Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

August 4, 2020

Douglas Clark, Executive Director
Patented Medicines Prices Review Board
Attention: PMPRB Guideline Consultations
Box L40 Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

* *Submitted via PMPRB Draft Guidelines Consultation Website*

Re: Biosimilars Canada Submissions Regarding
PMPRB Draft Guidelines 2020 Published June 19, 2020

Dear Mr. Clark,

On behalf of Biosimilars Canada, the biosimilars medicines division of the Canadian Generic Pharmaceutical Association, I am writing to provide feedback regarding the *PMPRB Draft Guidelines 2020* published on June 19, 2020.

The *PMPRB Draft Guidelines 2020* reflects a significant improvement over the previous draft with the inclusion of a complaints-based reporting requirement for patented biosimilars. As the PMPRB has noted, patented biosimilar biologic drugs pose a very low risk of excessive pricing in the domestic market, and Biosimilars Canada applauds the PMPRB for taking a practical approach with the inclusion of a complaints-based reporting for patented biosimilars.

To ensure the complaints-based process is used as intended the PMPRB should establish conditions for the launch of 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 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

Biosimilars Canada was pleased to see that the PMPRB has reconsidered its initial approach and included complaints-based reporting for patented biosimilars under the *PMPRB Draft Guidelines 2020* – 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.[1]

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 – it must operate within the marketplace policy frameworks established for all biosimilar biologic drugs.
- No market differentiation that can be achieved through the existence of a 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.
- With multiple biosimilars on the market it is possible that some biosimilars could have patents while others will not, which makes the PMPRB intervention ineffective as a price regulation tool and creating 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 already regulated by provincial governments to be lower than the brand price, which is already regulated by the PMPRB.

The complaints-based regime for patented biosimilar medicines as reflected in the *PMPRB Draft Guidelines 2020* currently does not include conditions to trigger an investigation. PMPRB Staff

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[1] Paragraph 89: *"Notwithstanding the above, in the case of patented Biosimilars, patented Generic medicines, patented medicines for veterinary use and over the counter (OTC) patented medicines, an investigation will only be commenced by Staff if a complaint is received."*

have advised Biosimilars Canada that they are open to receiving feedback in this area during the consultation period.

To ensure the complaints-based process is used as intended the PMPRB should establish conditions for the launch of an investigation into a patented biosimilar medicine as a safeguard to prevent misuse/abuse of the process. Biosimilars Canada is concerned that unconditional complaints-based reporting could lead to the lodging of frivolous complaints against patented biosimilar medicines.

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 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.

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 the *PMPRB Draft Guidelines 2020* 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 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 recommends that the existing Policy on Generic Medicines be replaced with a combined Policy on Generic and Biosimilar Medicines. The three conditions would be as follows:

- A complaint has been received in respect of the Patented Generic Drug or the Patented Biosimilar 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 or the patentee of the Patented Biosimilar Drug is the only company in Canada which is selling a Patented Biosimilar Drug of the active substance in Canada; and

- The Patented Generic Drug or the Patented Biosimilar 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 or a Patented Biosimilar Drug is subject to, and compliant with, a pricing agreement with pCPA will rest with the patentee for that Patented Generic Drug or Patented Biosimilar Drug.

Alternatively, a separate Policy on Biosimilar Medicines reflecting the three conditions could be implemented.

Biosimilars Canada Recommendation:

In order to establish safeguards that protect Canadians and patentees of patented biosimilar drugs against misuse of the complaints-based reporting regime for patented biosimilars, conditions to trigger an investigation into a patented biosimilar medicine must be established. The appropriate conditions to trigger an investigation for patented biosimilar medicines would be similar to those implemented for patented generic medicines. This could be implemented either by adding biosimilar medicines to the existing Policy on Generic Medicines or creating a separate Policy on Biosimilar Medicines with similar conditions to those currently applied to patented generic medicines.

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 remains concerned that price tests for patented originator medicines would be applied to patented biosimilar medicines under the *PMPRB Draft Guidelines 2020*.

As Biosimilars Canada noted in its February 2020 submission, international price comparisons for patented biosimilars are inappropriate as marketplace policy frameworks for biosimilars around the world are evolving rapidly. Several of these frameworks are not considered by sponsors to be sustainable, and several sponsors are exiting these markets as a result. For example, some markets are permitting originator companies to undercut biosimilars to undermine competition. 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. Biosimilar prices are regulated by provincial governments to be lower than the price of the patented reference biologic drug, which is already subject to PMPRB price tests.

As such any price tests requiring international price comparisons are not rooted in domestic or international realities for biosimilar sponsors in Canada.

Further, many biosimilars are licensed at the national level. Companies holding a license for Canada have no visibility into the pricing decisions made by another licensee in another

country. Pricing decisions are made based on Canadian market realities, and within the market frameworks established by the pCPA.

Biosimilars Canada Recommendation:

Biosimilars Canada proposes that, in the case of an investigation, the PMPRB establishes a separate test for patented biosimilars which takes into account the domestic price of the applicable reference biologic drug in Canada, as adjusted by CPI.

Based on the fact that the patented reference biologic drugs of patented biosimilars are already subject to PMPRB price tests as well as the difficulties associated with obtaining an accurate international price comparison for biosimilar drugs, international prices should not be used to determine a maximum non-excessive price for the Canadian market for patented biosimilars.

Categorization of Medicines

Biosimilars Canada supports the classification of patented biosimilars and patented generics as Category II drugs even if they would otherwise meet the criteria as outlined in the *PMPRB Draft Guidelines 2020*.[2] This decision reflects the low risk of excessive pricing posed by these products.

Biosimilars Canada Recommendation:

Retain this change in the final Guidelines.

Impact of Framework on Pricing for All Biosimilars

Biosimilars Canada remains concerned that changes to the overall PMPRB Framework creates a great deal of uncertainty and could have a negative impact on biologic drug competition in the future. As Biosimilars Canada noted in its February 2020 submission, the Canadian biosimilars market is still in its infancy and biosimilar sponsors face many barriers to market uptake.

The complex challenges facing biosimilar sponsors have also been recognized by the PMPRB. As the PMPRB noted in its two-part chart book *Biologics in Canada* "biosimilars offer an excellent opportunity for significant cost savings; but this is a complex market space, and these potential savings have yet to be fully realized." The PMPRB report estimates that if the uptake of biosimilars in Canada had matched the OECD median average at current prices in 2018, Canada's savings from biosimilars would have increased from an estimated $94 million to $346

[2] *PMPRB Draft Guidelines 2020*, Para. 60 and 81.

million.

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. This in turn may make biosimilars a less attractive policy for payers as the magnitude of potential savings from biosimilars in the future will be impacted.

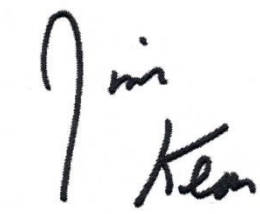
Biosimilars Canada Recommendation:

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 can be built and maintained in Canada.

In addition, interventionist policies including switching policies to support the growth of the biosimilars market in Canada will continue to be required.

Thank-you for reviewing these submissions of Canada's biosimilar medicines industry. I look forward to meeting with you in the near future to review these proposals in greater detail.

Sincerely,



Jim Keon
President