Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

February 14, 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 email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: Biosimilars Canada Submissions Regarding
Proposed PMPRB Guidelines Published November 21, 2019

Dear Mr. Clark,

On behalf of Biosimilars Canada I am writing to provide feedback regarding the proposed PMPRB Guidelines published November 21, 2019, and to request that the PMPRB reconsider its current proposed approach to patented biosimilar medicines. The current proposed approach completely fails to distinguish patented biosimilar medicines from patented originator medicines, and ignores the market realities for these products.

Biosimilars Canada proposes that the current exemption from PMPRB reporting requirements for patented generic drugs, veterinary drugs and over-the-counter drugs should be expanded to include patented biosimilars as well. Such a policy would not exempt patented biosimilars from the scope of PMPRB price regulation, but rather alleviates biosimilar sponsors of the burden of ongoing PMPRB reporting unless a complaint is triggered. Further, any price test involving a patented biosimilar in Canada should be linked to the public list price for its reference product. The maximum allowable price for the reference biologic drug should be the ceiling applied to all other products of the same active substance (i.e. biosimilar biologic drugs).

Biologic Drugs and Biosimilar Biologic Drugs

As defined by Health Canada, biologic drugs come from living organisms or from their cells, and are generally larger and more complex than chemically produced pharmaceutical drugs. Biologic drugs are listed in Schedule D of the *Food and Drugs Act*.

Biosimilar biologic drugs, or biosimilars, are biologic drugs demonstrated to be highly similar to a reference biologic drug that was already authorized for sale by Health Canada. As stated by Health Canada, biosimilars are approved based on a thorough comparison to the reference biologic drug, and may enter the market after the expiry of the original drug patents and data protection. Given that biologics are made in living cells rather than with chemicals, Health Canada is clear that a biosimilar and the original drug can be shown to be similar, but not identical. Biosimilar biologic drugs have the same clinical outcomes as their reference biologic drugs in approved indications.

Patented Biosimilar Biologic Drugs

A patented biosimilar biologic drug is no different than any other biosimilar biologic drug except it is in some way associated with a patent.

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.

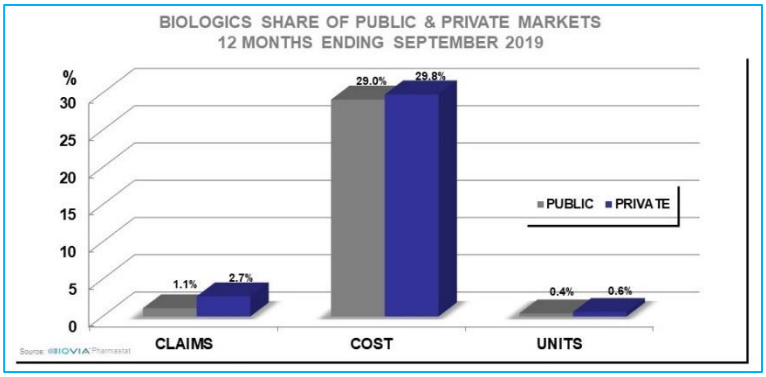
There is also no market differentiation that can be achieved through the existence of a patent. The Health Canada review requirements and approval process for biosimilar biologic drugs is different than for originator biologic drugs. The sponsor of a biosimilar biologic drug cannot make claims that it is better or more effective than its reference biologic drug in any way, regardless of whether it has a patent or not.

The PMPRB's mandate of jurisdiction over "patented medicines" was intended to protect Canadian consumers from originator monopolies. It was not intended to cover products like biosimilar biologic drugs which contain the same active substance as an originator product under the PMPRB's jurisdiction.

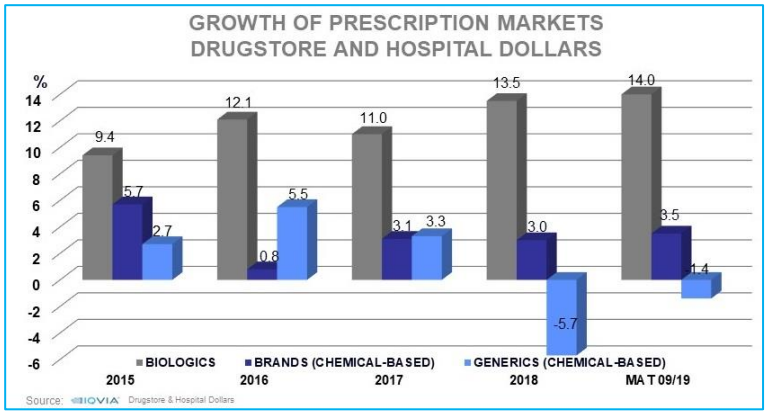
The PMPRB only has jurisdictions over patented medicines with patents. While virtually all originator prescription medicines have patents, the same is not true of biosimilar biologic drugs. While it is possible that some biosimilars could have patents, many others will not, making PMPRB intervention ineffective as a price regulation tool and creating inequities amongst competitors.

The Increasing Burden of Biologic Drugs for Public and Private Drug Plans

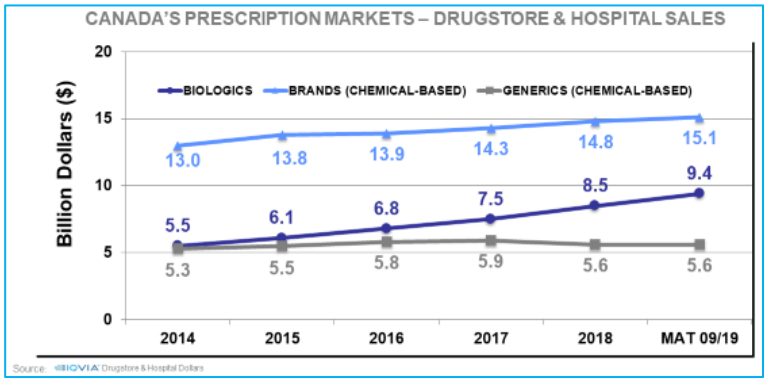
Biologic drugs are becoming an increasing burden on public and private drug plans in Canada. During the 12 months ending September 2019 the biologic drugs represented 1.1% of public drug plan claims but 29.0% of all public prescription drug expenditures, according to IQVIA data. In private markets, biologic drugs represented 2.7% of private drug plan claims and 29.8% of private drug plan expenditures during the same period. This reflects differences in the composition of biologic drugs included on public and private formularies.



Canada's prescription drug spend on biologic drugs has been experiencing double-digit increases for several years, and increased by 14.0% during the 12 months ending September 2019, according to IQVIA data.



Total biologic drug sales in Canada reached $9.4 billion during the same period. Sales of prescription biologic drugs have increased by more than $4 billion over the past six years. In 2014 the total value of prescription biologic drug sales in Canada was just $5.5 billion.



Biosimilars Are an Important Solution to Canada's Biologic Drug Expenditure Problem

Biosimilar biologic drugs can be an important solution to high biologic drug costs for Canadian payers.

The potential savings from biosimilar competition vary widely depending on type of therapy, market size, timing of biosimilar availability, payer policies, uptake and pricing. The PMPRB NPDUIS research initiative has examined the potential savings from biosimilars in Canada.[1] For acute therapies the PMPRB estimates potential savings at between 13% and 43%.

[1] See: https://www.pmprb-cepmb.gc.ca/view.asp?ccid=1304

For chronic therapies the PMPRB estimates potential savings at between 8% and 43%.

While the first biosimilar biologic drug was approved in Canada more than a decade ago the uptake of biosimilars biologic drugs has been slow, particularly for use in treating chronic conditions.

According to the new CIHI report *Prescribed Drug Spending in Canada, 2019* biosimilars accounted for only 12% of use when available. The report also noted that the uptake of biosimilars has been slower in Canada than in other Organization for Economic Co-operation and Development (OECD) countries.[2]

The PMPRB itself has recognized the potential benefits of biosimilar biologic drugs for Canadians. In 2016, the PMPRB released a report regarding the market for biologic drugs referred to as biologic response modifiers. These drugs are used in the treatment of chronic inflammatory diseases such as rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriasis. The PMPRB report noted that the sales and use of these originator biologic drugs are higher in Canada than in most comparable international markets. The same PMPRB report observed that aligning the prices of these originator biologic drug products with international levels, and using less expensive alternative therapies, such as biosimilars, would result in lower drug costs for Canadians.

The PMPRB has also recognized challenges with biosimilar market acceptance and utilization. A 2016 PMPRB report noted that biosimilar uptake was "modest" when referring to a biosimilar's 0.2% share of the original biologic drug's market after one year of the biosimilar being on the market.[3] In a 2017 PMPRB presentation entitled "Potential Savings from Biosimilars in Canada", the PMPRB reported that biosimilar savings in Canada have been modest, to date, due to "low uptake" of biosimilars.[4] These market penetrations for biosimilars are notwithstanding the significant discounts provided by these products (e.g. 47% discount relative to the original biologic, in the case of biosimilar infliximab).

In the case of Pfizer Infectra infliximab, almost six years after it first received an NOC (January 2014) it has only gained 4.7% of the value of the Canadian infliximab market, and 8.2% of Canadian infliximab prescriptions, according to IQVIA data. A second biosimilar infliximab – Merck Renflexis infliximab – has only gained 0.1% of the Canadian infliximab sales and 0.2% of prescriptions since it received an NOC in December 2017. In contrast, for the 12 months ending September 2019 reference biologic drug Janssen Remicade infliximab retained 91.6% of Canadian infliximab prescriptions, and overall sales of Remicade in Canada were valued at $1.155 billion, an increase of 5.3% over the value of sales in 2018. Similar challenges in gaining

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[2] See: https://www.cihi.ca/en/prescribed-drug-spending-in-canada-2019

[3] See: http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/PMBRB_16-240_MarketIntelligenceReport_E.pdf

[4] See: http://www.pmprb-cepmb.gc.ca/CMFiles/NPDUIS/Potential_Savings_from_Biosimilars_in_Canada_Biosimilar_Workshop_e.pdf

market share have been experienced for biosimilars referencing Amgen Enbrel and Sanofi-Aventis Lantus Solostar.

The Canadian biosimilars market for the 12 months ending September 2019 was just $229 million, according to IQVIA data. This is a small fraction of the overall biologic drug market for the same period, which was valued at $9.4 billion. While Health Canada has approved 18 biosimilar biologic drugs to date only 8 biosimilars were marketed and recorded sales during the 12 months ending September 2019.

To date, biosimilars have had substantial difficulty penetrating the Canadian market for a variety of reasons, including marketing activities by manufacturers of the reference biologic drug products. Biosimilar manufacturers must also engage in more expensive detailing of biosimilars to prescribers and private and public payers in an effort to gain market entry, and are currently required by payers to provide equivalent patient support programs to those provided for the reference biologic drug.

There has been increasing recognition on the part of public and private payers that interventionist policies are needed to support the adoption of biosimilar medicines. While there were some encouraging developments in 2019 such as the biosimilar transitioning initiatives announced by British Columbia, Alberta, Pacific Blue Cross and Green Shield Canada, the future of biosimilars in Canada remains somewhat uncertain.

Biosimilar manufacturers have invested enormous resources in bringing biosimilars to market. Biosimilar development can cost US$100-$300 million and take eight years to develop and bring to market.[5] Such development is more similar to brand drug development which has been reported as being, for example, US$1.3 billion. However, in the case of biosimilars, pricing is substantially less than the corresponding reference biologic drug, and the volume of sales is trivial by comparison to the corresponding reference biologic drug.

Given the low market penetration of biosimilars in Canada, the very high development costs for biosimilars and the low risk of excessive pricing for a patented biosimilar biologic drug, it would be premature to require PMPRB reporting, and impose a further regulatory burden on this nascent product category.

The Proposed PMPRB Approach an Ineffective Price Regulation Tool

There are often multiple products of the same active substance competing in the market, including the reference biologic drug. As such, regulating patented biosimilars is not an effective way to control biosimilar drug prices as patented biosimilars make up only a portion of the market for an active substance.

[5] See: http://www.igbamedicines.org/doc/Module4.pdf

As well, subjecting patented biosimilars to the same reporting requirements as a brand patentee would limit the ability of a patented biosimilars manufacturer to compete against other manufacturers of the same medicine who do not have patents, as the other biosimilars will be free to adapt to changes in the competitive environment and in marketplace policy frameworks. This could disadvantage sponsors of patented biosimilars in relation to other biosimilar sponsors.

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

There is no known case where a patent held by a biosimilar medicines manufacturer resulted in a monopoly or conveyed pricing power. No such cases are anticipated.

In addition, biosimilar biologic drugs are not deemed to be bioequivalent to their reference biologic drugs, which creates unique challenges for market entry that are not placed on generic medicines. Reference biologic drugs sponsors can retain significant market share and undertake a range of tactics aimed at undermining biosimilar competition.

The Proposed PMPRB Approach is Misaligned with pCPA and Other Payer Objectives

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 prepared at pCPA members' request.

At a time when provinces are actively seeking to adopt policies to increase the use of biosimilar medicines, imposing PMPRB price tests for patented biosimilars is incongruent with the pCPA's focus on increasing the use of these products to provide cost savings to their drug budgets.

To take such an approach would increase costs and create a burden for some biosimilar sponsors, and could discourage some biosimilar medicines from launching new biosimilar medicines in Canada in the future. This would not be in the best interest of pharmaceutical payers.

The PMPRB Proposed Approach would Increase Complexity, Cost and Burden for Some Biosimilar Sponsors

The PMPRB's proposed approach would create reporting burdens, red tape and other potential restrictions on a patented biosimilar that would not be applicable to other biosimilar biologic drugs they are competing with in the market.

The proposed approach would increase costs for patented biosimilars and negatively impact their ability to compete with both the reference biologic drug and other biosimilar biologic drugs in the market.

And while doing this it would achieve no public policy objectives, and harm some biosimilar sponsors.

The Proposed PMPRB Approach Would Make Canada an International Outlier

Canada would be misaligned internationally if the proposed approach proceeds. Canada would be the only jurisdiction in the world that would place unique requirements on patented biosimilars that do not apply to other biosimilars. In all other jurisdictions in the world the existence of a patent is irrelevant from a pricing and market perspective.

Global biosimilar sponsors are watching developments with the PMPRB closely and with great concern. They do not understand why Canada would seek to penalize them for the existence of a patent.

The proposed PMPRB approach has ramifications beyond the narrow focus of the PMPRB that extend to all of Canada. It sends a signal to global sponsors of biosimilar biologic drugs that Canada is not serious about fostering a sustainable biosimilars market. Biosimilars Canada has been advised that placing such a barrier on some biosimilar sponsors will discourage them from launching new biosimilars in Canada, to the detriment of Canadian payers and patients.

The Proposed PMPRB Approach Discourages Innovation and Patenting

The PMPRB's proposed approach would discourage biosimilar innovation and patenting in Canada at a time when the Government of Canada, through Innovation, Science and Economic Development Canada, is seeking to attract more patents and innovation to Canada.

The Way Forward

The proposed PMPRB Guidelines as currently drafted would impose a substantial burden on patented biosimilar biologics drugs, with no benefit to Canadian consumers.

This approach is not consistent with the Canadian government's initiatives to encourage domestic R&D investments and avoid unnecessary and inefficient regulation. It also runs counter to the desire of provincial governments to increase the use of biosimilar medicines.

Biosimilars Canada submits that, for the reasons described above, it is clear that patented biosimilar biologic drugs pose a very low risk of excessive pricing in the domestic market. As

such, a practical approach would be to exempt biosimilars from full PMPRB reporting for the time being.

Precedent for complaints-based regulation has already been established through PMPRB price regulation of generic, veterinary drugs and over-the-counter (OTC) drugs. This would be a more appropriate regulatory environment, in the context of a claim of jurisdiction by PMPRB.

Such an amendment would enable the PMPRB to take a “wait-and-see” approach to the regulation of the patented biosimilar product category, and in the meantime exempt patented biosimilars from burdensome reporting requirements given the low market power of biosimilars in Canada.

While this approach would be in the best interests of Canadians, it is possible that the PMPRB will not agree to include a complaints-based policy for patented biosimilar medicines in its Compendium of Policies, Guidelines and Procedures. If such an approach is not adopted then the following framework would be more suitable for patented biosimilars than to subject them to tests and other requirements designed for patented originator medicines.

1. Domestic Price of Reference Biologic Drug is the Only Relevant Test for a Patented Biosimilar Biologic Drug

A determination of excessive pricing for patented biosimilar medicines in Canada must be tied to domestic price tests as the price of biosimilar biologic drugs, which are negotiated through the pan-Canadian Pharmaceutical Alliance (pCPA) process, are set as a percentage discount off the list price of the reference biologic drug. Biosimilars must compete domestically with this product.

If a patented biosimilar medicine is priced below the PMPRB compliant price of the brand competitor, the patented biosimilar medicine price should be compliant, with no other reporting or tests required.

2. International Price Comparisons for Patented Biosimilars Are Inappropriate

Marketplace policy frameworks 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.

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

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

Biosimilars Canada proposes that for patented biosimilars, the PMPRB should take into account the price, in Canada and in other countries, of the applicable Canadian reference product, as adjusted by CPI.

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, and to work to develop a more rational and suitable approach to the PMPRB's approach to patented biosimilar medicines that would better meet the needs of Canadian payers, patients and biosimilar sponsors.

Sincerely,

Jim Keon
President
Biosimilars Canada