Canadian Hemophilia Society
Help Stop the Bleeding
Société canadienne de l'hémophilie
Arrêtons l'hémorragie

The tender process (RFP) for clotting factor concentrates in Canada

What is an RFP?

An RFP is a Request for Proposals. Both Canadian Blood Services (CBS) and Héma-Québec (H-Q) conduct periodic RFPs for blood products and their substitutes. They are similar to any government competitive tender for goods or services. In the case of CBS and Héma-Québec, the RFP includes recombinant FVIII and IX, FVIII/VWF, intravenous immune globulin (IVIG), sub-cutaneous immune globulin (scIG) and plasma fractionation services.

Why are some products included in the RFP and others are not?

To be included in an RFP, there must be at least two comparable products. For example, there are multiple brands of rFVIII which can compete in a tender; however, there is only one recombinant FVIIa. Instead of being part of a tender, rFVIIa is the object of direct price negotiation between the manufacturer, CBS and H-Q.

How does an RFP work?

CBS and H-Q conduct separate RFPs.

The RFP process starts almost a year before contracts expire. Six to eight months before the beginning of the next contract period, CBS and H-Q invite all manufacturers with products in Canada to submit bids. The RFP document includes detailed instructions on what information to submit, the deadlines for submission and decisions, and a generic contract. The bids are then reviewed by selection advisory committees for each category of product (i.e. factor concentrates, immune globulin, fractionation services …). Their recommendations go to the executive management teams at CBS and H-Q for final decisions, which are then reviewed and endorsed by the boards of directors. Contracts are then signed with the winning bidders.

Who sits on the selection advisory committees?

Let's take the example of the RFP for factor concentrates at CBS. The CBS Selection Advisory Committee is made up of:

- several members of the plasma protein product procurement team at CBS;
- several members of the finance team at CBS;
- a member of the CBS legal team;
- several members of the medical/scientific team at CBS;
- two physicians, experienced in hemophilia care, named by the Association of Hemophilia Clinic Directors of Canada (AHCDC);
- two patient representatives, experienced with blood product issues, named by the CHS.

What is the role of the CBS Selection Advisory Committees?

The members of the CBS Selection Advisory Committee …

- provide input to the CBS Executive Management Team on the ideal length of the contracts before the RFPs are issued;
- provide advice on the scoring criteria to be used;
- provide advice on the weighting of each criterion;
- review the hundreds of pages of documentation provided in support of each product;
- independently score each product on each criterion;
- meet with the other members of the Selection Advisory Committee and come to unanimous agreement on the score for each product on each criterion;
- come to a collective unanimous recommendation to make to the Executive Management Team.

The members of the Selection Advisory Committee sign confidentiality agreements and cannot discuss the deliberations of the committee.

What are the criteria used?

The exact criteria, scoring and weighting are confidential. They include items such as :

- Product description and monograph
- Manufacturing process and capability
- Number of manufacturing sites
- Approved indications for the product
- Potential new indications
- Dosage
- Packaging
- Administration device
- Shelf life
- Storage temperature
- Bar code compliancy
- Licensure issues
- Pharmacokinetic profile (recovery, half-life)
- Coagulation assay issues
- Safety of product, safety information
- Contraindications
- Body of published literature
- Product niche
- Market acceptance

How is the final product score calculated?

Each product is assigned a final score based on the agreed-upon criteria and weighting. Products must achieve a minimum score. This means a product cannot be further considered unless it is judged to be of sufficient safety, efficacy and quality. This scoring is done before the envelopes with pricing information are opened.

How is the final recommendation made?

The final recommendation is made based on “best value for money.” Not only is increased half-life accorded points in the product scoring, adjustments are also made in the final consideration of “value for money.” Because increased half-life results in decreased utilization, this is factored into the ultimate cost of the product. Therefore, the final calculation includes:

- product score
- per IU price
- adjustment for lower projected utilization (based on half-life)

The H-Q decisions, based on Treasury Board rules for government tenders, allocate 70% of the final score to product quality and 30% to price. In an environment where all factor concentrates licensed in Canada are judged to be safe, effective and of high quality, product scores tend to be somewhat similar, and therefore price plays an important part in the winning bid.

Can products not yet licensed by Health Canada be included in the RFP?

Yes. Both CBS and H-Q allow companies to submit bids for unlicensed products as long as the expected date of Notice of Compliance (NOC) from Health Canada falls before the date on which contracts must be signed. If NOC is not forthcoming, the product is removed from the RFP. This has proved extremely important in allowing certain products (e.g. extended half-life factors) to be considered in RFPs before NOC.

Why are RFPs conducted so often?

Before 2013, RFPs were not done in Canada for factor concentrates. Concerns over the risk of inhibitor development after switching products meant that switching was not encouraged by physicians. Contracts with suppliers changed very little. In the 2011-2013 period, however, tenders occurred in other countries, notably the U.K., which caused large numbers of patients to switch from one rFVIII to another. Surveillance of these switches showed no evidence of a higher rate of inhibitor development in previously treated patients. The first Canadian competitive RFP for rFVIII took place in 2013. Canadian and international data since 2013 have confirmed the observation that switching is not a safety concern.

Both the CHS and the AHCDC have urged CBS and H-Q to keep contracts to two or three years. The objective is to gain early access to novel products as they enter the marketplace. For example, extended half-life FVIII and IX products were approved in 2014. Medium-term contracts of two or three years allowed these products to be included in the H-Q RFP in 2015. In addition, recently approved rFVIII contracts at both CBS and H-Q expire in 2020. It is expected that novel coagulation products (e.g. emicizumab) will be licensed for hemophilia A at that time. Longer contracts extending beyond 2020 for 100% of the projected FVIII needs would mean a delay in even considering procurement of a novel product. Shorter contracts avoid this.

Other jurisdictions (e.g. U.K., Australia, Ireland …) schedule tenders for coagulation products every two to three years, like Canada.

Is the system perfect?

Everybody recognizes that product switching causes additional work for bleeding disorder treatment centres and concerns for patients/caregivers. However, both CBS and H-Q judge that the benefits of competitive tenders for patients and the health system outweigh the costs. Both the CHS and the AHCDC judge that being at the table allows us to influence the decisions in a positive way for patients.

Following the 2017-18 round of RFPs, there was criticism of the process, notably regarding proper representation of physicians and patients in some of the other RFP categories (e.g. primary immune deficiency). CBS has committed to undertake a review of the RFP process. This will include consultations with stakeholders like the CHS and a review of international practices.

Where can I find more information on the results of the most recent RFPs?

The CHS website contains many articles on the recent RFPs as well as information on currently available products.

www.hemophilia.ca/en	– Zonovate, now available in Quebec – Rebinyn enters the Canadian market – rFVIII products for 2018-2020 – rFIX products for 2018-2020 – Introduction of new rFVIII products by Héma-Québec – Update on CBS contracts for FVIII and FIX for 2018-2020

www.hemophilia.ca/en/ bleeding-disorders/ clotting-factor-concentrates	– Clotting factor concentrates licensed and/or available in Canada – Rebinyn, an extended half-life factor IX – Nuwiq, another recombinant factor VIII option – Bayer introduces Kovaltry to replace Kogenate FS in Canada – Eloctate, a longer half-life factor VIII, approved by Health Canada – Alprolix, a longer half-life factor IX, approved by Health Canada

What should I do if I have questions about my options for FVIII or IX?

You should read as much as you can about the different options and then speak to your physician.