

CSL Behring Canada
55 Metcalfe St., Suite 1460
Ottawa, ON K1P 6L5
Tel: 613-232-3111
www.cslbehring.com



February 06, 2020

Doug Clark
Executive Director
Patented Medicine Prices Review Board
Standard Life Centre, Suite 1400
333 Laurier Avenue West
Ottawa, Ontario K1P 1C1

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

RE: PMPRB Draft Guidelines Consultation

Dear Mr. Clark:

As the PMPRB works to update its Guidelines following the August 2019 amendments to the *Patented Medicines Regulations*, CSL Behring Canada Inc. ("CSL Behring") would offer a number of specific comments and recommendations for the Board's consideration in respect of our unique product portfolio and the realities of the market dynamics affecting our business operations in Canada.

By way of background, CSL Behring is a global biotechnology leader offering the broadest range of quality plasma-derived and recombinant therapies in our industry. These specialized therapies are used to treat a range of rare and serious conditions, including immunodeficiency and other autoimmune diseases as well as hereditary and acquired bleeding disorders. Importantly for the mandate of the PMPRB, many of our products are not patent-protected and thus fall outside of the PMPRB's jurisdiction. Other products have patent protection and fall within Board jurisdiction.

In Canada, plasma protein therapeutics are subject to robust procurement mechanisms administered exclusively by two established government-appointed agencies: Canadian Blood Services (CBS) and Héma-Québec. Embedded within our publicly-funded healthcare system, each agency employs sophisticated forecasting, inventory management and purchasing tools, including product tendering, to obtain optimal value for Canadian patients and Provincial and Territorial health budgets. In short, the market power for pricing and reimbursement of plasma protein therapeutics in Canada is actively managed and rests exclusively with CBS and Héma-Québec.

Irrespective of patent protection, the wider supply and market dynamics for these therapies as a category functions in a very different manner than the majority of other prescription medicines.

The global manufacturing and supply chain infrastructure required to support global markets, including Canada, is extensive and highly complex and specialized because of the nature of these products. CSL Behring is proud to have developed one of the largest and most efficient plasma collection networks at a global scale, which serves as our operational platform to provide safe and effective medicines for our patients around the world. While globally, both countries and industry are seeking to increase their plasma collection efforts, the current reality is that it can take up to two years from the time plasma is collected until it becomes one of the life-saving medicines that patients rely on.

As illustrated in the most recent CBS Immunoglobulin (Ig) tender process, the company that won the tender has encountered an issue in supplying the Canadian market, which has created some disruption. We would raise a serious concern about any policy change impacting tendered products which may discourage market participants from participating in procurements, exacerbating any fragilities in the overall product supply chain. Irrespective of PMPRB, a reduced level of competition in these procurements would not serve the interests of the Canadian taxpayer or the Canadian patients dependent on these therapies.

Over and above our investments in continued product innovation and capacity, the balance between supply and demand continues to evolve for all the market participants in our sector. Jurisdictions often compete fiercely to secure incremental but finite product supply as stakeholders work to anticipate and match product inventory with growing clinical demands for patient care. While the scale of investments is substantial, it is important to acknowledge the reality that lead times for bringing any new sources of supply to market are necessarily lengthy as a function of manufacturing requirements and associated regulatory requirements and scrutiny.

As the Canadian affiliate for CSL Behring, we are working on a continual basis to address Canadian market requirements with any available capacity in our global network. At all times, CSL Behring is committed to the highest standards of patient safety, product quality and is regularly engaged with Canadian agencies, such as Health Canada during the aforementioned supply problem, on a range of these issues related to supply and market requirements. Given the operational and structural realities of our industry and the markets we serve, CSL Behring regularly reminds stakeholders that any perceived or actual impediment in the Canadian system, including new regulatory burdens or other sources of operational and compliance uncertainty, only serve to reduce Canada's competitiveness. This in turn may impact our ability to respond to unanticipated Canadian demands in a complex and rapidly changing global marketplace.

CSL Behring

Accordingly, CSL Behring recommends that PMPRB explicitly account for the unique nature of the plasma products industry within its Guidelines in a proportionate and appropriate manner. Given the high degree of complexity of the plasma protein market and the commensurate expertise that is required, we recommend excluding these products from the new price determination factors and to minimize the overall compliance burden for patentees where products fall in the PMRPB's purview. CSL Behring accepts the PMPRB's ongoing requirement for regular reporting of any in-scope products and has no objection to maintain that obligation on a comparable basis going forward. However, the additional compliance burden of the application of new price determination factors is unwarranted given the well-established and complex reimbursement system currently functioning in Canada to manage all aspects of product supply and pricing.

We appreciate your consideration of these important issues for our industry and Canadian patients. Should Board staff have any questions regarding this submission or CSL's Canadian business, please do not hesitate to contact me directly at 613-232-5957, philippe.hebert@cslbehring.com.

Sincerely,



Philippe Hebert,
General Manager,
CSL Behring Canada