

**Expert Panel on Immune Globulin Product Supply and Related Impacts in Canada
REQUEST FOR INPUT: PATIENT / PRODUCT USER GROUPS SUBMISSION**

The Canadian Immunodeficiencies Patient Organization (CIPO)

1. Contact for submission: Whitney Goulstone, Executive Director
whitney.goulstone@cipo.ca
2. Our organization represents patients living with primary immunodeficiencies diseases (PI). CIPO's membership is over 1600 patients, care givers and healthcare professionals across Canada. PI consists of over 340 different genetic disorders is categorized by specific abnormalities or defects of the immune system. PI patients are born with part of their immune either broken or not working properly. For the majority of these patients, Immune Globulin replacement (IG) therapy remains the only option. Ig therapy given intravenously (IVIG) or subcutaneously (SCIG) is required in patients with certain PI diseases "characterized by absent or deficient antibody production and, in most cases, recurrent or unusually severe infection ... Replacement therapy for agammaglobulinemia and hypogammaglobulinemia in well-described immunodeficiencies such as Xlinked agammaglobulinemia (XLA) or common variable immunodeficiency (CVID) is necessary and life-saving" (Elena E. Perez, 2017).

Due to the continual life-long use of IG for PI patients, and the growing PI population (see point 3), CIPO advocates strongly for a diverse and sustainable supply of plasma and products in Canada.

3. Canada unfortunately does not have a patient registry for Primary Immunodeficiency (PI) despite efforts made by Dr. Christine McCusker at McGill University.
 - The most recent data from the Immune Deficiency Foundation in the United States, states that the relevance of PI is far more than estimated at 1 in 12,000 (IDF, 2017). A new study done at McMaster University concludes that there are 5,354 new PI cases annually in Canada (Robert B. Hopkins, 2017). Primary immunodeficiency affects roughly 50,000 Canadians, although %70 remain underdiagnosed (IPOPI, 2016).
 - 93% of diagnosed immunodeficiency patients in Canada are currently accessing this life-saving treatment (Tough, 2017)
 - IVIG and SCIG products are currently purchased by CBS and covered by the provinces. The current cost to patients is the ancillary supplies in home therapy.

- CIPO does track clinical trials relating to PI. Current and recent Health Canada trials have primarily been in SCIG domain. There have been a few in the rarer conditions.
4. CIPO does have a formal policy statement on compensated plasma. We have attached it to this submission. This statement reflects our advocacy efforts for sustainability and diversity of products and supply in Canada.
 5. The results of the CIPO membership survey of 2016 show that patients do not choose their method of treatment. Currently, among PI patients %51 are using SCIG and %42 IVIG (Tough, 2017).
 - This number is increasing each year in conjunction with the 5,354 newly diagnosed cases annually.
 6. Canadian Blood Services currently only supplies %17 of Canadian plasma needs and that number is expected to drop to %9 by 2021 if the collection does not increase dramatically. We support CBS' current proposal to increase plasma production in Canada to %50 sustainability within 5 years. We believe however, that it is an ambitious goal, and even unsustainable unless a compensation model is used in conjunction with the current volunteer donor model.
 - There has been a compensation model co-existing with the volunteer donation model in Manitoba for the past two decades, without any direct negative impact to the voluntary donor pool. They have shown to pull from two very different donor bases, those wishing for compensation and those wishing to "do good".
 - Since the safety of the industry and the end-products are no longer an issue, is the issue of compensation an ethical issue in Canada? Patients are already receiving product that is made from plasma from compensated US donors. It is CIPO's position that Canadian patients would rather receive Canadian plasma from compensated Canadian donors than US plasma from compensated US donors.
 - CIPO, and our international associations, are aware and concerned about the potential usage in China and India and growing awareness and diagnosis emerges. The US currently produces %80 of the world's plasma supply.

CIPO's position is fully in the best interest of PI patients in Canada for a sustainable and diverse supply of IG therapy and products.