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July 15, 2022

Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Subject: Merck Canada input on PMPRB's June 30, 2022 Notice and Comment on the proposed pricing review approach during the interim period

Dear PMPRB,

On behalf of Merck Canada Inc. (Merck), thank you for the opportunity to provide comments on the PMPRB's proposed pricing review approach during the interim period following the publication of the amendments to the *Patented Medicines Regulations*. Our submission aims to complement those made by our industry associations, Innovative Medicines Canada and BIOTECanada.

While we are encouraged by the PMPRB's proposal to apply a status quo approach during the interim period, we recommend in this submission additional measures to ensure a complete status quo approach is implemented and to avoid detrimental effects on access to new medicines and the life sciences sector. As well, we propose key considerations to help guide the PMPRB as it develops its new guidelines to operationalize the revised basket of countries.

1. Already-marketed medicines

Merck is pleased that the PMPRB proposes a status quo approach (i.e., applying the current non-excessive average price or NEAP) for medicines that are already marketed.

We recommend that this approach be maintained even once the new pricing guidelines are in effect. Companies need predictability and stability to operate optimally and guide their long-term planning. Further, changes to the way already-market medicines are priced would undercut a broad section of the health system, including drug developers, generics, pharmacists, pharmacies, distributers and wholesalers. This disruption could increase the risks of drug shortages at a very critical time for our health system. As well, there is no evidence that currently-marketed medicines are abusing patent monopolies or engaging in excessive pricing that would warrant reconsideration of their maximum list prices (MLP). Finally, for existing products under investigation, once that investigation is closed using the 2017 guidelines, we suggest that the same grandfathering approach apply to these products.

2. Medicines launched during the interim period

Merck is concerned about the lack of clarity and certainty regarding medicines launched between July 1, 2022 and the finalization of the new guidelines. Under the PMPRB's proposed approach,

pharmaceutical companies would have to launch these medicines at risk, as there is no visibility on what will be considered a non-excessive ceiling price under the new regime.

This uncertainty could deter companies from launching new medicines in Canada or delay these launches. As outlined further below, a recent study undertaken by IQVIA shows that Canada is already falling behind comparable countries when it comes to drug launches. The PMPRB should therefore avoid implementing an approach that further exacerbates this challenge.

Merck recommends that the MLP for these medicines be determined in a way that is consistent with the *Patent Act* and the previous guidelines. If so, the price should be deemed compliant with these guidelines and grandfathered from the application of the new guidelines. No excess revenues should be collected retrospectively for these medicines.

In sum, to avoid deterring or delaying launches of new medicines during the interim period, **the PMPRB should clearly commit to:**

- **not apply the new guidelines retroactively to these medicines**
- **not require payment of excessive revenues for these medicines during the interim period.**

3. Consumer Price Index

The PMPRB's June 30, 2022 Notice and Comment specifies that one of the requirements to avoid investigations of already marketed products is no list price increase during the interim period. In practice, this approach would lead to *de facto* price reductions during the interim period, especially given the current inflationary environment.

Changes in the Consumer Price Index (CPI) is one of the factors outlined in the *Patent Act* that needs to be **maintained under the new PMPRB pricing regime**. No rationale has been provided by the PMPRB for diverting from the current practice and the criteria set out in the *Patent Act*. Specifically, we ask that the PMPRB clarify that MLP of patented medicines will be allowed to increase based on CPI for the January to December 2023 reporting period.

4. Key considerations for the development of new guidelines

Merck remains concerned about the changes to the basket of countries and the impact that this will have on drug launches, drug supply, research investments in this country and on ongoing federal and provincial pharmaceutical strategies and initiatives.

As such, we recommend that the following principles guide the PMPRB in the development of its new guidelines:

- **Respecting PMPRB's mandate:** Recent court decisions have clearly confirmed that the PMPRB's mandate is restricted to ensuring patented medicines are not excessively priced as a function of patent abuse and does not extend to price control or consumer

protection.[1] The PMPRB's new guidelines and price tests used to determine MLPs of patented medicines will need to reflect this mandate. As well, Merck wants to highlight that it will continue to work with Canadian governments and private insurers to provide value to payers and patients and engage in responsible pricing of its medicines. Canadian governments already have access to much lower confidential prices through negotiations via the pan-Canadian Pharmaceutical Alliance (pCPA). Many private insurance companies also benefit from lower confidential prices through their own negotiation process.

- **Striking the right balance:** It will be important for the PMPRB to strike the appropriate balance between ensuring patented medicines are not excessively priced and supporting innovation and our health system. In fact, the Regulatory Impact Analysis Statement (RIAS) accompanying the regulatory amendments expressly references ongoing federal initiatives, including the Biomanufacturing and Life Sciences Strategy and the national rare disease strategy, as part of the rationale for making the changes. It expressly states that "the Government is now moving ahead with a suite of initiatives related to improving access to quality medicines and ensuring the sustainability of the healthcare system, while supporting innovation and investment in the pharmaceutical sector" *[emphasis added]*.[2] In this context, we want to stress that pricing guidelines that are too restrictive could lead to the following negative consequences:
    - **Delays in new medicine launches,** especially given that several US states are now looking at referencing Canadian prices. In this regard, recent research undertaken by IQVIA shows that the number of new drugs launched in Canada has declined significantly in recent years, which represents a departure from trends seen globally. Meanwhile, the median time to launch has more than doubled between 2020 and 2021 from 1 to 2.1 years.[3]
    - **Challenges in competing with other countries to attract international investments** to help grow the Canadian life sciences sector. Several other countries are stepping up with new measures and incentives to expand the life sciences sector and a regulatory approach to pricing that is too restrictive would hold Canada back compared to its peers and undermine efforts to rebuild our economy and health system. It would also undermine efforts across Canada, including by the federal government with the Biomanufacturing and Life Sciences Strategy, as well as Quebec and Ontario, which recently adopted and refreshed ambitious plans to attract increased investments to their jurisdictions.

[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/fr/qc/qcca/doc/2022/2022qcca240/2022qcca240.html?resultIndex=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] Regulatory Impact Analysis Statement, July 6, 2022, Canada Gazette Part II, Vol. 156, No. 14: https://www.gazette.gc.ca/rp-pr/p2/2022/2022-07-06/pdf/g2-15614.pdf

[3] https://lifesciencesontario.ca/is-canada-losing-its-status-as-a-priority-medicine-launch-country-preview_id6648preview_nonce0772186744previewtrue/

- **Undertaking meaningful consultations:** We are encouraged by the willingness of the federal government to engage more meaningfully with the pharmaceutical sector over the last few years to arrive at workable solutions, including in the context of the COVID-19 pandemic. We look forward to having the same constructive engagement with the PMPRB in the context of the upcoming consultations on the new pricing guidelines. In particular, it will be important for the PMPRB to set up working groups, involving pricing experts from the pharmaceutical sector, to carefully review how the pricing tests would work in practice in order to avoid unintended consequences. As part of this effort, we would strongly recommend that these working groups look at a range of case studies.

Finally, it will be important for the PMPRB to provide an appropriate transition period for the application of any updated guidelines. We recommend **a transition period of two reporting periods (i.e., 12 months)** from the date the new guidelines are finalized and issued by the PMPRB. This would be consistent with the PMPRB's previous commitment outlined in its Notice of April 16, 2021.[4] As stated above, companies need predictability and stability to operate optimally and guide their long-term planning, and this transition period would allow them the appropriate time to adjust their business plans to the new pricing guidelines.

We thank you for the opportunity to provide our comments. Please do not hesitate to contact me should you have any questions about this submission.

Sincerely,

Jennifer Chan
Vice President, Policy and Government Relations
Merck Canada Inc.

[4] https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/notice-comment-definition-gap/decision-definition-gap-medicines.html