Submission by:
Canadian Health Coalition
116 Albert St. Suite 300
Ottawa, Ontario K1P 5G3

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Good afternoon,

On behalf of Pauline Worsfold, RN, I am pleased to provide you with the Canadian Health Coalition's response to the questionnaire. We have registered for the Stakeholder Engagement dialogue session for January 19, 2022.

Please feel free to contact me if there is anything else required.

Regards,

Steven Staples

Steven Staples
National Director of Policy and Advocacy
Canadian Health Coalition
Policy@healthcoalition.ca
m 343-777-6283

Topic 1: Patient need – To ensure an adequate supply of immunoglobulin for Canadian patients who rely on this therapeutic product; to create certainty and security of domestic supply

Question: In a post-pandemic world, what value do you place on domestic security of supply of immunoglobulin?

Security of Canada's domestic supply is crucial and must address combined security and safety of supply specifically at times of contingency/crisis affecting global supply due to new pathogens such as prions.

As the COVID-19 pandemic demonstrates, global supply chains are vulnerable to multiple failure points, and cannot be Canada's main source of critical health items such as Immunoglobulin (Ig). Given the global shortage of plasma to make Ig, it is critical that CBS accelerate the implementation of its plan to increase voluntary plasma collection to achieve greater sufficiency.

As the COVID-19 pandemic also demonstrates, we must anticipate unknown new pathogens arising via non-human species. The drive to increase plasma collection should not compromise CBS's commitment to unpaid blood and plasma donations. Plasma collection should remain guided by the principles of the Krever Commission for Canada's national blood supply including that blood is a public resource and donors should not be paid. This is in line with the Expert Consensus Statement on achieving self-sufficiency in safe blood and blood products, based on voluntary non-remunerated blood donation issued

by the World Health Organization in 2012[1]. These measures will help ensure greater domestic security and safety of Ig supply and maintain the viability and safety of Canada's blood and plasma supply.

Question: How does security of domestic supply of immune globulin directly impact the patient population you represent?

CHC's mission to protect and improve public provision of health services to all Canadians patients via Medicare includes CBS's provision of blood, plasma and plasma products for emergency conditions and for ongoing medical care. The manner in which CBS plans for security of immunoglobulin supply impacts both the safety and security of Canada's entire supply of blood and plasma.

Topic 2: Sustainability and affordability of the system – To deliver an adequate supply of immunoglobulin for Canadian patients at an affordable cost to Canadian healthcare systems:

Question: What should be considered when determining "adequate supply of immunoglobulin"? A. From your patient population's perspective? B. From a system-wide perspective?

From a system wide-perspective, to determine what constitutes an adequate supply of immunoglobins CBS must

[1] provide the current conditions of Ig usage, including misuse and lack of standards for use,

[2] estimate the anticipated increased future Ig demands, and install mechanisms to identify and measure real-time trends in usage,

[3] evaluate the usage needed in contingency conditions to sustain [not enhance] Canadian lives during a sudden reduced availability of international product, especially US product, [Estimates suggest 25 to 50 % of Canada's current usage is required to keep patients with severe immune deficiency alive]

[4] urgently establish mechanisms to identify and monitor the ongoing purposes and volumes of immunoglobin product provided by CBS to Canadian health care providers and institutions,

[5] establish or facilitate standards of care for use of immunoglobulins, including triage use in contingency conditions of new pathogens, and

[6] proactively communicate the detrimental impact of commercial collection of plasma in Canada on the safety, security and contingency planning for collection of not only adequate plasma for immunoglobulins, but also for blood and plasma broadly.

Question: What should be considered when determining "sustainability"? A. From your patient population's perspective? B. From a system-wide perspective?)

The factors applicable to adequacy of supply of immunoglobulins noted above apply to sustainability [ie adequacy overtime and in crisis conditions]. In addition, to achieve long-term sustainability CBS must advocate and support research initiatives to develop new technology for the manufacture of plasma protein products by alternative, non-plasma-dependent processes, such as recombinant technology.

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[1] "Expert Consensus Statement on Achieving Self-Sufficiency in Safe Blood and Blood Products, Based on Voluntary Non-Remunerated Blood Donation (VNRBD)*" (World Health Organization, June 2012).

Topic 3: Management opportunities – Various approaches are available to mitigate the risks, including but not limited to: increasing plasma collection, purchasing more immunoglobulin, commercial sector contributing to plasma sufficiency, and/or optimizing evidence-based utilization.

Question: What considerations should be kept in mind as these ideas are pursued on their own or in combination?

Increased voluntary plasma collection in Canada is crucial and requires public engagement, earned via CBS transparency and demonstration of CBS commitment to its public good [non-commercial] mandate.

Purchasing more Ig made from commercially sourced plasma is acceptable only to the extent that CBS fails to collect voluntarily collected plasma adequate for self-sufficiency needs. Purchase of Ig must not become the driver for acceptance of commercially collected plasma.

Installing mechanisms to achieve evidence-based utilization of immunoglobulin in Canada is the most urgent measure to advance Ig self-sufficiency. Canada is misusing immunoglobulins, as the 2nd highest user world-wide due in large part to the lack of institutional/hospital control over the prescribing of Ig.

In the longer term, as noted, **to achieve sustainability CBS must advance research initiatives to develop new technology for the manufacture of plasma proteins by alternative, non-plasma-dependent processes, such as recombinant technology**.

CHC strongly opposes "Commercial sector contributing to plasma sufficiency". This adds danger to plasma products during a time of new pathogen contingency. If CBS combines higher-infectious-risk commercially collected plasma with the voluntary lower-risk plasma during fractionation by contract, Canadians lose the safeguard of sequestered lower-risk voluntarily-collected plasma so crucial in the event of a new unknown blood-borne pathogen not amenable to pathogen deactivation procedures in the fractionation process.

Combining purchased commercial plasma with voluntary plasma for fractionation would be cheaper, but would forsake an important safeguard in the advent of a new non-heat-treatable pathogen, such as a prion.

Thank you very much for your participation.
We look forward to working with you in January 2022!