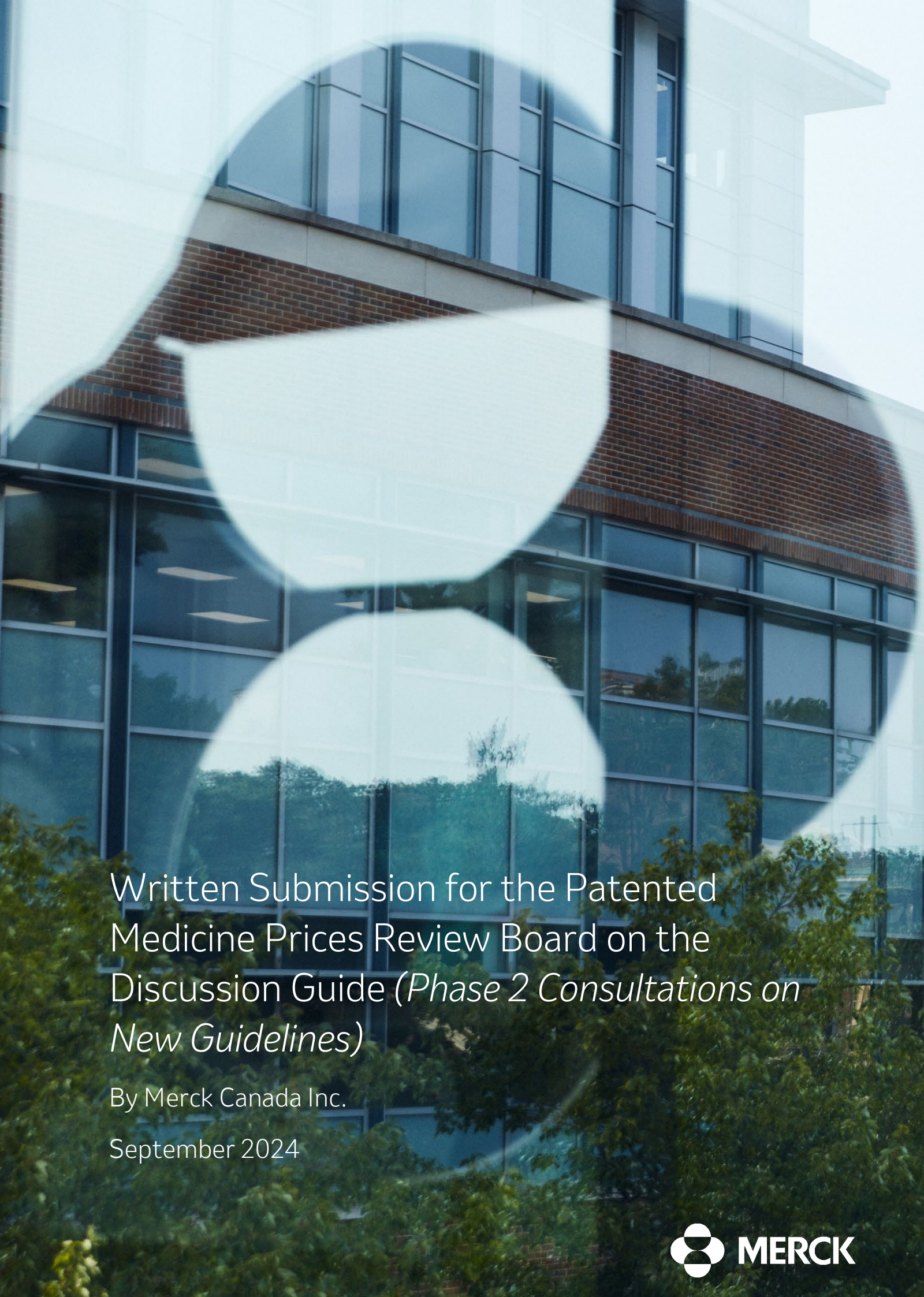

Written Submission for the Patented Medicine Prices Review Board on the Discussion Guide *(Phase 2 Consultations on New Guidelines)*

By Merck Canada Inc.

September 2024

MERCK

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MERCK

On behalf of Merck Canada Inc. (Merck), thank you for the opportunity to provide comments on the Patented Medicine Prices Review Board's (PMPRB's) Discussion Guide released in the context of Phase 2 of the consultations on new guidelines.

Our submission aims to complement those made by our industry associations, Innovative Medicines Canada and BIOTECanada.

Summary of Recommendations

1. Adopt the Highest International Price (HIP), which is aligned with the PMPRB's legal mandate
2. No re-benching of medicines to provide a more predictable pricing framework
3. Full grandfathering of "existing medicines" to avoid significant market disruptions
4. More predictability and transparency required for in-depth reviews
5. Implement a complaints-based approach for vaccines to enhance administrative efficiency
6. Implement a complaints-based approach for Antimicrobial Resistance (AMR) medicines to help address public health threats
7. Maintain existing methodology for Consumer Price Index (CPI) increases to ensure consistency
8. Restrict complaints to support market stability
9. Conduct real and meaningful consultations with the industry, including through the establishment of technical working groups

Rationale for Recommendations

1. Adopt the HIP

The HIP is the only pricing threshold that aligns with the PMPRB's legal mandate, which the courts have confirmed is restricted to assessing whether drug prices are excessive as a function of patent abuse.[1]

By definition, a price can only be deemed excessive if it is higher than the HIP, particularly given the new composition of the basket of countries (i.e., the PMPRB11). These countries were specifically chosen because they regulate the price of medicines, which means that the price of a medicine in any of these countries cannot be considered excessive.
Price levels lower than HIP, such as the Median International Price (MIP) and the midpoint between the MIP and the HIP, fall outside of the jurisdiction of the PMPRB and would be deemed unconstitutional based on court rulings.[2] These benchmarks are arbitrary and would significantly constrain drug pricing, effectively imposing price controls, which is inconsistent with the PMPRB's legal mandate.

Further, using the MIP or the midpoint test would impose a significant administrative burden, which goes against the Board's stated goal of enhancing administrative efficiency, as outlined in the Discussion Guide. The guide highlights that in 2023, 53% of patented medicines had a list price higher that the midpoint level and 78% of them had a list price above the MIP.[3]

Finally, pricing assessments should only occur when there are prices available in a least five countries or three years have passed since the medicine's introduction on the market. Conducting assessments based on the price from only two countries, as proposed in the Discussion Guide, could delay the introduction of medicines in Canada. In this case, manufacturers could decide to wait to launch their products in Canada until more international pricing data is available.

2. No re-benching of medicines

The PMPRB should not re-bench medicines in cases where the list prices do not increase above the CPI. There should only be an initial price review at launch of medicines when there is PMPRB11 data in five countries or three years have passed, and prices should subsequently be only monitored against the CPI.

A non-excessive price cannot later become excessive simply by the application of a new threshold. The PMPRB's role is not to bring down prices over time, as this would be akin to imposing price controls, which is inconsistent with its mandate of preventing patent abuse.

A competitive and strong pharmaceutical market requires long-term stability and predictability regarding how drug prices can be set. However, the reassessment of prices on an annual basis would create significant uncertainty for innovators as well as other key stakeholders in pharmaceutical ecosystem. This could also involve continuous renegotiation or adjustments of product listing, distribution and dispensing agreements, imposing an excessive administrative burden on provincial governments, insurers, pharmacies and distributors.

Re-benching prices would therefore go against the Board's objective in the Discussion Guide of providing "transparency and predictability to Rights Holders regarding the process typically engaged in by PMPRB staff ("Staff") in identifying patented medicine that may be at a greater risk for excessive pricing for an in-depth review or a potential hearing" and the Board's statement that it "believes that transparent, predictable, and procedurally fair Guidelines provide and efficient way for rights-holders to manage risk".[4]

3. Full grandfathering of "existing medicines"

Existing medicines (i.e., those with an NOC issued before July 1, 2022) that were not considered excessively priced under the previous pricing framework should not suddenly be deemed excessive due to changes in that framework. As mentioned earlier, once a product has been evaluated for excessive pricing, no further adjustments are necessary unless the manufacturer raises the price above the CPI. Lowering the pricing thresholds for existing medicines solely because of the introduction of a new framework would be arbitrary and amount to price control.[5]

Changing price thresholds for existing medicines would also create significant market instability. If the HIP is chosen as the new threshold, 61% of existing medicines' Drug Identification Numbers (DINs) would be subject to in-depth reviews. This figure rises to 82% if the Median International Price (MIP) is used.

Pharmaceutical companies have developed their business plans and financial forecasts based on the framework in place at the time these medicines were launched, with the reasonable expectation that the rules would remain relatively stable. Operating effectively in a constantly changing pricing regulatory environment is not feasible; companies require predictability and stability for optimal operation and long-term planning. This need for predictability is in fact explicitly recognized by the Board in the Discussion Guide.[6]

In addition, changing price thresholds for existing medicines would disrupt the entire pharmaceutical ecosystem. Pharmaceutical companies, governments, insurers, pharmacies, and distributors would be forced to implement widespread price changes simultaneously within a limited timeframe. This across-the-board adjustment for all existing medicines could lead to significant operational challenges and negatively impact the procurement and distribution of medicines.

Existing medicines should therefore be grandfathered and only subject to review if their prices exceed the allowable CPI increase.

4. More predictability and transparency required for in-depth reviews

The new pricing regime should be based on predictable pricing benchmarks to ensure that rights holders are provided with sufficient clarity on how to appropriately price their medicines. However, the currently proposed regime falls short of this objective. It relies on a more opaque and highly discretionary process where the PMPRB staff would conduct "in-depth reviews" in which it would consider multiple price factors across different product scenarios or case studies.

The Discussion Guide provides very limited details on how these reviews would be conducted. The guide indicates that the staff would identify and determine the relevance of comparators but does not outline a clear and transparent process for doing so. Additionally, there is concern that the PMPRB staff may lack the necessary clinical expertise to execute this work effectively.

Further, Merck is not currently able to provide input on the issue of similarity of comparators for the Therapeutic Class Comparison (TCC) and the role of the Human Drug Advisory Panel (HDAP), which hinges on the reviews of comparators. These complex issues require a more substantive dialogue between the PMPRB and the industry through the creation of technical working groups. Such groups should include pricing experts from the sector to carefully consider how these tests would work in practice, looking at a range of case studies.

Further, in-depth reviews should not lead to setting price levels below the International Price Comparison (IPC) with allowances for annual increases aligned with the CPI. If it is determined that a price above this threshold is excessive, excessive revenues should be calculated based on this threshold rather than on a further ratcheted down price below this level, as this would amount to price control. Under this scenario, rights holders should be allowed to submit a Voluntary Compliance Undertaking (VCU) to reduce the price below the level of IPC and CPI adjustments.

5. Adopt a complaints-based approach for vaccines

Most vaccines are subject to an established and well-functioning vaccine recommendation and reimbursement mechanism through the National Advisory Committee on Immunization (NACI) and centralized procurement via the federal government on behalf of the provinces and territories. This process includes competitive tenders and price negotiations and also factors in important considerations related to the procurement of vaccines such as the predictability of supply. In the minority of cases where vaccines are procured individually by Canadians, they are subject to standard market pressures like consumer products because

of the high price elasticity of demand. In the very rare instances of potential abuse of market exclusivity, complaints to the PMPRB would address any issues.

Given this comprehensive public health procurement system and the very low risk of excessive pricing for vaccines, the PMPRB should only assess the prices of vaccines if a complaint has been filed. Adopting this approach will ensure that the PMPRB does not impede Canadians' access to new and existing vaccines due to additional unnecessary price assessments. It will also help achieve the Board's goal of enhanced administrative efficiency as stated in its Discussion Guide.

6. Implement a complaints-based approach for AMR medicines

Anti-microbial resistance (AMR) poses a significant challenge to Canadian hospitals, the health of hospitalized patients, and the economy. In 2018, around 26% of infections were resistant to first-line antimicrobials, and this resistance is projected to increase to 40% by 2050.[7]

Despite the substantial threat that AMR presents, there are very few new medicines being developed and commercialized in Canada to combat this issue. Merck is among the few large pharmaceutical companies that continue to invest in R&D for medicines targeting bacterial infections.

To strengthen the Canadian market and revitalize the pipeline for AMR medicines, incentives are urgently needed. In light of this, we urge the PMPRB to adopt a more flexible approach to these medicines to ensure they can be rapidly introduced in the Canadian market, helping to address one of the most pressing global public health threats. Specifically, we recommend implementing a complaints-based approach for these critically needed therapies.

7. Maintain existing methodology for CPI increases

The PMPRB must consider each subsection 85(1) factor and cannot ignore any one factor in the context of an investigation.[8] Given that the CPI is one of the factors in subsection 85(1) of the *Patent Act*, rights holders should always be permitted to take CPI increases, as they always have since the inception of the PMPRB. CPI should be calculated based on Option 2 proposed in the Discussion Guide and the PMPRB should maintain the lagged CPI methodology for consistency and efficiency in processes.

8. Restrict complaints

Under the new pricing framework, clear benchmarking rules should be favored, as they provide a more objective and consistent basis for setting prices. Benchmarking ensures that prices are aligned in a more fair and transparent way, reducing the need for arbitrary price adjustments based on subjective perspectives.

Complaints should therefore be restricted and assessed against the clear benchmarks outlined in the new Guidelines, such as the IPC with permitted CPI increases. In particular, eligibility of complaints should be limited to the federal/provincial/territorial health ministers.

Adopting a more restricted complaints process is essential as frequent and unchecked complaints can create significant uncertainty in the market, undermining the pricing rules that are understood and followed by rights holders. When complaints are allowed without clear limitations, they can disrupt the stability and predictability of the market, causing confusion and eroding trust in the system for rights holders.

9. Conduct real and meaningful consultations with the industry

The PMPRB needs to engage more iteratively and meaningfully with the industry, including by establishing technical working groups, which were standard practice for reviewing proposed Guideline amendments before 2016.

Working groups would lead to better outcomes and help avoid unintended consequences, such as delays in access to medicines. Canadians already wait more than twice as long as their peers in the European Union and the United States to access new medicines.[9] The PMPRB should therefore avoid new rules that would create additional barriers to patient access to medicines.

Working groups would also help develop clearer and more understandable rules, allowing rights holders to more easily comply with a new price review regime and promoting a more efficient system.

In particular, many aspects of the Discussion Guide, such as in-depth reviews, necessitate a more thorough dialogue and exchange between the PMPRB and the industry. A more in-depth engagement is essential to fully understand the impact of the proposed changes and to implement a regime that is practical and effective.

However, despite repeated requests from the industry for the PMPRB to establish working groups to discuss the more technical aspects of the new Guidelines, there has been no action to date to set these up or indication of any plans to do so. As well, Merck, along with its industry associations, submitted several specific questions at the PMPRB's request to be answered in the context of its August 13th webinar. However, these questions have yet to be addressed by the PMPRB.

We thank you for the opportunity to provide comments on the Discussion Guide and look forward to more in-depth and iterative engagement with the PMPRB as the new Guidelines are developed.

References

[1] *Merck Canada Inc. et al* v. *Canada (Attorney General) et al*, Quebec Court of Appeal, decision rendered Feb. 18, 2022: https://www.canlii.org/en/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?autocompleteStr=2022%20QCCA%20240%20&autocompletePos=1; *Alexion Pharmaceuticals* v. *Canada (Attorney General)*, 2021 FCA 157: https://decisions.fca-caf.gc.ca/fca-caf/decisions/en/item/500849/index.do

[2] *Ibid* at paragraph 49.

[3] See p. 18 of the Discussion Guide : https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/discussion-guide-phase2.html

[4] See p. 4 of the Discussion Guide : https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/discussion-guide-phase2.html

[5] See paragraph 146 of Merck Canada Inc. et al v. Canada (Attorney General) et al, Quebec Court of Appeal, decision rendered Feb. 18, 2022: https://www.canlii.org/en/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?autocompleteStr=2022%20QCCA%20240%20&autocompletePos=1

[6] See p. 4 of the Discussion Guide : https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/discussion-guide-phase2.html

[7] Council of Canadian Academies, When Antibiotics Fail: The Expert Panel on the Potential Socio-Economic Impacts of Antimicrobial Resistance in Canada, Ottawa, 2019: https://cca-reports.ca/reports/the-potential-socio-economic-impacts-of-antimicrobial-resistance-in-canada/

[8] See, for example, paragraph 120 of Innovative Medicines Canada v Canada (AG), 2020 FC 725, decision rendered June 29, 2020: https://www.canlii.org/en/ca/fct/doc/2020/2020fc725/2020fc725.html?autocompleteStr=2020%20FC%20725%20&autocompletePos=1, and paragraph 47 of Teva Neuroscience GP v Canada (AG), 2009 FC 1155, decision rendered November 12, 2009: https://www.canlii.org/en/ca/fct/doc/2009/2009fc1155/2009fc1155.html?resultIndex=1

[9] Waiting for new medicines in Canada, Europe, and the United States 2018-2023, Canadian Health Policy Institute, Charts 6 & 7, 2024: https://www.canadianhealthpolicy.com/product/waiting-for-new-medicines-in-canada-europe-and-the-united-states-2018-2023/

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to save and improve lives around the world

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About Merck Canada Inc.

We Use the Power of Leading-Edge Science to Save and Improve Lives

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Merck is a global biopharmaceutical company with a diversified portfolio of prescription medicines and vaccines. Present in 70+ countries globally, Merck has been well-established in Canada since 1911.

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Merck is committed to supporting Canada as a destination for research, investment, and clinical trials – activities that promote Canada's economy and international competitiveness. As one of the top R&D investors in Canada, Merck is currently investing in over 190 clinical trials involving 500+ research sites and 3,000+ patients across Canada.

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190+
Clinical trials
across Canada

600+
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in high-skilled jobs

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Vaccines

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We also play an important role in discovering and developing innovative medicines to treat and prevent infectious diseases.