



CBS Board Statement

June 20th, 2019

Toronto, Ontario

Good morning. Thank you ladies and gentlemen of the board, Mr. Chair, and the executive with us today. Thank you once again for the opportunity to address the board on these important issues facing the immunodeficiency patient population.

Our patient population is life dependent on IG, with no alternatives available. While global conversation continues around securing supply to IG, it is our responsibility at CIPO to ensure that primary immunodeficiency patients in Canada have a continuous access to IG.

It doesn't stop there, however. It is not enough to ensure that PI patients have access to IG therapy. It is our responsibility to ensure that PI patients have access to their method of treatment of choice and their product of choice. It is the treating specialist's responsibility to provide the best treatment for the patient. And furthermore, it is CBS' responsibility to provide that continuous access and ensure that there is a continuous supply of IG in Canada.

Today we have a problem in the system, one which could have potentially been avoided. For the first time in Canada we are experiencing a shortage in IG therapy. This was partially due to an increase of 50% in home use. However, we need to keep in mind that total IG use has remained steady, growing at 8-9% a year. This would imply that the massive 50% increase is due to patients moving from hospital to home therapy, a transition that makes sense on so many levels.

In December 2017, we addressed this board about the growth of SCIG, and the push to move patients to home care. It is beneficial to patients, hospitals and provinces. SCIG allows patients with compromised immune systems to stay out of the hospital environment, freeing up costly bed space, saving the hospital and province healthcare dollars. It is a win, win, win. General treating protocols have been moving towards SCIG first, then IVIG, due to decreased side effects and adverse events with SCIG.

So, what happened this year? Why, when in 2017, we were at 25% did it rise to 50%? There were a few things. First, a positive recommendation from the Ontario Health Technology Assessment Committee for SCIG did not go unnoticed. Ontario has the largest population in Canada, and coming out of this recommendation, there was a huge uptake in patients transitioning from IVIG to SCIG in Ontario. Second, the Health Canada indication approval of Chronic Idiopathic Demyelinating Polyneuropathy (CIDP) for SCIG. This indication allowed for

large dose neurology patients to come into home infusion. These were two big factors that led to a dramatic change in already increasing change from IVIG to SCIG.

From what we currently understand, there are approximately 500 patients waiting to start their training for home IG therapy and CBS can expect anywhere from 600-800 new SCIG patients in 2020, as we continue to see patients choose home therapy over IVIG.

We ask this board to ensure that immunodeficiency patients have long term continued access to SCIG.

We ask this board to expect the trend of patients choosing home infusion to continue to grow.

We ask this board to ensure that all immunodeficiency patients have access to home therapy.

We ask this board that an alternate product be made available to ensure that this situation does not happen again.