Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

December 20, 2023

Patented Medicine Prices Review Board
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Submitted via PMPRB Online Submission Form

I am writing to provide comments of Biosimilars Canada on the Scoping Paper for the consultation on the Board's 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

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

It is the position of Biosimilars Canada that the PMPRB's role is to ensure that prices of patented medicines in Canada are not excessive. Given that generic and biosimilar medicines in Canada are priced significantly lower than the prices of their innovator reference products, prices of these medicines are, by definition, not 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 $465 million from its biosimilar switching policy since it was first adopted in May 2019. To date, eleven provincial and territorial drug plans have adopted such policies.

Prices of biosimilar medicines are negotiated by the pan-Canadian pharmaceutical Alliance (pCPA) and are significantly lower than the price of the reference biologic drug. The pCPA also

requires biosimilar sponsors to provide patient support services that are similar to those provided by the originator company, which are very costly for biosimilar companies to operate given the lower prices and market share biosimilars have in comparison to the original biologic drug. The prevalence of patient support programs is unique to Canada as the cost of infusion and injection support services are covered by the public health system in other jurisdictions.

As the PMPRB 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.

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 in place for patented generic medicines.

Biosimilars Canada also remains concerned about the application of price tests designed for patented originator medicines to investigations of patented biosimilars, which does 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.

In addition, Biosimilars Canada remains concerned about the uncertainty and potential impact of changes to the PMPRB Framework on originator medicines prices and corresponding negative impacts on biologic drug competition that could result from such changes.

Complaints-Based Reporting for Patented Biosimilar Medicines

The PMPRB has included complaints-based reporting for patented biosimilars under previous versions of the Draft Guidelines – an approach that has already been implemented for other products with low risk of excessive pricing, including patented generic drugs, veterinary drugs and over-the-counter drugs. This approach should maintained in the future PMPRB Guidelines.

Such a complaints-based reporting regime reflects 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
- The prices for biosimilar medicines are negotiated through the pan-Canadian Pharmaceutical Alliance (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.

The complaints-based regime for patented biosimilar medicines as reflected in the recent PMPRB Guidelines does not include conditions to trigger an investigation. Such a safeguard is needed. Biosimilars Canada remains concerned that unconditional complaints-based reporting requirements could lead to the lodging of frivolous complaints against patented biosimilar medicines by originator companies and others.

A lack of safeguards could undermine the intent of the complaints-based reporting regime for patented biosimilars. It could also have the effect of diverting limited PMPRB investigative resources from high-risk originator patented medicines, which is not in the best interests of Canadians.

A lack of safeguards could also financially harm and consume the resources of the patented biosimilar sponsor, negatively impact their ability to compete in the market and provide a potential market advantage to its competitors which include both originator and non-patented biosimilar medicines. Indeed, originator companies have proven themselves to be innovative in their tactics to undermine competition from cost-saving biosimilar medicines, and remain under scrutiny by the Competition Bureau.

Biosimilars Canada believes that the appropriate conditions to trigger an investigation for patented biosimilar medicines would be similar to those implemented for patented generic medicines. Such an approach would be fully consistent with the risk-based approach reflected in recent draft guidelines and would address the biosimilar industry's concerns regarding misuse of the complaints-based reporting regime for patented biosimilars.

Under the Policy on Generic Medicines (B.8.4), which was added to the *Compendium of Policies, Guidelines and Procedures (Compendium)* in February 2017 and has applied since the July 1, 2016 reporting period, Board Staff will commence an investigation into the price of a patented generic drug medicine if all of the following three conditions are met:

- A complaint has been received in respect of the Patented Generic Drug;
- The patentee of the Patented Generic Drug is the only company in Canada which is selling a generic version of the drug in Canada; and

- The Patented Generic Drug is not the subject of a pricing agreement with the pan-Canadian Pharmaceutical Alliance (pCPA) to which it is compliant. The onus of proving to Board Staff that a Patented Generic Drug is subject to, and compliant with, a pricing agreement with pCPA will rest with the patentee for that Patented Generic Drug.

Biosimilars Canada Recommendation:

For the reasons outlined above Biosimilars Canada recommends that a specific Policy on Patented Biosimilar Medicines be included in the *Compendium* as follows:

Board Staff will commence an investigation into the price of a patented biosimilar drug if all of the following three conditions are met:

- *A complaint has been received in respect of the Patented Biosimilar Drug;*
- *The patentee of the Patented Biosimilar Drug is the only company in Canada which is selling a product in Canada; and*
- *The Patented Biosimilar Drug is not the subject of a pricing agreement with the pan-Canadian Pharmaceutical Alliance (pCPA). The onus of proving to Board Staff that a Patented Biosimilar Drug is subject to, and compliant with, a pricing agreement with pCPA will rest with the patentee for that Patented Biosimilar Drug.*

Price Tests Required for Patented Biosimilar Medicines Investigations

With respect to the price tests to be applied to patented biosimilar medicines in the event an investigation for a patented biosimilar is triggered, Biosimilars Canada is concerned that price tests for patented originator medicines could also be applied to patented biosimilar medicines in the Guidelines.

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 noted above, the unique Canadian requirement for biosimilar sponsors to fund costly patient support services are also not taken into account in international price comparisons for biosimilar medicines.
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 to review its price in comparison to the applicable reference biologic drug. Alternatively, the PMPRB could simply review the price of the patented biosimilar against the price for other biosimilars of the same active substance in Canada.

Biosimilars Canada Recommendation:

Biosimilars Canada proposes that the PMPRB establish a separate test for patented biosimilars which takes into account the price of the applicable reference biologic drug, in Canada and in other countries, as adjusted by CPI. Alternatively, the PMPRB could simply review the price of the patented biosimilar against the price for other biosimilars of the same active substance in Canada.

Given the difficulties associated with obtaining an accurate international price comparison for biosimilar drugs, international prices of biosimilar medicines should not be used to determine a maximum non-excessive price for the Canadian market for patented biosimilars.

Reducing the Impact of the new Guidelines on Current and Future Competition

There are increasing concerns worldwide, including in Canada, about the state of the prescription medication supply. It is the view of Biosimilars Canada and its member companies that governments need to be more attentive to this growing issue.

Biosimilars Canada remains concerned that changes to the overall PMPRB Framework creates 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 the 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 will 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 is Biosimilars Canada's recommendation that application of the final Guidelines be effective on the date of their application and not retroactive. Existing products should be fully grandfathered from new Guideline requirements.

Biosimilars Canada Recommendation:

Existing products should be fully grandfathered from the new Guideline requirements.

Payers will need to recognize that lower originator biologic drug list prices in the future will necessitate smaller percentage discounts for biosimilars to ensure a sustainable biosimilars market can be built and maintained in Canada.

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