



CANADIAN SOCIETY OF ALLERGY AND
CLINICAL IMMUNOLOGY
SOCIÉTÉ CANADIENNE D'ALLERGIE ET
D'IMMUNOLOGIE CLINIQUE



Network of Rare Blood Disorder
Organizations
Réseau des Associations Vouées
aux Troubles Sanguins Rares



Association of Medical Microbiology
and Infectious Disease Canada
l'Association pour la microbiologie
médicale et l'infectiologie Canada

December 5, 2017

Dr. Graham D. Sher
Chief Executive Officer
and Canadian Blood Services Board of Directors
Canadian Blood Services
1800 Alta Vista Drive
Ottawa, Ontario, K1G 4J5

Dear Dr. Sher,

As a group of Canadian specialists in Immunology, Infectious Disease and Hematology, we are responding to your letter of October 31, 2017 announcing the Plasma Protein Products Request for Proposal Results. Specifically, there is to be a transition away from CSL's subcutaneous immunoglobulin (SCIG) Hizentra to Shire's 20% SCIG formulation, Cuvitru. The proposed change is to take effect by April 2018. Intravenous immunoglobulin products (IVIG) will also undergo significant changes with a decreased number of options. The rationale for this transition, as stated in your letter, is substantial cost reduction for CBS. While we understand the importance of fiscal responsibility, and appreciate CBS's commitment to this principle, we would like to express our concerns, with various aspects of the proposed changes.

Immunodeficiency affects people of all ages and is associated with significant morbidity. Our patients depend on immunoglobulin replacement, either SCIG or IVIG as their primary treatment. It is critical that some access to multiple products in both modalities be maintained, as not all patients tolerate a particular product/method. With the current tender decision, opportunities to maintain and expand this flexibility have been lost, especially with SCIG. The new RFP also eliminates the possibility of providing frail patients with the choice of pre-filled syringes, which while costly, may have allowed them to start the in-home use of SCIG which may reduce the use of hospital resources.

Transitioning all SCIG patients to a new product will have an additional and significant impact on health care delivery as these patients will need medical visits to explain these changes, address their concerns, obtain informed consent, and receive training.

The timelines to enable this transition seem quite tight, even with the assurance of industry to have a fully functional industry-supported transition program in place for the new products. Finally, by relying on a decreased number of products (especially with respect to SCIG) we are deeply concerned about the safety of supply. Lack of supply of individual products has happened frequently in the past--as recently as five years ago in the US. It is not feasible to expect patients to move between SCIG and IVIG should that occur.

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As such, we ask:

For the safety of supply, and to cover patients who may not tolerate switching SCIG products, we request some ability to access other SCIG products, including for those that could leave hospitals by switching to pre-filled syringes, all while still taking into account the fiscal responsibilities that CBS has.

That the transition timeline be extended to take into account clinical/practical realities and to mitigate patient risks: this is the largest transition in history of patients from one immunoglobulin product to another.

That CBS provide financial support to ensure that this transition takes place in a safe and organized manner. This transition will require multiple interactions between patients, health care providers, and blood bank personnel, not to mention staff training. Such interactions come with a price, which may have been included in CBS's cost analysis.

That CBS involve in their future deliberations a broader grouping of physicians who are experienced with these clinical populations and that, now and in the future, CBS consider the impact of their decisions on patients and the health care delivery system, before these decisions are made.

We look forward to further discussions, and would be happy to provide our co-operation and input going forward.

Regards,



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