CSL Behring

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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 (Version October 2022)

Dear Mr. Clark:

In respect of the current draft Guidelines consultation, CSL Behring Canada Inc. ("CSL Behring") appreciates the opportunity to provide our comments and recommendations for consideration. This is further to our submissions to prior Board consultations, and is consistent with of all current public policy, legal and operational implications of the draft Guidelines. CSL Behring is also pleased to endorse the concurrent submission of our trade association, BIOTECanada on this matter. Our comments in the foregoing are additional and specific to CSL Behring's business in Canada.

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 autoimmune diseases and 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. However, CSL Behring does market products with patent protection which thus fall within Board jurisdiction.

As we have communicated to the Board in the recent past, we would reiterate the fundamental reality of the Canadian market and reimbursement landscape for many of our products. Currently, plasma protein therapeutics are subject to robust procurement mechanisms administered exclusively by two established public agencies: Canadian Blood Services (CBS) and Héma-Québec. Each agency is a direct extension of and accountable to our public healthcare system. Each agency also employs sophisticated forecasting, inventory management and purchasing tools, including competitive product tendering, to obtain optimal value for Canadian patients and Provincial and Territorial health budgets. In this manner, the entire market structure and dynamics for the pricing and reimbursement of plasma protein therapeutics in Canada is actively and exclusively managed by CBS and Héma-Québec.

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The advanced manufacturing and supply chain infrastructure required to support global markets, including Canada, is extensive and highly complex for our product areas. While CSL Behring continues to invest in our therapeutic innovation and worldwide industrial capacity, the overall balance between supply and demand remains relatively narrow for our entire industry. Canada is not unique in having to anticipate and secure sufficient product inventory to respond to evolving clinical requirements.

While the current draft Guidelines propose differential treatment (complaints only) for vaccines, biosimilars and over the counter (OTC) products, comparable treatment is not extended to plasma protein products. This lack of recognition does not adequately reflect the procurement reality occurring at CBS or Héma-Québec and the consequent market risk for Canadian stakeholders. Similar arguments as would support treating those other categories of products on a complaints-only basis extend and apply equally to the plasma protein therapeutics market. Given the current proposals, there is no rationale or argument offered to not manage plasma protein products in a similarly proportionate, risk-adjusted manner. In addition to policy consistency, this adjustment would allow Board resources to be directed towards other higher-need areas of investigation.

Therefore, CSL Behring strongly encourages the Board to reconsider the treatment of plasma protein therapeutics in the draft Guidelines and move to ensure the inclusion of plasma protein products in the class of “complaints only” medicines for the purposes of triggering PMPRB investigations. This would be a proportionate and appropriate approach consistent with the Board’s proposed treatment of other low-risk product categories.

Reflecting on the overall direction of these proposals, the draft Guidelines appear to be moving towards a much more active and discretionary price management approach. This is a distinct and unfortunate departure from the Board’s established practice of promoting consistency in enforcement based on clear, up-front expectations and a demonstrated openness to and promotion of voluntary compliance. The draft Guidelines also reduce the recognition of innovation entirely in favour of a regressive therapeutic class comparison approach.

This is a regrettable and unwarranted shift in focus. Not only is this a clear departure from the Board’s mandate to regulate non-excessive prices, but the draft Guidelines would also introduce new and avoidable uncertainties for the Canadian market with highly probable impacts on launch decisions for new therapeutic innovations. Medicines for rare diseases, an area which the Government of Canada has separately placed some level of policy focus and financial resources against, would be heavily and negatively impacted by the Board’s proposals. The absence of any detailed impact assessments raises the real possibility of moving towards a volatile future launch environment with untold consequences.

Simply put, Canada cannot afford to transition to a “case-by-case” negotiated compliance system given our global position and the nature of medical innovations on the horizon, particularly relevant for the areas of curative or precision therapies. We would therefore strongly encourage the Board to step back and reconsider this consequential operational approach and take the necessary time to design a modern, efficient, and fit-for-purpose compliance system consistent with the Board’s mandate, recent jurisprudence, and the stated policy intent of the Government of Canada to bring certainty and a predictable investment environment to the Canadian life sciences sector.

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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 philippe.hebert@cslbehring.com.

Sincerely,

Philippe Hebert
General Manager

CC
Dr. Graham D. Sher, Chief Executive Officer, Canadian Blood Services
Mrs. Nathalie Fagnan, President and Chief Executive Officer of Hema Quebec