Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

September 11, 2024

Patented Medicine Prices Review Board
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Submitted via PMPRB Online Submission Form

This submission provides Biosimilars Canada's feedback on the Discussion Guide for PMPRB Phase 2 Consultations on new Board Guidelines.

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.

Background Context – Biosimilar Medicines

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 in the biologic drug space.

Prices of biosimilar medicines are negotiated by the pan-Canadian pharmaceutical Alliance (pCPA) and 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.

As with generic medicines, 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. BC Health Minister Adrian Dix recently confirmed that the province has saved $732 million from its biosimilar switching policy since it was first adopted in May 2019. All ten provinces, two territories, and some federal and private drug plans have adopted such policies.

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It is crucial for the Board to recognize that patented biosimilar or patented generic medicines are sold in multi-source, competitive markets with other biosimilar or generic medicines of the same active substance that have no patents. The association of a biosimilar or generic medicine 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. Such requirements or actions are also a completely ineffective price control tool, as this is already the purview of the pCPA.

Topic 2: The length of time Staff should wait, following the implementation of the Guidelines, to determine whether the IPC identification criterion for an Existing medicine is met.

Biosimilars Canada remains concerned 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. As originator biologic prices are reduced in the future 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 in the future. It may cause sponsors to more carefully assess the business case for bringing new biosimilar medicines to the Canadian market in the future.

To reduce the impact of these concerns, it remains Biosimilars Canada's recommendation that currently marketed products should be fully grandfathered from new Guideline requirements. Specifically, currently marketed patented biosimilars should be assessed and treated in the same manner as patented generic drugs under the current Compendium of Policies, Guidelines and Procedures, as updated in February 2017.

Biosimilars Canada notes that the current Board position as included in the Discussion Guide is to provide a transition period for existing products, and not grandfather existing medicines from the new Guideline requirements. In advance of the August 13 webinar, Biosimilars Canada submitted a question asking for additional information to be provided with respect to the Board's rationale for not grandfathering existing medicines. Our question was not addressed during the webinar.

The Phase Two Discussion Guide seeks feedback on whether the transition period should be one, two or three years. If the Board ultimately does not agree to grandfather existing medicines despite the significant concerns raised by Biosimilars Canada and other organizations, we request that the Board consider a transition of period of at least five years to minimize the disruption to the pharmaceutical supply chain for biosimilar and generic manufacturers, patients, and other pharmaceutical stakeholders.

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Biosimilars Canada Recommendation:

Biosimilars Canada recommends that the Board reconsider our earlier proposal to grandfather existing medicines. In this regard, currently marketed patented biosimilars should be assessed and treated in the same manner as patented generic drugs under the current Compendium of Policies, Guidelines and Procedures, as updated in February 2017. Alternatively, a longer transition period of at least five years should be provided to minimize disruption to the Canadian drug supply system.

Topic 4: The individuals/groups permitted to submit a complaint

Biosimilars Canada is encouraged that the Discussion Guide recognizes the need to prevent misuse to reduce administrative burden and maintain predictability for Rights Holders with respects to a complaints process.

As noted in previous submissions, Biosimilars Canada remains of the view that safeguards are needed to ensure that the complaints-based reporting system operates smoothly, achieves its intended objectives, and avoids the potential for frivolous complaints.

Frivolous complaints would have the effect of diverting limited PMPRB investigative resources from high-risk originator patented medicines, which is not in the best interests of Canadians and is inconsistent with the mandate of the PMPRB as prescribed under the *Patent Act*. It would also be a drain on resources for a company that is required to respond to the frivolous complaint.

Narrowly restricting the scope of individuals permitted to submit a complaint is the most powerful and effective safeguard that the Board can put in place to prevent misuse of the complaints-based reporting system.

Biosimilars Canada is of the view that *Option 1: limit complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts* would significantly reduce the potential for misuse of the complaints-based reporting system and is consistent with s. 86(2) of the *Patent Act.* Further, Biosimilars Canada does not support Option 2B, Option 3 or Option 4 as these options do not provide sufficient safeguards to prevent misuse of the complaints-based reporting system.

Biosimilars Canada Recommendation for Topic #4:

Biosimilars Canada supports *Option 1: limit complaints to the Federal Minister of Health or any of his/her Provincial or Territorial counterparts* as this would significantly reduce the potential for misuse of the complaints-based reporting system and is consistent with s. 86(2) of the *Patent Act.*

Topic 5: Expanding the list of products that would only be subject to an in-depth review following a complaint to include biosimilars and/or vaccines.

Biosimilars Canada supports Option 2, whereby the PMPRB will only open a review for patented biosimilars and/or vaccines when a complaint is received. 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.

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. A patented biosimilar biologic medicine does not receive a higher price or special treatment over a non-patented biosimilar biologic medicine – it must operate within the marketplace policy frameworks established for all biosimilar biologic drugs.
- 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 others 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.

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- 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.
- Biosimilar prices are regulated by provincial governments to be lower than the originator price, which is already regulated by the PMPRB.

To ensure the complaints-based process is used as intended the PMPRB should establish conditions that must be met to trigger an investigation into a patented biosimilar medicine as a safeguard to prevent misuse/abuse of the process. Such safeguards are currently in place for patented generic medicines, and should be maintained.

With respect to in-depth reviews resulting from a complaint, clarity is needed with respect to how these will be conducted by the PMPRB for patented biosimilar and patented generic medicines.

In-depth reviews are considered by rights holders as the main Guideline policy that they must account for when making pricing and launch decisions. Price tests for originator medicines are not appropriate for medicines that are approved by Health Canada based on bioequivalence or similarity to a reference originator medicine and are direct competitors to a reference originator medicine (e.g., biosimilar and generic medicines),

Price tests designed for patented originator medicines do not take into account the market realities and other important considerations for biosimilar medicines. A separate test for biosimilars that is focused on the domestic market is needed for investigations into patented biosimilar medicines.

As Biosimilars Canada has noted in previous submissions to the PMPRB, international price comparisons for patented biosimilars are inappropriate as marketplace policy frameworks for biosimilars around the world are evolving rapidly.

For example, some markets have tender-based procurement policies and permit originator companies to undercut biosimilars to undermine competition and retain market share. While this may lead to short term price advantages, this type of approach is not conducive to long-term sustainable competition and continuity of drug supply systems. As a result of such procurement policies, significant rates of drug shortages and stockouts for biosimilars medicines are common in European and other markets, and need to be avoided for Canadians patients.

As such, any price tests requiring international price comparisons are not rooted in domestic or international realities for biosimilar sponsors in Canada. **The most relevant way to assess whether the price of a patented biosimilar is excessive is, depending on the factual circumstances, to review its price in comparison to the applicable reference biologic drug in Canada.**

Biosimilars Canada Recommendations:

Biosimilars Canada supports *Option 2: The PMPRB will only open an in-depth review for biosimilars and/or vaccines when a complaint is received.*

In-depth reviews designed for originator medicines are not appropriate for medicines that are approved on the basis of bioequivalence or similarity to a reference originator medicine and are direct competitors to a reference originator medicine (e.g., biosimilar and generic medicines). The most relevant way to assess whether the price of a patented biosimilar is excessive is, depending on the factual circumstances, to review its price in comparison to the applicable reference biologic drug.

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 to develop a suitable approach to patented biosimilar medicines.

Sincerely,

Jim Keon
President