Biosimilars Canada
The Voice of Biosimilar Medicines in Canada

October 28, 2016

Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Submitted via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Dear Board and PMPRB Staff,

Biosimilars Canada is the voice of Canada's biosimilar medicines industry. We represent companies that are at the forefront of the global development and marketing of biosimilar medicines.

The Patented Medicine Prices Review Board (PMPRB) has embarked on consultations with respect to changes which could be made to the PMPRB's policies, guidelines, procedures and regulatory enforcement approach.

Biosimilars Canada is pleased to have this opportunity to provide information that will be helpful to the PMPRB in considering an appropriate approach to biosimilar medicines.

We are encouraged that the PMPRB appears to be moving to more of a market-driven approach whereby analysis may be conducted through a competition vs. market power lens. It is our view that this refocusing of PMPRB mandate will naturally lead to a new and less onerous approach to biosimilar medicines.

What Are Biosimilar Medicines?

A biosimilar is a biologic drug that is approved by Health Canada that enters the market subsequent to a version previously authorized and has demonstrated similarity to a reference biologic drug. The demonstration of similarity is based upon all relevant data from non-clinical and clinical studies.

Biosimilar medicines present a significant opportunity to improve patient access to biologic therapies while addressing the cost-effectiveness demands on healthcare systems in Canada – but only if federal and provincial policies will support their approval, reimbursement and market acceptance.

Biosimilar medicines are still in their infancy in Canada, and their future in this country remains uncertain. The first biosimliar was approved in Canada in 2009 and there are now a total of five biosimilar medicines approved by Health Canada. Even so, the total domestic sales for these products for MAT June 2016 were just $7.7 million[1]. In contrast, the total biologic drug market in Canada for the same period was $5.7 billion[2]. Put a different way, after seven years experience with biosimilars they comprise less than 0.14% of the Canadian biologic drug market.[3]

How Are Biosimilar Medicines Approved?

While sponsors of biosimilar medicines must file New Drug Submissions with Health Canada, the data and other information that Health Canada requires a biosimilar to sponsor to file is different than that of a new innovative drug.[4] A biosimilar medicine is approved by Health Canada as being similar to a reference biologic drug, with no clinically meaningful differences to the reference biologic drug, based on the totality of evidence provided.

Biosimilars sponsors are required to navigate the domestic intellectual property framework for pharmaceuticals, which applies equally to synthetic and biologic molecules. This includes data protection, the patent linkage system with 24-month automatic injunction against competition, and the risk of post-launch patent infringement actions.

Canadian Agency for Drugs and Technologies in Health (CADTH) also has different health technology assessment submission requirements and criteria for biosimilars[5] than for innovative new drugs.

In addition, the pan-Canadian Pharmaceutical Alliance (pCPA) conducts biosimilar price negotiations and has published First Principles for Biosimilar Price Negotiations[6]. The pCPA is currently developing an even more comprehensive biosimilar price negotiation framework. The pCPA has clearly stated that prices for biosimilar medicines will be 1) negotiated collectively through the pCPA and 2) will be transparent.

[1] IMS Health data.
[2] IMS Health data.
[3] IMS Health data.
[4] http://www.hc-sc.gc.ca/dhp-mps/brgtherap/applic-demande/guides/seb-pbu/seb-pbu_2010-eng.php. Health Canada has consulted on revisions to this guidance document, and has publicly indicated plans publish revised Guidance for Sponsors in November 2016.
[5] https://www.cadth.ca/media/cdr/process/CDR_Submission_Guidelines.pdf, pages 25-32.
[6] http://canadaspremiers.ca/phocadownload/pcpa/2016/seb_first_principles_20160401.pdf

Canada Viewed Internationally as a High Barrier Market for Biosimilars

The uptake of biosimilar medicines in Canada has been very slow. The Canadian biosimilars market is perceived internationally as an uncertain one with high barriers to entry. Additional layers of reporting and other requirements by the PMPRB for biosimilar medicines would be yet another barrier to an already fragile and tenuous situation.

- The current pan-Canadian Pharmaceutical Alliance (pCPA) price negotiation process is slow and bureaucratic. There is no priority for these competing products that have the potential to generate significant savings. It can take a biosimilar a year or longer to be listed on a provincial formulary, which is needed to ensure the sponsor can effectively sell its product and gain market share.

- Private plans typically follow provincial formulary listing decisions. Delays in the pCPA therefore create a corresponding delay in access with private insurance plans.

- Delays are providing opportunity to deploy aggressive tactics aimed at retaining market share and undermining the potential adoption of biosimilars.

- Canada has a complex and uncertain pharmaceutical intellectual property regime that allows originators to launch an infringement action following a patent linkage proceeding.

Biosimilars and Patents

A recent Federal Court of Appeal decision[7] confirmed the PMPRB's jurisdiction over patented generics. These cases have been followed closely by biosimilar medicines sponsors and with concern.

Some biosimilar medicines may be associated with a patent or patents, in ways that are similar to how a generic medicine may be associated with a patent. A biosimilar medicine may be associated with a patent through a cross-license arrangement or a patent may be granted to a biosimilar sponsor for a process innovation.

Biosimilar patents do not confer market power, as biosimilars are approved based on similarity to a reference biologic drug which is already subject to PMPRB oversight. In addition, biosimilar medicines are subjected to strict pricing requirements as negotiated through the pan-Canadian Pharmaceutical Alliance (pCPA).

Biosimilars Canada is aware that some biosimilar sponsors may not be filing patents in Canada that have been filed in other jurisdictions specifically due to the current uncertainty regarding the approach of the PMPRB and whether the medicine could be subject to the same onerous reporting requirements as innovative drugs. This chill on patent filings for biosimilar medicines is

[7] Canada (Attorney General) v Sandoz Canada Inc, *2015 FCA 249*.

concerning to Biosimilars Canada, and runs counter to both the objectives of the Government of Canada's Federal Innovation Agenda and the strategic industrial competitive interests of sponsors.

Recommended Approach for Biosimilars

The PMPRB regime was created to limit the prices set by patentees of brand drugs sold in Canada, to ensure that those prices are not excessive.

Biosimilars are not new innovative drugs, and any patents sponsors may have do not confer market monopoly power. They are medicines approved as being similar to an innovative reference biologic drug.

Consumer price protection is not an issue with respect to biosimilars as the prices in Canada are already heavily regulated. Instead, biosimilars present an important solution to patient access and the affordability of biologic medicines.

As described above, there are already many barriers to bringing a new biosimilar medicine to the Canadian market. Our members already have tremendous challenges in building a business case for their headquarters that will lead to a decision to bring a new biosimilar medicine to Canada. The current PMPRB approach represents unnecessary and duplicative red tape that is yet another domestic deterrent for sponsors of biosimilar medicines.

If the PMPRB must have a system in place for biosimilars, Biosimilars Canada recommends that a complaints-based approach be taken, similar to the well-established systems for veterinary and over-the-counter drugs.

This complaints-based system should only trigger a review if the following criteria are met:

- a complaint is received by the PMPRB regarding the pricing of the Patented Biosimilar Drug;
- the Patented Biosimilar Drug is the only one available on the market (i.e. no other biosimilar or brand drug available);
- the price is higher than the highest (historical) brand price, adjusted for CPI increases over the years as permitted by the pCPA and formulary rules; and
- the Patented Biosimilar Drug is non-compliant with pCPA or provincial formulary pricing, including any price increases permitted within those regimes.

It is also important to note that international price comparisons for biosimilar medicines are problematic as the same products are often not available in other jurisdictions. It is also the case that some indications may not be available in one jurisdiction or another due to intellectual property considerations.

In addition, patient support programs in Canada create barriers and costs for biosimilar sponsors in Canada that do not exist in other jurisdictions and must be factored in to domestic

pricing for biosimilars. Biosimilars may well require higher prices in Canada than in other jurisdictions in order to compete within the confines of the market framework for biologic drugs that has developed over the years, complete with the expansive patient support programs Canadian patients and clinicians have come to expect.

Conclusion

The approach taken by the PMPRB to patented biosimilar medicines should be given careful consideration. Applying the same framework as for originator products is not an appropriate approach for these products, which are poised to provide tremendous value to the Canadian patients and the Canadian health care system.

A complaints-based approach to biosimilars that is triggered only if specific criteria are met would be the most appropriate approach for the PMPRB to pursue given the unique considerations associated with biosimilar medicines, and given the new market-driven approach to regulation that has been signalled by the PMPRB to ensure the best targeting of its resources.

On behalf of Biosimilars Canada and its member companies I would like to thank you for taking the time to review this submission. We would welcome the opportunity to meet with the PMPRB and its Board to discuss in greater detail.

Sincerely,

Jim Keon
President
Biosimilars Canada