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Patented Medicine Prices Review Board
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BIOTECanada is providing written feedback on the PMPRB's proposed Guideline changes announced on July 15, 2021. BIOTECanada represents more than 240 member companies which include innovators at all stages of the product lifecycle from basic research and development to commercialization. Some member companies are patentees who report to the PMPRB, but many focus on early research and development in the hopes of bringing new therapies to patients and the health care system in the future, not just in Canada but globally. BIOTECanada's members include developers and manufacturers of vaccines and the latest technological advances to address unmet medical needs.

As federal and provincial governments look beyond the COVID-19 pandemic, they are identifying the existing gaps and a way forward which would fortify Canada's biotech ecosystem as a more holistic model. BIOTECanada has consistently called on the government to recognize the connectivity of all elements of the ecosystem and to develop a holistic strategic approach whereby all components are recognized and connected.[1] The government announced July 28, 2021 a five pillar biomanufacturing strategy to guide its undertakings over the period ahead including "enabling Innovation by Ensuring World Class Regulation: … this will make Canada a more attractive destination for leading life sciences firms to establish and grow. BIOTECanada has urged the government to partner with the global companies and ensure that whatever capacity is developed is commercially viable in non-pandemic times and supports the growth of Canada's ecosystem. Overall, this will help grow a strong and competitive domestic life sciences sector for a more holistic model which would embrace the multinational companies as foundational partners rather than cost-drivers and, ensure Canada's readiness for future pandemics or other health emergencies.

Health Canada has worked effectively with the industry to deliver solutions to combat the pandemic, most notably therapeutics and vaccines using Emergency Orders and interim measures to accelerate the access to these important new medicines and vaccines. The federal government provided an exemption for COVID-19 therapeutics and vaccines from being subject to the new pricing rules clearly demonstrates that the rules would impact access. During the pandemic, Health Canada delayed the implementation of PMPRB due to these unprecedented circumstances and to give industry time to prepare and analyze impact these Guidelines will have on their businesses. PMPRB is introducing additional proposed changes that would further impact the value of important medicines for Canadians, and importantly has announced these material changes shortly after an announced delay by the Government. This is clearly inconsistent with the stated intentions of Health Canada when announcing the delay in implementation of the changes until January 1, 2022.

The proposed adjustment of the definition of Gap medicines is a significant change which is counter to the intent of the current six-month delay which was intended to provide industry with additional time to prepare for and comply with the changes introduced in the previous amendments. The existing proposed Guidelines were already complicated to interpret, and these latest changes add significant, and unnecessary complexity including the use of two separate sets of comparator countries; one from an active set of Regulations and one from an expired set of Regulations that Health Canada elected to replace. This complexity also appears to be the product of a misalignment between Health Canada and the PMPRB.

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Patentees have also recognized there is an additional lack of predictability with these latest proposed Guideline changes. Business decisions are made based on current/anticipated Guidelines and with more changes there is increased business uncertainty. For example, the new proposal to change the price test for most Grandfathered Medicines from Highest International Price (HIP) PMPRB11 countries to Median International Price (MIP) to PMPRB7 countries is unexpected. Again, the government's stated intent of the six month delay in implementation was for the purpose of providing patentees with additional time to adjust to the Guidelines as they were proposed in 2020. In this context, making a significant change at this time is completely inconsistent with the stated intent for the delay.

Planning for an appropriate and transparent evaluation of PMPRB reform is important, especially in view of the lack of consensus on the new Regulations and Guidelines and the serious concerns raised by the industry and other key stakeholders – concerns that the inherent market uncertainty and potential for unprecedented price limits will discourage the availability of new treatments for Canadian patients. It remains a concern of BIOTECanada that PMPRB reform has again been undertaken in isolation and works at counter purposes to these broader "whole of government" approach to industry policy. With the government announcement of a delay to the implementation of the new Regulations and Guidelines are instead met with additional seemingly punitive changes to the proposed Guidelines by PMPRB, irrespective of the proposed Regulations.

The announced implementation delay by Health Canada on June 29, 2021, the biomanufacturing initiative announced July 28, 2021, the investments into the ecosystem announced in the recent spring federal budget, and other policy undertakings, all offer a timely and important opportunity for the government and industry to work in partnership to develop solutions which will ensure Canadian patients have access to the new technologies emerging from the global industry and establish the industry as an important partner in enhancing the competitiveness and accelerating the growth of Canada's biotech ecosystem. This presents an important and timely opportunity for Canada to generate even more positive returns intrinsic to a successful biomanufacturing industry. From this success comes the potential for a modern, effective, and competitive regulatory environment ensuring safety, while encouraging the development and adoption of innovative new products and services. A high performing regulatory system should be predictable, efficient, consistent, and transparent, so as not to present barriers to global business investment, innovation and ultimately, economic growth and values with improved outcomes that benefit Canadians. The industry is developing game-changing innovative therapies and technologies such as gene editing, artificial intelligence, and nanotechnology. A consistent, predictable, and competitive regulatory process will help ensure Canada is remains a destination for new therapies and treatments over the years ahead.

Sincerely,

Andrew Casey
President and CEO

References:
[1] Publications - BIOTECanada (biotech.ca)