal government to review its approach to better address the sector’s concerns. Ultimately, we are arguing for a more balanced approach developed in collaboration with the various stakeholders, so that Quebec patients can benefit from rapid access to innovative medicines and so that our research ecosystem can continue to grow and contribute to the province’s prosperity and health in the post-pandemic world.

In closing, we thank you for taking the time to study this important issue, and we hope our submission will help inform your discussions and recommendations in this study. Please do not hesitate to contact us if you would like more information.

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

Yours sincerely,



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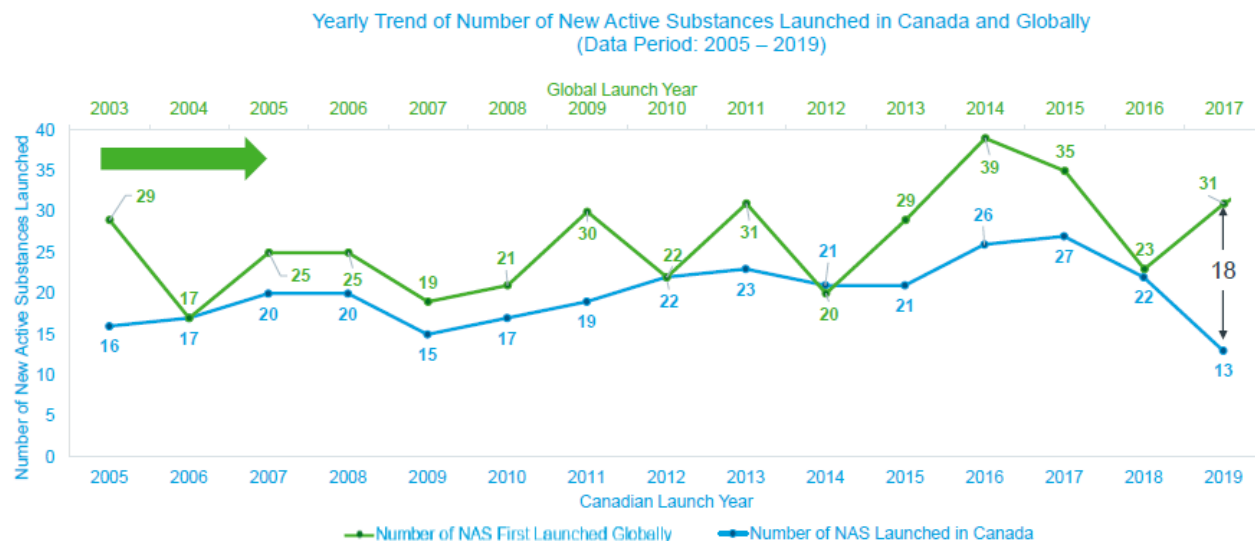
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Appendix A: Study on the Launch of Medicines in Canada⁹

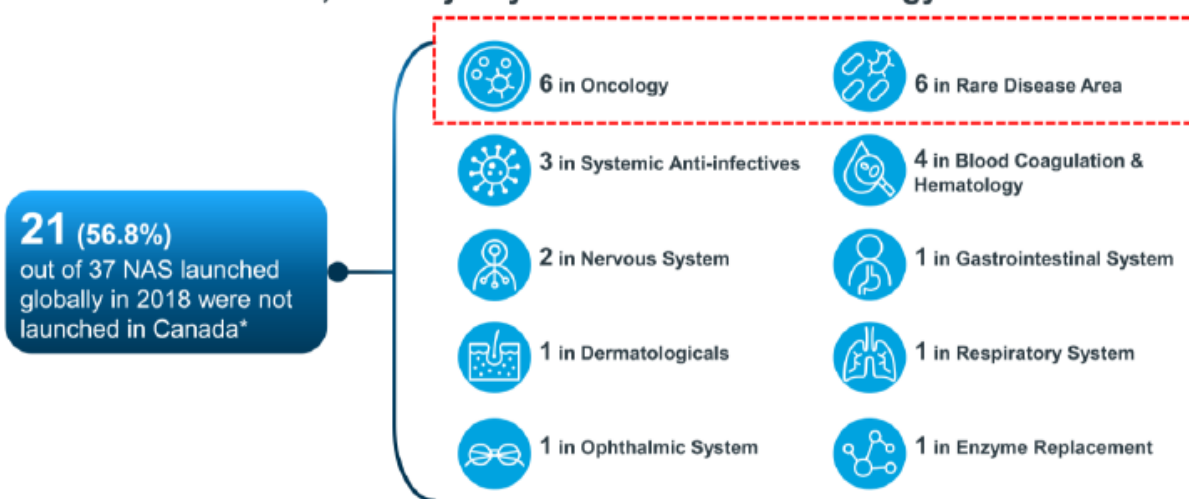
By directly comparing Canadian launches with global launches from 2 years past, the correlation, and drop in 2019, becomes far more apparent



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
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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 study by IQVIA, New Medicine Launches: 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