Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

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Patented Medicine Prices Review Board
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Submitted via PMPRB Online Submission Form

This submission provides Biosimilars Canada's feedback on the PMPRB's draft guidelines as published on December 19, 2024.

Biosimilars Canada is a national association representing Canada's biosimilar medicines industry. We represent companies that are at the forefront of the global development and marketing of biosimilar medicines. Biosimilars Canada is a division of the Canadian Generic Pharmaceutical Association.

A biosimilar medicine is a biologic drug that is approved by Health Canada that enters the market subsequent to a previously approved originator reference biologic drug, and has demonstrated similarity to the originator reference biologic drug in terms of quality, safety and clinical efficacy. Biosimilar medicines provide important competition to original patented biologic drugs.

Maximizing the use of lower cost biosimilar medicines provides a significant contribution to the sustainability of drug plans and healthcare systems while supporting positive outcomes for patients. This is reflected in policies that have been adopted by payers since 2019 to transition patients with chronic conditions from costly originator biologic drugs to lower-cost biosimilar biologic drugs under the supervision of their clinician.

Prices of biosimilar medicines are negotiated by the pan-Canadian pharmaceutical Alliance (pCPA) and subject to a prescribed pricing framework. This negotiation has the effect of regulating the prices of all biosimilars. Moreover, biosimilars are significantly lower than the price of their reference biologic drug. As such, the prices of these medicines – regardless of whether the biosimilar is associated with a patent or not – cannot be excessive.

Importantly, as for generic medicines, the association of a biosimilar with a patent does not confer market power, exclusivity or preferential pricing for that biosimilar or generic medicine. Such requirements or actions would negatively impact the ability of the patented biosimilar or

patented generic medicine to effectively compete in the market, and have broader implications for the Canadian drug supply system.

This submission focuses on two Biosimilars Canada recommendations:

1. The need for a complaints-based reporting regime for biosimilar medicines.
2. The need for a transition period for existing medicines that is longer than one year, in order to minimize impact on off-patent medicines (biosimilars and generics).

1. The need for a complaints-based reporting regime for biosimilar medicines

As the PMPRB itself has noted, patented biosimilar biologic drugs pose a very low risk of excessive pricing in the domestic market. Previous versions of the draft guidelines included a complaints-based reporting requirement for patented biosimilars, which should be maintained under the future PMPRB Guidelines.

Biosimilars Canada is disappointed that the Board did not include a complaints-based reporting regime for biosimilars in the draft guidelines. In our view, this decision demonstrates a lack of understanding of the Canadian biosimilars market and the very low risk of excessive pricing in that market.

It should be noted that such a complaints-based approach has already been implemented for other products that also have a low risk of excessive pricing, including patented generic drugs, patented veterinary drugs and patented over-the-counter drugs.

Such an approach would reflect the low risk of excessive pricing for patented biosimilar medicines due to the following:

- Patents on biosimilar biologic medicines do not confer a market monopoly or market advantage in the same manner that patents on generic medicines do not confer a market monopoly or market advantage. Biosimilars require, by definition, a reference product which has market share and against which the biosimilar must compete. The price of the biosimilar must be a percentage of the reference biologic. Excessive pricing as a form of patent abuse in the biosimilar market is thus implausible.
- A patented biosimilar biologic medicine is not priced higher or treated differently in the marketplace than a non-patented biosimilar biologic medicine – it must operate within the same marketplace policy frameworks established for all biosimilar biologic drugs. Excessive pricing as a form of patent abuse in the biosimilar market is thus implausible.
- No market differentiation can be achieved through the existence of a biosimilar patent. The Health Canada review requirements and approval process for biosimilar biologic drugs is different than for originator biologic drugs. The sponsor of a biosimilar biologic drug cannot make claims that it is better or more effective than its reference biologic drug in any way, regardless of whether it has a patent or not.
- While it is possible that some biosimilars could have patents, many do not, which makes the PMPRB intervention ineffective as a price regulation tool and creates inequities amongst competitors.

- There are often multiple products of the same active substance competing in the market, including the reference biologic drug. Excessive pricing as a form of patent abuse in the biosimilar market is thus implausible.
- The prices for biosimilar medicines are negotiated through the pCPA. During the negotiation process, the pCPA has awareness of prices in other jurisdictions through their own research and the NPDUIS reports. Excessive pricing as a form of patent abuse in the biosimilar market is thus implausible.
- Biosimilar prices are regulated by provincial governments to be lower than the originator price, which is already regulated by the PMPRB. Excessive pricing as a form of patent abuse in the biosimilar market is thus implausible.

2. The need for a transition period for existing medicines that is longer than one year

Biosimilars Canada was disappointed that the draft guidelines reflect a transition period for existing medicines of just one year.

Biosimilars Canada reiterates its concern that changes to the overall PMPRB Framework will create a great deal of uncertainty and could have a negative impact on the current and future supply and availability of cost-saving biosimilar medicines.

Biosimilar prices in Canada are negotiated by pCPA as a percentage discount off the originator price. The prices for existing originator biologics will be reduced as a result of changes to the *Patented Medicines Regulations* and revised Guidelines.

Biosimilars Canada is concerned that it may be more difficult for biosimilar sponsors to compete as sustainable pricing levels require lower percentage discounts off of originator list prices. It may also cause sponsors to more carefully assess the business case for bringing new biosimilar medicines to the Canadian market in the future as it becomes more difficult for these companies to achieve sustainable and predictable pricing levels for their off-patent products.

While the PMPRB was originally created to protect Canadians from higher drug costs brought by an increase in the length of patents, a failure by the PMPRB to provide for an adequate transition period could also lead to higher drug costs through reduced or delayed competition from off-patent products. This is not in the best interest of Canadians.

It should be noted that sponsors typically make significant investments to bring a biosimilar to the Canadian market at least three to five years in advance of an anticipated launch date. The transition period of five years that we had recommended in our previous submission was to avoid disruption for the market entry of these new cost-saving biosimilars for the Canadian market.

Biosimilars Canada asks the Board to reconsider its decision, and provide a longer transition period for existing medicines. This will avoid the unintended consequences for pro-competitive market launches for off-patented medicines over the next five years, and minimize the disruption to pharmaceutical supply chains, patients, payers and other pharmaceutical stakeholders.

Conclusion

Thank-you for reviewing the submission of Canada's biosimilar medicines industry. I look forward to meeting with you in the near future to review these proposals in greater detail, and to work with the PMPRB Board and staff to develop a more suitable approach to patented biosimilar medicines.

Sincerely,

Jim Keon
President