
INFORMATION ONLY

Plasma Protein Products Request for Proposal Results
Customer Letter # 2017-42

2017-10-31

Dear Customer:

Canadian Blood Services is very pleased to announce the results of our recent request for proposals (RFPs) for plasma protein products. RFPs were completed with the direct participation and inputs from both external physician and patient groups. The final decisions made by Canadian Blood Services will allow for continued benefits for the at home and in hospital patient community with continued access to innovative products. We are also enabling significant product cost savings for the system, and will ensure we maintain the safe, affordable and secure supply of plasma protein products for the coming years.

Fractionation Services and Fractionated Products

Canadian Blood Services is awarding new 3 year contracts with two one-year extension options to suppliers (fractionators) who will make the required plasma derived products from human plasma we provide.

Canadian Blood Services will continue with Grifols Therapeutics and CSL Behring as its fractionators. As a result, we will continue to provide limited quantities of CSL Behring's products: Privigen, Alburex, RiaStap and Humate-P as well as Grifols' products IVIGnex and Albumin, each made from plasma provided by CBS.

Commercial Immunoglobulins & Albumin

The volumes of products manufactured from plasma Canadian Blood Services provides does not meet our total national need. To supplement our requirements, Canadian Blood Services is awarding new three-year contracts with two one-year extension options to suppliers for commercial brands of Ig (i.e. product made from fractionator's own plasma).

Canadian Blood Services is awarding approximately 80 percent of our commercial volume to Shire (formerly Baxalta). This includes Shire's Intravenous (Gammagard Liquid 10%) and Subcutaneous (Cuvitru 20%) formulations. We will also be awarding the approximately remaining 20% volume to Grifols Gamunex 10% (2.5 g, 5 g, 10 g) to meet the remaining commercial volume requirements. As a result, we will be transitioning away from CSL's subcutaneous Hizentra as well as any further purchases of CSL's commercial Privigen and Octapharma's Panzyga. The availability of Shire's Cuvitru 20% product and the timing for transitioning from CSL's Hizentra will be determined and communicated to hospital customers under separate letter.

Commercial Albumin to supplement our national requirements will be of CSL's Alburex product. We will also continue with Grifols' commercial Plasbumin 5 percent 50 mL Albumin as we do today.

Standard Half-Life (SHL) and Extended Half Life (EHL) Recombinant Factors VIII and IX

Canadian Blood Services is awarding new two year contracts, with two one-year extension options for the products below.

Canadian Blood Services has determined that the existing standard acting portfolio remains unchanged. As a result, we will continue distribution of Bayer's rFVIII product Kovaltry, Pfizer's products: Xyntha (rVIII) and BeneFix (rFIX), as well as Octapharma's rFVIII product Nuwiq.

Products with extended half-life (EHL) properties were also evaluated as part of the recent RFP. Canadian Blood Services is pleased to announce that we will continue providing EHL products for Canadian patients and physicians. Shire's extended half-life (EHL) rFVIII ADYNOVATE will be made available as will Novo Nordisk's rFIX EHL Rebinyn (pending upcoming Health Canada approval this Fall) under new contracts. Canadian Blood Services will be transitioning away from Bioverativ's (formerly Biogen) EHLs rFVIII, Elocate and rFIX, Alprolix.

Transitioning

Any product changes will be introduced gradually, starting when new products can be made available. These availability dates are being determined and will be communicated. Patient transitioning will then occur over the following months with as many patients as possible being transitioned by April 1, 2018. We will continue to consult with physicians and the hospital community to determine how quickly transitions can be completed with as little disruption as possible. Existing inventories of discontinued products will be fully utilized and our order forms will be updated accordingly with the removal of discontinued products.

For IVIG patients, the quantities available of each IVIG brand will vary under these new contracts. Of the remaining brands, much of the use will be with Shire's Gammagard Liquid and centers will be required to migrate to it.

For sub-cutaneous Ig patients, Canadian Blood Services will work with CSL Behring, Shire, as well as the involved patient groups, to help ensure a successful transition from CSL's Hizentra Care program to a comparable Shire program. Further announcements pertaining to Shire's transition plans, timing, as well as physician, nursing and patient support programs will be forthcoming. Once the new product, Cuvitru becomes available, transitions will commence as noted above.

For hemophilia patients, timing for required EHL hemophilia patient transitions will be determined in consultation with Hemophilia Treatment Centers (HTC), while allowing for sufficient quantities of existing EHLs to support our transition period. Once the new products, ADYNOVATE and Rebinyn become available, transitions will commence gradually as noted above. Canadian Blood Services is committed to working with HTCs, on a named patient basis with specific volume needs, to allow for current Elocate patients on Immune Tolerance Induction (ITI) treatments or those in their first 50-100 exposure days to be given continued access to Elocate until such time as those treatments finish. No additional Elocate volume will be provided beyond what is agreed to in support of the transition period as deemed appropriate for these two groups of patients. Volume will be held for specific HTC needs, on a named patient basis, with ordering mechanisms to be put in place to distribute these capped quantities.

All other existing hemophilia A patients and any new patients will have ADYNOVATE made available to them, as well as the current SHL products. All Alprolix patients will be required to switch. Canadian Blood Services, in partnership with the manufacturers, is committed to working with the physicians

(Association of Hemophilia Clinic Directors of Canada), nursing staff (Canadian Association of Nurses in Hemophilia Care), and patients (Canadian Hemophilia Society and its chapters) during this transition as requested or required.

All Other Products: further to the changes noted above, all other products on the Canadian Blood Services formulary will continue to be made available as they are today.

We acknowledge that these changes will mean that hospital customers will have to create new products in their laboratory information systems and that some patients will be required to change the current brand of plasma protein product that is part of their treatment. While this will require additional effort from many stakeholders, there are significant savings to be realized while still being able to provide physicians and patients with product choices that will provide similar or better outcomes.

The financial outcome of these RFPs is significant. The cost reduction in year one is approximately \$125M, the cost reduction / avoidance in year two is approximately \$190M (cost savings of \$65M and cost avoidance of \$125M) and cost avoidance of \$145M in year three for the fractionated product contracts only. Canadian Blood Services and the manufacturers are committed to working with our hospital customers and patients to make this transition as smooth as possible, and we thank you in advance for your cooperation as we all play a role in helping to keep the Canadian healthcare system affordable. New product information to support hospital system updates will be provided in data formats that are required.

We will provide subsequent customer letters with additional details including sizes and timing of availability as this information becomes available and necessary transition plans are finalized. Communication will also be provided under a separate letter at a later date regarding the final quantities for the fractionation services and fractionated products made from Canadian Blood Services supplied plasma and the total immune globulin shares and albumin volumes for 2018/2019.

This customer letter can also be viewed at www.blood.ca in the “Hospitals” section. If you have questions about this letter, or if you require it in an accessible format, please contact your local hospital liaison specialist.

Sincerely,



Rick Prinzen
Chief Supply Chain Officer