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June 21, 2021

SUBMISSION FILED VIA ONLINE FEEDBACK FORM: https://www.canada.ca/en/patented-medicine-prices-review/services/consultations/consultation-guideline-monitoring-evaluation-plan.html#form

Attention: Patented Medicine Prices Review Board
Dr. Mitchell Levine, Chairperson of the Board

RE: Consultation on the Guideline Monitoring and Evaluation Plan (GMEP)

Dear Dr. Levine:

This submission is in response to the PMPRB's Consultation on the Guideline Monitoring and Evaluation Plan. In conjunction with this submission, AbbVie is supportive of the positions expressed by Innovative Medicines Canada (IMC) and BIOTECanada (BTC), two industry associations of which AbbVie is a member.

AbbVie is an innovation-driven, patient-focused specialty biopharmaceutical company. Our mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people's lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women's health, and gastroenterology. AbbVie is presently the 2nd largest biopharmaceutical company operating in Canada, and with the recent acquisition of Allergan, we are proud to employ nearly 1,000 employees. AbbVie has Canadian headquarters in Markham, Ontario, and Montreal, Quebec.

Discontinue the regulatory changes and better assess the anticipated impact

Before commenting further, AbbVie would like to make reference to the May 18th, 2021 letter addressed to Prime Minister Justin Trudeau (with copy to Minister of Health Patty Hajdu) which AbbVie co-signed along with our IMC co-members.[1] In that communication, we outlined that the collective priority of Canadian governments, our industry and other health stakeholders has been and must continue to be the fight against COVID-19, and we respectfully submitted that the rationale for suspending the July 2021 implementation of the regulations is the same as it was in December 2020. We would also like to highlight the May 31st, 2021 communication from Ontario's Minister of Health and Minister of Economic Development, Job Creation and Trade, to their federal ministerial counterparts, is also asking for a pause.[2] Finally, we are aware that on May 14th, 2021, the Attorney General of Quebec filed a brief with Quebec's Court of Appeal in the context of the litigation led by several pharmaceutical companies challenging the constitutionality of these regulations – submitting that the amendments should be struck down as they infringe on areas of provincial jurisdiction under the Constitution.[3] Given these critical concerns and ongoing legal disputes, we encourage the government to immediately suspend the July 2021 implementation of the PMPRB regulatory changes.

Remove the proposed areas of focus that are outside of the PMPRB mandate

The PMPRB has a dual mandate: in its regulatory role, it ensures that the prices of patented medicines are not excessive; in its reporting role, it provides information on pricing trends in the pharmaceutical industry.

[1] Innovative Medicines Canada. Letter to The Honourable Prime Minister. 18 May 2021.
[2] Deputy Premier and Minister of Health, and Minister of Economic Development, Job Creation and Trade, Government of Ontario. Letter to Minister of Health, and Minister of Innovation, Science and Industry, Government of Canada. 31 May 2021.
[3] La Presse. Québec s'oppose au « cheval de Troie » du gouvernement Trudeau. 21 May 2021. https://www.lapresse.ca/affaires/2021-05-21/prix-des-medicaments/quebec-s-oppose-au-cheval-de-troie-du-gouvernement-trudeau.php

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Meanwhile, the PMPRB is proposing a GMEP that will assess four key areas of focus: I) prices of medicines; II) access to medicines; III) the pharmaceutical ecosystem; and IV) PMPRB processes. On items II and III in particular, AbbVie respectfully submits that these areas are outside of the PMPRB's mandate and should not form part of the GMEP. One prime example demonstrating the PMPRB's lack of expertise in these areas can be seen in the GMEP consultation document, where the PMPRB incorrectly states: "There have been no material variations in recent years in the number of clinical trials and new medicines approved in Canada." In fact there is significant evidence to the contrary, with recent research in the *Canadian Health Policy Journal* pointing to a 26% decrease in the number of phase III/IV clinical trials in 2020 compared to 2015-2019.[4]

Mandate a third-party and independent evaluator to assess the impact of any future changes

The PMPRB should not "self-audit" its regulatory activities in order to maintain its integrity as a quasi-judicial body. The future evaluation of any PMPRB reform should only be conducted by an independent third party with expertise in program evaluation, and with input from an advisory panel composed of experts and key stakeholders. The mandate, scope, terms of reference, and any baseline metrics and assessment periods considered within the GMEP should also be independently determined. Additionally, key stakeholder input on the GMEP should be sought with sufficient time for the evaluator to review, consider, and integrate the feedback provided, which is unlikely in the current scenario where feedback is being sought just 10 days prior to the coming-into-force of the new regime.

In summary

While we appreciate the opportunity for consultation on this GMEP, we have serious concerns that it would inform policy decisions based on inaccurate reporting. Furthermore, AbbVie maintains that the PMPRB regulatory changes will have significant unintended negative consequences on patient access to the newest medicines and treatments, while also diverting R&D and investment away from Canada's life sciences sector. A suspension in the PMPRB's regulatory changes would provide the appropriate time and process to develop a comprehensive strategy to build a thriving life sciences sector in Canada.

We look forward to future opportunities to provide feedback to the PMPRB and will continue to engage in future consultation processes.

Sincerely,

Tracey Ramsay
Vice-President and General Manager
AbbVie Canada

[4] Rawson, Nigel. (2021). Clinical Trials in Canada: Worrying Signs that PMPRB Changes will Impact Research Investment. *Canadian Health Policy Journal*. https://www.canadianhealthpolicy.com/products/clinical-trials-in-canada--worrying-signs-that-pmprb-changes-will-impact-research-investment.html

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