

FINAL REPORT  
NOVEMBER 20, 2018



PRESENTED BY:  
CANADIAN IMMUNODEFICIENCIES PATIENT ORGANIZATION

IG TRANSITION REPORT

## IG TRANSITION BACKGROUND

Due to recent outcomes in the latest Canadian Blood Services RFP, patients currently using CSL's Hizentra for subcutaneous immunoglobulin (SCIG) home infusion, will be transitioned to Shire's Cuvitru. Cuvitru is a new product to the Canadian market. There are roughly 3000 patients using Hizentra in Canada.

Patients using Intravenous Immunoglobulin (IVIg) in hospital will also have some mandatory changes to their products as well, however this report will only be looking at the impact to SCIG Primary Immunodeficiency patients in Canada.

### TRANSITION

| PPP Mix 2013-2018 | Sizes                          | PPP Mix 2018-2021(23) | Sizes                          |
|-------------------|--------------------------------|-----------------------|--------------------------------|
| Gamunex           | 2.5g, 5g, 10g, 20g             | Gamunex               | 2.5g, 5g, 10g, 20g             |
| IVIGnex           | 20g                            | IVIGnex               | 20g                            |
| Privigen          | <b>2.5g, 5g, 10g, 20g, 40g</b> | Privigen              | 10g, 20g                       |
| Gammaguard Liquid | 5g, 10g                        | Gammaguard Liquid     | <b>2.5g, 5g, 10g, 20g, 30g</b> |
| Panzyga           | 2.5g, 5g, 10g, 20g, 30g        |                       |                                |
| Hizentra          | 1g, 2g, 4g, 10g                |                       |                                |
|                   |                                | Cuvitru               | 1g, 2g, 4g, 8g                 |

## IG TRANSITION BASICS

With almost 3000 SCIG patients transitioning from Hizentra to Cuvitru, this is the largest SCIG transition globally in history, with potential savings to the health ministries of the provinces of up to \$498 million over three years.

The transition began in April 2018 and was originally forecast to complete in September 2018, but will most likely be complete in December 2018.

## CIPO ENGAGEMENT

CIPO became involved to facilitate ease of transition for patients and caregivers, expecting difficulties and frustrations from the primary immunodeficiency community due to the scale of the transition.

CIPO engaged in many ways throughout the transition process. Including: taking part in the Canadian Blood Services RFP for Plasma Protein Products, taking part in a transition planning meeting in December 2017, coordinating and facilitating transition events across Canada for patients and families, holding two webinars, sending out monthly transition newsletters to our members, following up with clinics, collecting data regarding the transition and writing a report.

### IG TRANSITION GOALS

- CIPO's goal throughout this transition was to assist patients and caregivers, physicians and healthcare providers to ensure that the transition was being executed in the best possible way for the patient's interests and health experience.

### IG TRANSITION EVENTS

CIPO coordinated IG transition events in several cities across Canada to better educate patients and carers in regards to the upcoming transition. Events were coordinated with local treating specialists and Canadian Blood Services. A member from the OnePath Patient Assistance Program was in attendance and where possible, a transfusion medicine specialist and the local infusion nurse.

#### TEAM ROLES AND RESPONSIBILITIES

Each event followed the same format. The event began with a presentation from Canadian Blood Services with the basics of the transition, followed by an hour Q & A with the panel. The panel consisted of the specialist, the CBS rep, the OnePath rep, and the infusion nurse and transfusion medicine rep (if present).

#### IG Transition Events

| City     | Specialist               | CBS Rep        | TM/Nurse |
|----------|--------------------------|----------------|----------|
| London   | Dr. Winder Gill          | Rick Trifunov  | No       |
| Toronto  | Dr. Stephen Betschel     | Peter Saunders | Yes      |
| Ottawa   | Dr. Juthaporn Cowan      | Peter Saunders | Yes      |
| Winnipeg | Dr. Chrystina Kalicynski | Rick Trifunov  | Yes      |
| Edmonton | Dr. Bruce Ritchie        | Peter Saunders | Yes      |
| Calgary  | Dr. Jennifer Grossman    | Peter Saunders | Yes      |

#### QUESTIONS

Questions regarding patient safety, training, product choice and accessibility frequently arose at these events. Through the efforts of the representatives present, questions were addressed during the session. A summary of questions can be found attached to this report. (APPENDIX A)

#### POTENTIAL ISSUES

On the announcement of the RFP results, at the CBS Open Board meeting in December 2017 and at the first transition meeting in December 2017, CIPO, based on discussions with our Medical Science Advisory Committee and our members, brought to light certain potential issues that may arise during the transition.

- Adverse Events/Reactions:** As with all products, patients may react to a new product. However, IG is not a generic, especially in the case of Primary Immunodeficiency patients. Subtle changes in IG and how it is formulated may affect PI patients differently. Because of this, CIPO advocate for patient choice and the ability for patients and their specialist to choose the best treatment option. Price should NEVER be a consideration.
- Patient Training:** Due to the nature of Primary Immunodeficiency, all patients should have their first infusion of a new product with a healthcare professional present. With some clinics transitioning over 100 patients the timeline imposed was not practical and some patients were not properly trained.

- **Clinic Staffing/Administration Constraints:** Not all clinics have dedicated nurses or administrative support to oversee the transition. Those that do have dedicated staff, will have to put all their resources toward the transition and all other services on hold.
- **Patient Support:** Patients have come to rely on the patient support program in place, and in some areas, the nurse that comes with that program. A seamless transition to a new patient support program is vital, with all patients being registered for the new patient support program before beginning on the new product
- **Patient Confusion/Anger** Patient unhappiness in dealing with change is almost unavoidable. However, reports of patients falling through the cracks, not being informed of the transition, not receiving training, not receiving the correct product, receiving expired product, IS avoidable.

#### OTHER ISSUES

At the transition meeting in Toronto in December 2017, other potential issues (not within CIPO's remit) came up.

- **Product Supply:** Blood banks and clinics raised concerns regarding the short transition timeline. The two main questions were: Would there be enough of the new product in country in time to start transition and training? Would there be enough of the old product to see patients through the transition and training?
- **Product Storage:** Clinicians and transfusion medicine staff were concerned in the difference in product monographs regarding product storage. There was concern over possible confusion, due to the 12-month room temperature storage for Cuvitru, where Hizentra has 36-month room temperature storage. An application to Health Canada to extend the room temperature storage for Cuvitru to 24-months was approved post- transition.

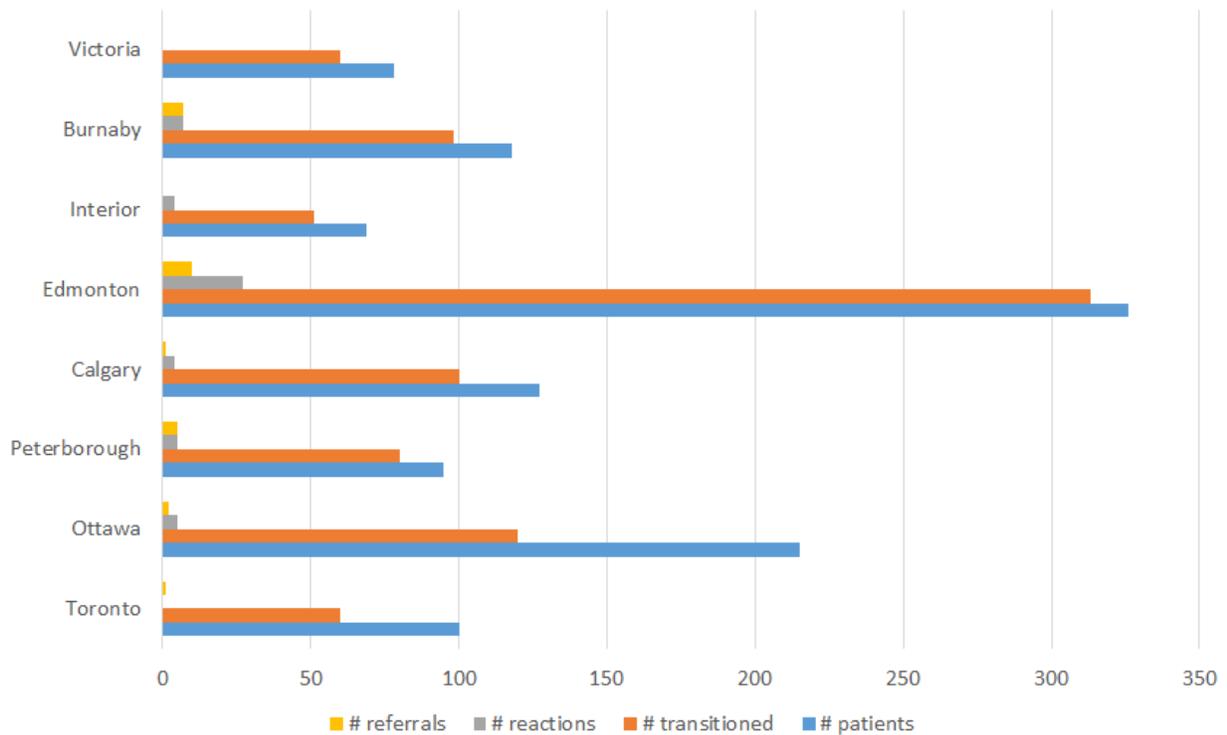
#### IG TRANSITION FOLLOW-UP

##### IG TRANSITION CLINIC FOLLOW-UP

Between September 1st and October 1st, CIPO reached out to 10 clinics across Canada regarding the transition. We asked each clinic the same 6 questions:

1. How many SCIG patients do you currently treat?
2. How many patients have you transitioned?
3. How many reactions have you recorded (including mild reactions)?
4. Of these, how many have been severe?
5. How many patients have you referred, or will you be referring to another product?
6. Do you have any comments or thoughts on the transition in general you would like to share?

### Hizentra/Cuvitru Transition Across Canada



#### REACTION RATES

With the evidence gathered from the 10 clinics, we have data from 1128 patients, and 882 patients that have already transitioned. Of these 882 patients, 5.89% (52) have had a reaction to Cuvitru during the transition from Hizentra, and 3.4% (30) have been, or will be, referred to another product. Initially, in the transition process, reaction rates were lower, around 1%-2%, but as more patients have completed transition, rates have increased.

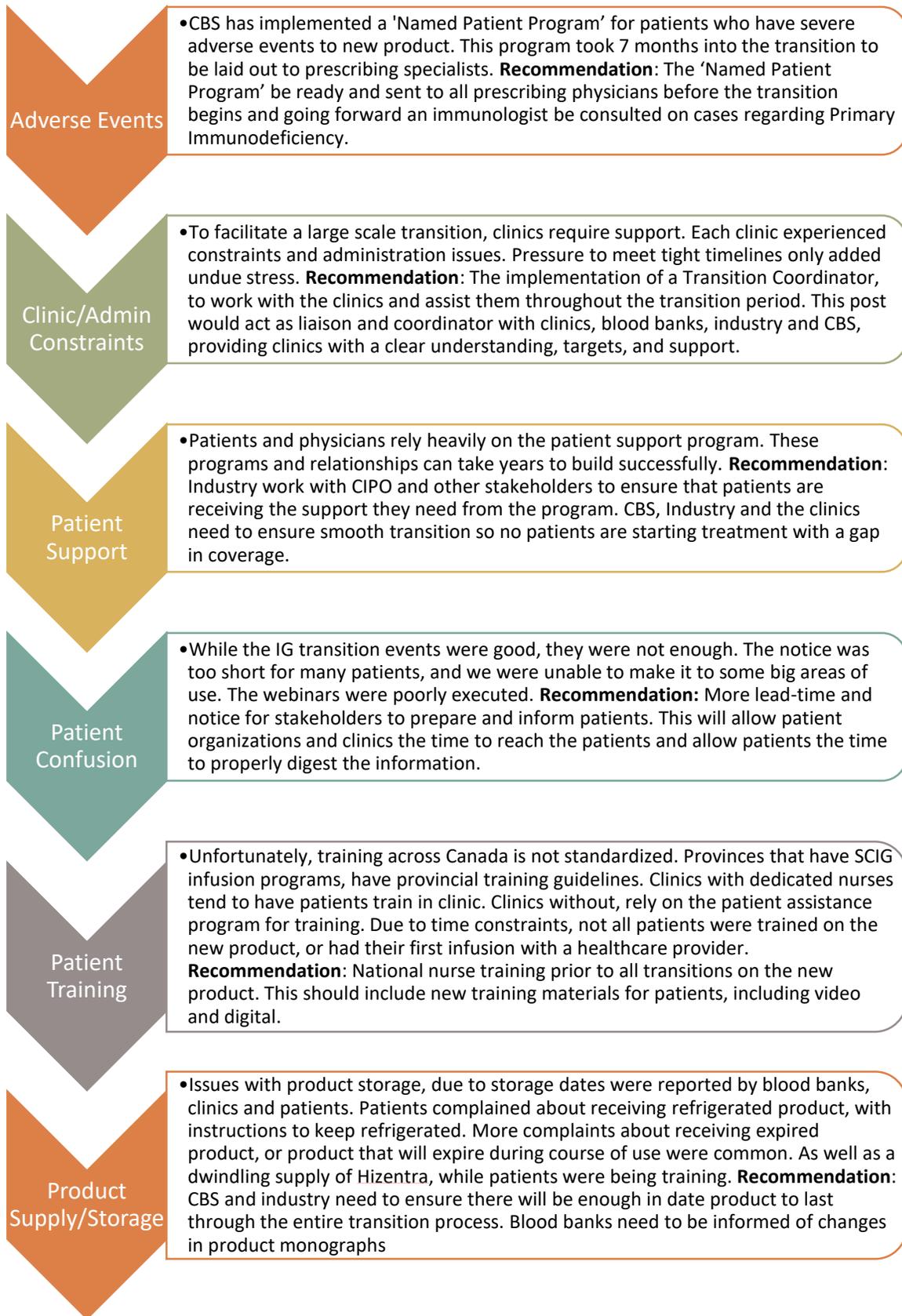
#### CLINIC INPUT

The clinic feedback from the transition follow-up allowed CIPO to understand the pressure that the clinic staff have felt during this process. Comments about tight turnaround, administrative constraints, product supply issues, product expiration dates, lack of time for patient training were frequent. While we understood issues surrounding supply and soon to be expired product to be isolated to one area and resolved, this was not the case, as we heard multiple accounts from clinics across the country. At the time of this report, the issues were still unresolved. The general tone from clinic staff across the country was a feeling of frustration with CBS and the handling of the transition.

#### CHANGE MANAGEMENT PROCESS

##### POSSIBLE SOLUTIONS

CIPO has identified possible steps to resolve some of the issues which have arisen with the transition. Through collaborative efforts, we hope that our recommendations can work towards implementing a satisfactory resolution.



## REVIEW FOR UPCOMING RFPs

### RECOMMENDATIONS

The CIPO board, along with the CIPO Medical Science Advisory Committee, have reviewed these recommendations and found that if implemented in coordination and cooperation with interested stakeholders, industry, prescribing physicians, transfusion medicine and clinic staff, upcoming IG transitions will have less disruption and a significantly smoother roll-out.

We understand that CBS has undergone an independent review of the RFP process and we look forward to seeing the results.

CIPO looks forward to continuing to work with CBS to achieve the best possible outcomes for PI patients in Canada.

## APPENDIX A

## FREQUENTLY ASKED QUESTIONS:

1. Why is my product being changed?
2. Because it is a cheaper product, does that make it inferior?
3. Will I have to change again in 3 years?
4. Why don't I get to choose which product I use?
5. Where is the saving of \$400m going? Will I be seeing any benefit in my care?
6. Will I still be using the same product?
7. Will there be a stoppage/disruption to my treatment?
8. Will Cuvitru have PFS?
9. What about Hizentra Care?
10. Will the new product pay for my supplies?
11. What about my nurse?
12. What if the new product doesn't work?
13. Can I switch back if I don't like it?
14. What if I have a reaction?
15. What if I'm allergic to the new product?
16. What if I get a rash?
17. Is it the same product?
18. Will it do the same thing?
19. Will I be able to do it in the same amount of time (IVIG)?
20. Do I need to pre-medicate?
21. Does it need to go in the fridge?
22. How much can I pick up at one time?
23. Will I be receiving the same amount as before?
24. How does one enroll in the One Path Program?
25. Is there a cost to enroll in the OnePath Program?
26. What do I do now with all of the supplies I currently have?
27. Will the pump I use now still work?
28. I'm IGA deficient, the info pack for Cuvitru states "not recommended for IGA deficient patients", what can I do?
29. Does my physician switch me to the new brand or does it automatically happen?
30. Does Hizentra ask me to enroll into the OnePath Program or do I ask them to do this?
31. Is there a deadline to enroll on the OnePath?
32. How do I enroll in OnePath?
33. Will I get to see my specialist before the switch?
34. Will I be trained on the new product?
35. My blood bank didn't know about any changes, why not?
36. I heard from the blood bank that if I put Cuvitru in the fridge that I will reduce the shelf-life, is this true?

37. Will my infusions take longer with the new product? (IVIG)
38. Do I have to start infusion rates from the slowest rate now? (IVIG)
39. Will I have the same nurse?
40. What is the timeline for the switch?
41. I had a horrible reaction to a product before and ended up in hospital, do I still need to try the new product to see if I have a reaction?
42. How will I be notified of the switch?
43. When will I be switching?
44. When will I know it is time to switch?
45. I will be switching from PFS to vials, how will I have the right supplies ready if I am not enrolled on the program before starting?