November 6, 2020

Mr. Ron McKinnon, M.P.
Chair, Standing Committee on Health (HESA)
House of Commons
Ottawa ON K1A 0A6

Submitted online via portal.

RE: CSL Behring Canada Inc. comments to the House of Commons Standing Committee on Health regarding the Patented Medicine Prices Review Board's Final Guidelines

Dear Mr. McKinnon,

On behalf of CSL Behring Canada Inc. ("CSL Behring"), I appreciate the opportunity to provide the Standing Committee on Health (HESA) with our comments in response to the final Patented Medicine Prices Review Board (PMPRB) Guidelines as released on October 23, 2020. Given the significant implications of these changes for Canadians, we welcome the Committee's interest in and examination of this important topic.

As background, CSL Behring is a global biotechnology leader offering the broadest range of quality plasma-derived and recombinant therapies in the industry. Our innovative products 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.

Plasma protein therapeutics are highly specialized and quite distinct from other medicines used in Canada in a number of important respects. Most importantly, plasma protein products are subject to robust procurement mechanisms administered exclusively by Canadian Blood Services (CBS) and Héma-Québec as extensions of Canada's publicly funded and administered healthcare system. Each agency manages its product procurements in a highly structured manner, through the use of extensive tendering approaches, demand forecasting and ongoing inventory management.

This existing procurement framework centralizes and concentrates purchasing power with Provincial and Territorial health systems. It is a key pillar of delivering coordinated and financially sustainable patient care across many health conditions. This process has evolved over time and allowed Canada to secure tangible value and appropriate supply arrangements for Canadian patients.

We encourage HESA to note the global market dynamics for plasma protein therapies, which are also quite distinct from most other types of medicines. Manufacturing and supply-chain

issues occupy an even more crucial role in developing and delivering our therapies around the world. CSL Behring is proud of our significant investments in our global supply chain, which stands as a best practice for our industry. Our manufacturing infrastructure is extensive and subject to the highest quality tolerances and international regulatory compliance.

At the same time, we must acknowledge the fundamental reality that despite global efforts to increase plasma collection from donors, it can still take up to two (2) years from initial collection to finished products being made available to patients. Jurisdictions including Canada continue to compete aggressively for any incremental increases in global supply, which require significant lead times to bring online. We are challenged on an ongoing basis to anticipate and plan for shifts in market demand – reinforcing the imperative of strong dialogue with our partners.

This is relevant context for assessing both the impact and operational feasibility of the PMPRB Guidelines. As a general observation, we remain concerned about any Canadian policy change which introduces additional barriers or compliance uncertainty for our already highly regulated and centrally managed product portfolio, some of which may fall under the PMRPB's jurisdiction.

Overall, the final Guidelines remain highly complex. They will introduce a destabilizing element of increasing PMRPB staff discretion in key areas such as investigator powers and the determination of levels of therapeutic improvement. The final Guidelines do make limited reference to the differential nature of both vaccines and plasma protein products. This is an important reflection of the Canadian reality, but unfortunately still falls well short of what would be appropriate to the established market and pricing context for these products. Simply making this consideration available to Board staff within an active investigation context is insufficient and provides no meaningful recognition of the distinct nature of this product category and the extensive reimbursement system which has evolved in Canada to manage their purchase and distribution.

CSL Behring strongly urges HESA to recognize clearly the distinct nature of the plasma protein product category and recommend a completely separate, proportionally risk-based approach within the Guidelines. The goal should be to reflect structural market realities and to minimize unwarranted barriers to the Canadian market, while retaining the appropriate level of PMPRB oversight in the event it is ever required to meet its mandate.

We accept the PMPRB's ongoing requirement for regular reporting of any in-scope products, and we have no objection to maintaining that obligation for plasma protein patentees in the future. However, the absence of an appropriately distinct approach to plasma protein therapeutics, combined with the extraordinary increase in complexity and compliance burden placed on all patentees in the final Guidelines, creates unhelpful distractions and new barriers to continuing our legacy of close collaboration with our health system partners in Canada, notably Canadian Blood Services and Héma-Québec.

We appreciate HESA's careful consideration of this submission. With HESA's direction and recommendations, we remain hopeful that the PMRPB can fully account for the important differences of the plasma protein products marketplace in Canada and properly reflected in its Guidelines at the earliest opportunity.

Sincerely,

Philippe Hebert
General Manager
CSL Behring Canada Inc.