

# Plasma Protein Products: A Model to Inform Discussion on National Pharmacare

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## Canadian Blood Services

Canadian Blood Services is an independent, not-for-profit organization that operates at arm's-length from governments and serves health-care systems by providing products and services in the fields of transfusion and transplantation medicine. It is regulated by Health Canada and funded by the provincial and territorial (P/T) governments (excluding Quebec). The P/T ministers of health serve as corporate members and appoint the Canadian Blood Services board of directors.

The organization was created in 1998 in response to the inquiry led by Justice Horace Krever into the tainted blood tragedy. In the wake of the Krever Commission, the organization was given the mandate for a national blood supply system that assures access to a safe, secure and affordable supply of blood, blood products and their alternatives.

Within that context, we manage the national supply of blood, blood products and stem cells and related services, for all provinces and territories (excluding Quebec, whose blood supply is managed by Héma-Québec). Our role includes development and management of the national public cord blood bank, and stewardship as the sole procurer, contract manufacturer and distributor of plasma protein products in Canada (excluding Quebec).

On behalf of P/T health systems, Canadian Blood Services bulk-purchases, inventories and distributes approximately 45 brands of plasma protein products from Canadian and international suppliers. These products include those available for patients under the Health Canada Special Access Program.

We also lead an integrated, interprovincial system for organ donation and transplantation for all of Canada. We operate the ground-breaking Canadian Transplant Registry and related programs, which are improving and saving the lives of Canadians waiting for transplants. We understand the Standing Committee on Health is interested in hearing from us on the *Call to Action* report, a strategic plan to improve organ and tissue donation and transplantation performance in Canada. It was tabled with federal, provincial and territorial governments in 2011 on behalf of the country's organ and tissue donation and transplantation communities. We look forward to reviewing this report and next steps in organ donation and transplantation in Canada with you in the near future.

Canadian Blood Services provides value through improving patient outcomes, enhancing health-system performance and optimizing cost-efficiency. We operate an integrated, pan-Canadian service delivery model; our national scope, infrastructure and governance make our organization unique in the Canadian health-care landscape.

### **Equitable access to plasma protein products: a microcosm for a national drug program**

Canadian Blood Services has sole responsibility for bulk purchasing and managing a pan-Canadian formulary of plasma protein products, or plasma-derived drugs and their synthetic alternatives, worth about \$600 million a year, on behalf of P/T governments except Quebec. We also operate an integrated national health-care supply chain using a publicly funded, accountable, cost-shared approach to service delivery.

Over the years, we have leveraged the synergies of these two programs to enable and enhance desirable health-system outputs and outcomes often associated with a national drug program. For patients across the country needing plasma-derived drugs, these include equity of access and quality, as well as security of supply. Our publicly tendered approach to bulk purchasing also benefits health systems by including stakeholder input and delivering competitive pricing without sole sourcing or a loss of product choice.

Taken as a whole, our system supports a level of health equity that remains out of reach for some other patient groups served by individual provincial health systems, who may face an all-too-common “postal code lottery” when it comes to accessing certain medicines. By offering our input as a successful made-in-Canada model, we hope to highlight relevant aspects of how we deliver a value-added approach to pan-Canadian bulk purchasing and supply chain management in support of the committee’s discussion. Canadian Blood Services has been providing universal and equitable access to plasma protein products at no cost to patients for nearly two decades.

### **Plasma protein products**

Plasma is the protein-rich liquid in blood that helps other blood components circulate throughout the body. Donated plasma can be transfused directly into hospital patients to help fight infection and promote clotting. Plasma-derived drugs, also called plasma protein products, are highly specialized drugs made from human plasma. Pharmaceutical companies, called fractionators, in the U.S. and Europe make them by pooling the plasma donations of many thousands of pre-screened voluntary and paid donors. The pooled plasma then goes through rigorous, multi-tiered processes and tests to eliminate pathogens and other contaminants, making the finished products extremely safe. A number of these plasma protein products are now synthetically manufactured through recombinant engineering processes. All of the drugs in this class of products are expensive biological agents.

These products, such as immune globulins, albumin and blood clotting factor products, are essential, widely used medicines in Canadian hospitals and clinics and around the world. They are used to treat people with hemophilia and other bleeding disorders, as well as patients with inherited and acquired immune conditions, burn and trauma victims, and many others.

## **Closing the value gap**

Advocates for a national drug program have argued that the lack of a broad national bulk-purchasing capacity creates a serious value gap for Canadians. This statement is premised on the idea that value includes patient outcomes and health-system performance, as well as cost. While governments have made progress lowering the cost of some drugs, price is only one part of the disparity. Canadian Blood Services' bulk-purchasing practice addresses all three elements in the equation: we leverage our national supply chain and bulk purchasing practices to address health-system and population needs, as well as price. These efforts have delivered added layers of value to Canadians, including:

### **Stakeholder engagement and a secure, diverse supply**

Canadian Blood Services maintains long-term relationships with key stakeholder groups (patients, physicians, suppliers). Stakeholder input is factored into all steps of our procurement process, and the input is highly relevant to decisions made. In addition to giving patient groups and the prescribing medical community a voice in the decision-making process, our procurement program strives to offer users a reasonable degree of product choice. Wherever possible, we carry multiple brands of a product class; purchase them in smaller, diverse lots; and negotiate a dedicated and guaranteed "safety stock." We do this without resorting to single-sourcing, and yet at the same time, our bulk purchasing power ensures highly competitive pricing. Equally, if not more importantly, this strategy delivers its greatest value in terms of ensuring both security and diversity of supply.

### **An evidence-based, efficient evaluation process**

Within our product selection process, we collaborate with and draw on the expertise of the Canadian Agency for Drugs and Technology in Health to provide pharmaco-economic analysis when new drug categories are considered. This collaboration is an important part of the procurement program and ensures the appropriateness of drugs being added to the formulary of plasma protein products for Canadian patients. It also ensures shorter, more efficient approvals and reviews, making potential access times for new products some of the shortest in Canada. And unlike other similar processes in the country, ours also facilitates end-to-end support for the drugs we carry, from the initial request for proposals (RFP) to providing expert advice on appropriate patient use and utilization management.

### **Significant cost savings through bulk-buying power and price negotiation on behalf of provincial and territorial governments (except Quebec)**

One of our greatest successes is our use of public tendering as a competitive, transparent mechanism to achieve best pricing via multi-year RFPs for a single product or group of products. Leveraging both the economy of scale of purchasing for all provinces and territories, and the open, competitive tendering program, funding governments have derived significant price and cost advantage.

This advantage is best exemplified by two recent procurement outcomes. In a recent round of tendering for a suite of plasma protein products, we were able to negotiate a \$600 million reduction in costs over five years (2013–2014 to 2017–2018). Furthermore, we have driven pricing for some of the major classes of these drugs to below 2009 pricing levels — a testament to our commitment to delivering value for Canadians. More recently, in March 2016, we negotiated an additional \$60 million in savings per year as a result of a national RFP for only two drugs — recombinant clotting factor concentrates used to treat patients with hemophilia. These examples clearly underscore the value of national bulk purchasing of

expensive pharmaceuticals. Most importantly, this value is achieved without sacrificing either product choice or diversity of supply.

To help ensure efficiencies and optimum product usage, we also collaborate with transfusion medicine experts, physicians and P/T governments across the country to develop clinical practice guidelines and to promote optimal utilization practices. At the level of individual products, our model also allows provinces or territories to introduce access guidelines as each deems appropriate, to be managed provincially or at the hospital level. National criteria developed by Canadian Blood Services and national physician groups affiliated with the blood system are also possible. These options, namely national guidelines and jurisdictional access, allow P/T governments flexibility in managing their usage of these essential, yet expensive biological drugs.

#### **Quality assurance and risk management**

Canadian Blood Services independently qualifies new suppliers and audits them periodically, adding an additional layer of vigilance and product safety for patients. Our contractual relationships with suppliers require early and regular reporting of any supply or quality disruptions. This requirement ensures supplier issues in bringing products to market or maintaining adequate Canadian supplies are known and acted upon expeditiously, which helps mitigate the risk of product shortages. Our skilled procurement and legal groups are also well-versed in the specifics of bulk buying, which we leverage to the advantage of provincial and territorial funders. This is an important additional layer of value in managing a national bulk-purchasing and distribution system, and is aimed at ensuring uninterrupted patient access to these lifesaving drugs.

#### **Expertise supporting better patient care**

As part of our program management, we collaborate with the prescribing medical community and the hospital sector in which these drugs are used. Specifically, Canadian Blood Services leverages the expertise and presence of our hospital liaison specialists, who maintain strong relationships with blood banks and physicians, to manage and work through any issues regarding supply, product choice or adverse event monitoring. Our on-staff medical directors also provide expert advice when a physician encounters an issue with a patient that could benefit from the perspective of an additional specialist.

#### **Equitable access to plasma products across the country**

Once a plasma-derived drug is accepted into our portfolio, it is available in all member jurisdictions, supporting access for patients no matter what hospital they are served in. Canadian Blood Services distributes plasma products to hospitals in urban, rural, and northern and remote centres across the country via the logistics and infrastructure built for the blood system. This practice further reduces added costs to health systems and levels the playing field for patients served by hospitals in more remote areas. This equity of access is in line with the principles of universal access informing the Canada Health Act and medicare.

#### **Leveraging government investment brings long-term value**

The plasma products portfolio was transferred to Canadian Blood Services at the height of the tainted blood crisis in 1997. Almost 20 years later, through careful stewardship and committed partnership with governments and stakeholders, our national supply chain and bulk purchasing practices facilitate long-

term value for health systems and for Canadians depending on plasma-derived products. Whether they live in Vancouver, Iqaluit or St. John's, the vast majority of patients we serve enjoy barrier-free access to these products.

Today, governments are coming together in pan-Canadian forums to discuss how they can avoid a much different kind of crisis: one driven by our current fiscal environment, our aging population, and the need to protect and improve access to a variety of medications for patients across the country. Canadian Blood Services' approach to bulk purchasing plasma protein products is not a "cookie cutter" solution for the many substantial challenges that must be resolved should governments enact aspects of a national pharmacare program. Rather, our experience provides evidence that bulk purchasing can be done transparently and successfully while maintaining product choice and security of supply. We have brought these points to the committee today to demonstrate that pan-Canadian collaboration in the complex area of drug acquisition and utilization can be achieved in a manner that minimizes the concerns raised by many stakeholders. As interested parties continue to study this complex issue, we would be pleased to answer questions and explore any of these ideas further if they are of interest.