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Eli Lilly Canada's Submission to the Patented Medicine Prices Review Board Re the Proposed Consequential Amendments to the January 1, 2021 Guidelines: Changes to the Definition of Gap Medicines and the Timeline for Compliance.

This document represents Eli Lilly Canada's (Lilly's) response to the Patented Medicine Prices Review Board's (PMPRB's) invitation for comment on the most recent proposed amendments to the Guidelines, namely the revised definition of Gap medicines and the shortened timeline of one six-month filing period for Grandfathered and Gap medicines to come into compliance.

Along with Innovation Medicines Canada (IMC) and BIOTECanada (BTC), Lilly supports the proposed definition of Gap medicines as those for which a DIN was assigned on or after August 21, 2019, and first sold in Canada prior to July 1, 2021. Further, in agreement with IMC and BTC, Lilly is opposed to the PMPRB's proposal to reduce the length of time to come into compliance from two six-month periods (i.e., twelve months) to one six-month period. Indeed, the shortening to six months is at odds with the stated intent of the Government of Canada to avoid "the imposition of new administrative burden on industry when it is facing increased demands related to supply chains and shortages in response to the COVID-19 pandemic."[1] The Canada Gazette[2] of December 29, 2020, goes further still, extending its lens beyond industry: "moving ahead too early would introduce new reporting obligations at a time when the COVID-19 pandemic continues to challenge *all stakeholders*" [emphasis added].

The Provinces and Provincial Jurisdiction

Most surely, the provincial governments are stakeholders of preeminent concern to the Government of Canada. The provinces have seconded many staff to COVID-19-related tasks, such as vaccines and ICU care, and have been forced to leave gaps in other areas of healthcare as they struggle to manage many policy and operational issues. As recently as mid-January, the province of Ontario declared a second emergency related to high numbers of COVID-19

[1] Canada Gazette, Part II, Volume 155, Number 2. Regulations amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), No 2: SOR/2020-298. Regulatory Impact Analysis Statement. December 29, 2020.
[2] Canada Gazette, ibid.

cases and the increasing presence of variants.[3] In the same period, Alberta announced the death of 55 patients and a total of 262 cases in a single nursing home.[4]

It is puzzling then, in a time of some chaos in the health system, that the PMPRB is causing undue pressure for industry by proposing to reduce the length of time for coming into compliance for thousands of patented medicines. Yet, the industry has worked with exceptional diligence to deliver vaccines and new treatments for COVID-19 with unprecedented speed. We believe that industry's efforts to do so should be supported.

Under the Constitution Act, 1867[5], the provinces hold authority for managing a broad swath of health care in Canada. In rendering a decision in the Quebec Superior Court on December 18, 2020[6], the Honorable Sophie Picard JS.C. was clear that the provinces do bear a formidable responsibility in that regard. She emphasized their power to legislate in relation to health, including issues of cost and efficiency, the administration of hospitals, provincial drug insurance plans, and the regulation or control of prices and profits. Importantly she questioned whether the PMPRB is necessary in directing public drug plans at all, given the tools the provinces have in place now (e.g., CADTH, pCPA) to achieve prices acceptable to them on their own. Therefore, given the challenges that the provinces are facing, and the potential for pricing issues to interfere with provincial responsibilities at a crucial time for health care, it seems appropriate for the PMPRB to maintain at least a 12-month transition period for Gap and Grandfathered drugs to come into compliance.

Practical Concerns

The visual depiction, immediately below, summarizes the operational and feasibility challenges inherent in attempting to meet a single six-month compliance period. In addition to patentees, these challenges cause significant burden and disruption to public payers, and a broader set of stakeholders along the supply chain. As the nexus amongst stakeholders, public payers face a weighty burden on their time, as they coordinate the change right through to PLAs, distributors, and pharmacies. And it is not their only task. This work falls most heavily on them when human resources are depleted by COVID-19. These stakeholders are the ones Health Canada saw the need for was concerned about in implementing a delay in the coming into force of the PMPRB Regulations. An extension for patentees to 12 months is not out-of-step with that approach.

[3] Ontario. Office of the Premier. Ontario Declares Second Provincial Emergency to Address COVID-19 Crisis and Save Lives. Toronto: January 12, 2021.
[4] Short D. COVID-19 outbreak at west Edmonton care home linked to 55 deaths and more than 200 total cases. Edmonton Journal. January 23, 2021.
[5] Sections 92(13), 92(16) and 92(7).
[6] Merck Canada Inc., Janssen Canada Inc., Servier Canada Inc., Boehringer Ingelheim (Canada) Ltd., Bayer Inc., Theratechnologies Inc., And Avir Pharma Inc v. Attorney General of Canada.

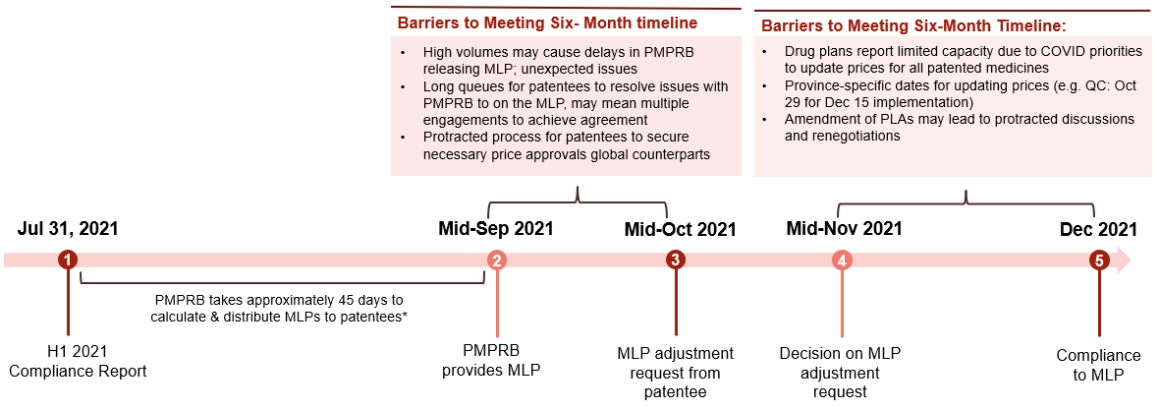

Figure 1. Potential Barriers to Meeting Six-Month Compliance Timeline. *Please note this is an estimate based on PMPRB's current timelines in providing NEAPs.

It is also important to consider that after the roughly 45-day period for the PMPRB to set a Maximum List Price (MLP), the window for manufacturers to come into compliance is actually closer to four months than six. Further, it is a matter of debate as to whether the PMPRB can meet the expected timeframe of 45 days for the very large number of DINs to be assessed. And it is reasonable to expect that manufacturers will need to engage with the PMPRB for clarity on the changes to the MLP. Many Canadian affiliates must engage with their global pricing teams for analytics and approvals, adding time to the process.

Summary

Lilly's position that the PMPRB abandon its proposal to shorten the timeline for coming into compliance from two six-month filing periods to one is aligned with the stated position of the Government of Canada that the changes to the PMPRB Regulations could cause unpredictable hardship for the pharmaceutical industry and other stakeholders "at a time when the COVID-19 pandemic continues." The same would apply to the PMPRB Guidelines. At the annual western meeting of the Canadian Association for Healthcare Reimbursement (CAHR), held on February 9th, 2021, the three Executive Directors of western provincial drug plans were unequivocal that COVID-19 continues to "keep them up at night", citing current drug shortages, vaccines, and secondment of staff to other areas as significant issues. One cited an additional 15 meetings per week just to manage the COVID file. To sum up, then, it appears prudent on all fronts to implement a twelve-month transition period for Grandfathered and Gap medicines.

Regards,

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