Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario
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February 13, 2020

Re: PMPRB Draft Guidelines Consultation

We are writing to you today on behalf of the Canadian Biosimilars Forum. The Forum is an alliance of companies who represent the breadth of the biosimilars industry and have come together to maximize the positive impact of biosimilars on patients, on clinicians and on the sustainability of Canada's health system. The Forum today encompasses Merck Canada, Pfizer Canada, Sandoz Canada, and Teva Canada and considers itself to be the leading voice on biosimilars policy across the country.

The Forum is focused on accomplishing three fundamental goals. First, raising awareness of biosimilars and serving as a credible resource for evidence-based information regarding biosimilars. Second, informing and supporting public policies that encourage access, awareness and adoption of biosimilars. Third, providing an opportunity for companies developing biosimilars for the Canadian market to work with key stakeholders – like the Patented Medicine Prices Review Board – on topics instrumental to biosimilars and patient care.

The purpose of this letter is two-fold. First, the Forum wants to commend the PMPRB (the Board) for its sustained focus on quantifying the savings that biosimilars could deliver to payers and policymakers across Canada. Through the National Prescription Drug Utilization Information System (NPDUIS) – and supported by colleagues from across the country – the Board has worked diligently to not only model the gap between actual and potential savings, but also identify the mix of policy instruments most likely to capture the full value that biosimilars represent. With so many myths and so much misinformation clouding discussions around biosimilars policy, the Board has been a consistent source of leadership on these issues.

Second, we want to bring to your attention some concerns we have about the proposed draft Guidelines accompanying the newly amended *Patented Medicines Regulations*. Our overarching fear is that the reforms the Board is contemplating could have the effect of inadvertently undermining a fledgling Canadian biosimilars market you are working so hard to promote. We believe there are 3 specific dynamics at play that are worthy of elaboration:

1. Canada's Biosimilars Market Remains Young and Unstable

The biosimilars market in Canada remains in its infancy, and is far from established, stable or predictable. As the Board's own data shows, biosimilar uptake in Canada has been slow and the market share of biosimilars lags far behind other OECD countries.

Although the past eight months have seen two provinces introduce frameworks to support the controlled switching of patients from reference biologics to biosimilars, it is far too soon to gauge the success of those policies or to fully understand their impact on the rest of the country.

As a result, the Forum believes it would be misguided for the PMPRB to include biosimilars under its mandate as proposed in the draft Guidelines, especially if that very inclusion would counter or complicate the efforts of individual jurisdictions to expand the use of products the Board itself has referred to as a source of massive future savings.

2. Uneven Regulation May Distort a Competitive Market

Beyond the fundamental immaturity of the Canadian biosimilars market, a second challenge relates to the variability of patents across biosimilars themselves. As you know, some biosimilars are patented medicines, but not all of them. Given the PMPRB's mandate to review all patented medicines, the application of the current Guidelines would leave the Board with jurisdiction over a subset of biosimilars. This situation could leave patented biosimilars at a competitive disadvantage to their non-patented peers due to the reporting and regulatory burden associated with PMRPB review.

The Forum believes that creating a robust and sustainable biosimilars market is the only measure that will drive down the net cost of biologic medicines by reducing the use of a reference biologic when its market exclusivity has ended. If reporting requirements discourage manufacturers of patented biosimilars from launching in Canada, market competition will decrease at exactly the time when an increase is most needed.

3. PMPRB Will be Challenged by CADTH's Decision to Bypass Biosimilars

The process outlined in PMPRB's Guidelines relies on pharmacoeconomic reviews from the Canadian Agency for Drugs and Technologies in Health (CADTH) as a key process input. However, as of June 1, 2019 CADTH no longer conducts biosimilars reviews, either through the Common Drug Review (CDR) or the pan-Canadian Oncology Drug Review (pCODR). INESSS

continues to review biosimilars, which results in further uncertainty as to the application of the draft Guidelines.

CADTH's decision not to conduct biosimilar reviews was made in consultation with public drug plans and the pan-Canadian Pharmaceutical Alliance and reflects the Agency's view that the reimbursement process for biosimilars should be as simple and streamlined as possible given their identity as a source of much-needed system savings.

A Proposed Way Forward

The PMPRB Regulations posted in August 2019 state that *"Consideration was given to also including other products such as biosimilars, other patented generic medicines that are not authorized for sale by way of an ANDS and brand versions of patented generics, but there was insufficient evidence to determine whether these products pose a sufficiently low risk of excessive pricing."*[1]

The Forum shares the Board's belief in the importance of embedding sufficiency of evidence into policymaking. At the same time, we believe that the Canadian biosimilars market is simply too young, too unstable and too divided – between patented and non-patented molecules - for the Board to have come to an accurate conclusion about the risk of excessive pricing.

As a result, we are requesting that PMPRB defer implementation of the Guidelines for biosimilars, including exemption from both automatic regulatory review and from its annual reporting requirements – a decision that would see the Board treat biosimilars in the same way as it does veterinary and generic medicines. This delay will allow the organization to more accurately assess both the strength and stability of the Canadian biosimilars market and the risk of excessive pricing.

The Forum would welcome the opportunity to work with the PMPRB on a forthcoming biosimilars market evaluation process. We believe the Board is committed to playing its part in the creation of a sustainable and competitive biosimilars market – and to identifying ways to reduce the regulatory burden on medicines bringing system savings into Canada – and we are committed to collaborating with the organization to identify and address any perverse outcomes that could undermine those laudable goals.

[1] http://www.gazette.gc.ca/rp-pr/p2/2019/2019-08-21/html/sor-dors298-eng.html

Thank you again for this opportunity to share our views in a more structured and formal way, and we look forward to continuing our engagement over the coming months. In the meantime, please do not hesitate to follow up through the Forum's Secretariat, who can be reached at secretariat@canadianbiosimilarsforum.ca.

Yours sincerely,

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