INNOVATIVE MEDICINES CANADA CONSULTATION RESPONSE: PROPOSED GUIDELINE MONITORING AND EVALUATION PLAN

June 21, 2021

Innovative Medicines Canada (IMC) is the national association of 47 biopharmaceutical and vaccine companies who comprise the majority of patentees subject to the PMPRB's jurisdiction and are working steadfastly with Canadian governments to address the COVID-19 pandemic. Guided by a strict Code of Ethical Practices, we work with governments, insurance companies, healthcare professionals and stakeholders to advance the field and enhance the wellbeing of Canadians and are committed to being valued partners in Canada's healthcare system.

IMC member companies produce the vaccines, diagnostics, and medicines that are enabling Canada to emerge from the global COVID-19 pandemic that continues to have devastating impacts on the health and prosperity of Canadians. According to Statistics Canada, in 2018 the sector added almost $15 billion in value added (GDP) to the Canadian economy and supported over 100,000 full-time equivalent jobs within Canada. Additionally, it invested nearly $2.0 billion on research and development. This far exceeds PMPRB's assessment based on a 1987 *Income Tax Act* R&D definition.

We offer this submission in response to PMPRB's consultation on its proposed Guideline Monitoring and Evaluation Plan (GMEP). In our view this assessment discussion is premature given that a meaningful consultation on the underlying policy approach is still required.[i] Due to the severe anticipated impact of the pending PMPRB changes on timely patient access to new medicines and vaccines and the negative impact to Canada's domestic life science capacity, it is inappropriate to be moving forward with the controversial changes now, and only studying the impacts later through the GMEP.

Key Recommendations

1. Discontinue the regulatory changes until the pandemic has abated.

A suspension of the July 1st, 2021 scheduled implementation of changes to the PMPRB is needed to allow all parties to address the COVID-19 pandemic and to provide more time to discuss alternative PMPRB changes that will still meet government's policy objectives but not impact the timely launch of new medicines in Canada. The imposition of flawed and controversial policy changes during an international health crisis is inappropriate and unreasonable given the need for governments, industry, and other stakeholders to prioritize resources to address COVID-19. The government should delay the implementation of PMPRB changes until the COVID-19 pandemic has abated.

2. Due to two court rulings invalidating PMPRB access to confidential third-party rebates, PMPRB should clarify that that its "maximum rebated price" concept will be discontinued.

The PMPRB 2020 Guidelines are based on having access to *ultra vires* information. Without access to third-party payments, or "rebates", the PMPRB cannot implement its maximum "rebated" price (MRP) concept. As such, the PMPRB must propose and consult on substantially revised Guidelines.

The revised Guidelines should focus on predictable list price ceilings and international price referencing anchored to the principle that future Canadian prices should generally be at the median level of relevant and appropriate international prices. Furthermore, IMC notes that it is not possible to provide meaningful comment on an impact assessment plan when critical details of the policy itself still lack clarity, notably the role and use of the experimental new economic factors and MRP.

3. Replace the PMPRB-led Guideline Monitoring and Evaluation Plan with an independent assessment by an objective third-party to conduct the analysis at arms length.

Given the highly controversial nature of the reforms, any future assessment be conducted separately from the PMPRB by a party jointly determined by patentees and other stakeholders. The mandate, scope, terms of reference, and critically, any baseline metrics and assessment periods should also be independently determined. Data used in any impact assessment must be appropriately sourced, transparent, and available to all to validate. Recent reports in the media related to access to information requests by Canadian legislators have called into question the objectivity and neutrality of PMPRB consultation processes. Given the strong reaction to these reports, it is clear that many stakeholders will not perceive any evaluation plan developed and administered by PMPRB to assess the impact of its own Guidelines as a credible process.

4. Remove metrics which are beyond the PMPRB's jurisdiction.

The PMPRB does not have a mandate to study many of the metrics it has proposed, including clinical trial intensity, "health technology assessment, price negotiation and reimbursement", availability of new medicines, pharmaceutical ecosystem, economic footprint, etc. These metrics should be removed from the GMEP and future Annual Reports. These metrics could, however, be included in the reports conducted by a third-party assessment that is independent of the PMPRB, as noted above.

5. Limit PMPRB's data reporting information sources to those derived from regulatory filings.

PMPRB should discontinue spending on costly commercial databases (e.g., comparative pricing) as part of PMPRB Annual Reports or other possible GMEP outputs. These data sources cannot enable reliable international price comparisons. The PMPRB's presentation of these data present an erroneous view of pricing in the Canadian market and do not constitute a sufficient basis for regulatory purposes or to inform policy making. The PMPRB should limit its analysis to consider data it has through actual patentee regulatory filings. These data show that on average median international prices for patented products are 16% higher than Canadian prices and Canadian prices are increasing less than the rate of inflation, as measured by the Consumer Price Index (CPI).[ii]

6. Replace or supplement PMPRB's 1987 definition of R&D with the more comprehensive and credible Statistics Canada assessment.

PMPRB continues to employ and report using an outdated 1987 definition of pharmaceutical R&D, which does not capture the full extent of industry investments in Canada. The PMPRB and Health Canada have been made aware of this deficiency on numerous occasions yet continue to promote this reporting, which presents a misleading view of the biopharmaceutical industry's important and substantial economic contribution to Canada. In contrast, according to the most recent data from

Canada's official statistics agency, Statistics Canada, the sector generates almost $15 billion in economic activity, and approximately $2 billion annually in R&D spending. Based on this data, the industry has an R&D-to-sales ratio more than twice as high as that reported by the PMPRB. The PMPRB should request that Health Canada allow it to formally adopt Statistics Canada's reported R&D metrics, or at a minimum, cite this material in future Annual Reports.

In conclusion, we note that the innovative medicines and vaccines industry has called on the federal government to join the industry in a roundtable discussion about the path forward to an actionable national life sciences strategy that will build a more vibrant life sciences sector and enhance patients' access to new medicines and vaccines. Such a strategy must address critical issues like domestic manufacturing, a more streamlined review process, and a more balanced and predictable price regulatory system. This can be accomplished while addressing affordability and pharmaceutical system sustainability considerations. Our industry stands ready to collaborate with governments on changes to the PMPRB that will be less damaging to Canada's domestic life sciences capacity and timely access to medicines and vaccines for all Canadians.

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[i] IMC understands that the PMPRB intends to apply Guidelines within the framework of the amendments to the Patented Medicines Regulations, which are not yet in force. While IMC is committed to constructive engagement with the PMPRB on the Guidelines, IMC's engagement is not intended and should not be interpreted as supporting the amendments to the Regulations or the Guidelines. On June 29, 2020, the Federal Court of Canada declared that subsection 3(4) of the amended Regulations on the net price calculation is invalid, void, and of no force and effect for being ultra vires the *Patent Act*. On December 18, 2020, the Superior Court of Québec ruled that same amendment was unconstitutional. IMC continues to have grave concerns about the practicality and legality of the remaining amended Regulations as well as the PMPRB's Guidelines. IMC reserves the right to oppose any aspect of the amended Regulations or Guidelines that exceed the jurisdiction of the Board. It should also be noted that there are a number of Guidelines related issues that had been identified in previous IMC submissions that have not been addressed and would benefit from more transitional time and discussion (please see IMC's February 2020 and August 2020 submissions).

[ii] Source: PMPRB Annual Report 2019. PMPRB could, however, leverage Statistics Canada's R&D information as discussed in point 6, below.