Produits sanguins
Cellules souches
Tissus humains

HÉMA-QUÉBEC

Saint-Laurent, le 29 mars 2017

PAR MESSAGER

[redacted]

OBJET : Votre demande d'accès à l'information datée du 16 février 2017

[redacted]

En complément de réponse à votre demande d'accès à l'information, vous trouverez ci-joint une copie du contrat intervenu entre Héma-Québec et Green Cross Biotherapeutics.

Veuillez noter que certaines informations contenues dans ce document ont été caviardées puisque celles-ci contiennent des renseignements ne pouvant être communiqués pour l'un ou l'autre des motifs suivants prévus à la *Loi sur l'accès aux documents des organismes publics et sur la protection des renseignements personnels* (ci-après la « LAI ») :

1. Il s'agit de renseignements dont la communication pourrait causer un préjudice aux parties impliquées et qui porteraient atteinte à leurs intérêts économiques ou procurerait un avantage indu à une personne, au sens de l'article 21 de la LAI;
2. Il s'agit de renseignements constituant des secrets financiers et commerciaux d'Héma-Québec dont la divulgation risquerait de causer préjudice à l'organisme ou de procurer un avantage appréciable à une autre personne, au sens de l'article 22 de la LAI;
3. Il s'agit de renseignements industriels, financiers, commerciaux, scientifiques ou techniques fournis par Green Cross Biotherapeutics, traités confidentiellement par ceux-ci et pour lesquels nous n'avons pas leur consentement à les communiquer, conformément à l'article 23 de la LAI;
4. Il s'agit de renseignements dont la divulgation risque de causer une perte financière à Green Cross, de procurer un avantage appréciable à une autre personne ou de nuire de façon substantielle à leur compétitivité, et pour lesquels nous n'avons pas le consentement de Green Cross Biotherapeutics à les communiquer, conformément à l'article 24 de la LAI.

Enfin, nous tenons à vous informer qu'il vous est possible de demander à la Commission d'accès à l'information de réviser la présente décision. Vous trouverez ci-annexée une note explicative à cet égard.

Veuillez agréer, [redacted], l'expression de nos sentiments distingués.

ORIGINAL SIGNÉ

Isabelle Allard, conseillère juridique
Responsable de l'accès aux documents et de
la protection des renseignements personnels
Tél. : (514) 832-5000 poste 5240
Courriel : isabelle.allard@hema-quebec.qc.ca

IA/rn
p.j.

FRACTIONATION AND SUPPLY AGREEMENT

PROVISION OF FRACTIONATION SERVICES

BETWEEN

HÉMA-QUÉBEC

AND

GREEN CROSS BIOTHERAPEUTICS INC.

FRACTIONATION AND SUPPLY AGREEMENT
PROVISION OF FRACTIONATION SERVICES

THIS FRACTIONATION AND SUPPLY AGREEMENT is made effective as of the date of last signature hereto (hereinafter referred to as "**Effective Date**")
BETWEEN:

HÉMA-QUÉBEC
4045 Côte-Vertu Blvd.
Saint-Laurent (Québec) H4R 2W7
CANADA
(hereinafter "**HQ**")

AND:

GREEN CROSS BIOTHERAPEUTICS INC.
Technoparc Montréal (Lot 14)
7140 Albert-Einstein, suite 200
Montréal (Québec) H4S 2C1
(hereinafter "**Supplier**")

(HQ and Supplier are hereinafter collectively referred to as the "**Parties**")

WHEREAS, HQ is the exclusive distributor of human plasma derived proteins in the Province of Québec;

WHEREAS, HQ collects HQ Plasma (as defined below) which may be used for the production of human plasma derived protein products;

WHEREAS, Supplier provides Fractionation Services and supply of Products (as defined below) for use in the Province of Québec;

WHEREAS, HQ wishes to retain the services of Supplier for the provision of Fractionation Services and for the supply of Products;

NOW THEREFORE in consideration of the premises, covenants and agreements contained herein, the Parties agree as follows:

1. DEFINED TERMS AND INTERPRETATION

1.1 Definitions

Where used in this Fractionation and Supply Agreement or any amendments thereto, the following terms shall have the following meaning:

(a) "**Agreement Year**" means

(i) the period of twelve (12) months commencing on the date when all the following conditions have been satisfied, and ending on the last day of the twelfth month after such date:

HQ

(A) Immunoglobulin produced by Supplier shall have been approved by Health Canada

(B)

(C) If required, Supplier shall have obtained an authorization from the Autorité des marchés financiers pursuant to section 21.17 and following of An Act respecting contracting with public bodies (Québec); and

(D)

(ii) and each period of twelve months thereafter.

(a) "Business Day" means any day other than a Saturday, Sunday or statutory holiday in the Province of Québec;

(b)

(c) "Consumers" means individuals infused with Products or the legal guardians/trustees of such individuals;

(d)

(e) "Delivery Requirements" shall have the meaning given to it in Schedule "E";

(f) "Delivery Schedule" shall have the meaning given to it in Section 5.2;

(g) "Domestic Product(s)" means products fractionated by Supplier using HQ Plasma;

HQ

(h) "Effective Date" shall have the meaning given to it in the introductory paragraph of this Fractionation and Supply Agreement;

(i)

(j)

(k)

(l) "Food and Drugs Act (Canada)" means the Statute of Canada cited as R.S.C. 1985, c. F-27 and regulations thereto, as amended from time to time;

(m) "Fractionation and Supply Agreement" means this Fractionation and Supply Agreement including the Schedules referred to in Section 1.2, and includes any amendment;

(n) "Fractionation Products" means products resulting from the Fractionation Services;

(o) "Fractionation Services" means all of the services to be provided by Supplier hereunder, including, but not limited to, the process of fractionating Plasma in order to manufacture Fractionation Products;

(p) "HQ Event of Default" shall have the meaning given to it at Section 14.1;

(q) "HQ Plasma" means plasma collected in the Province of Québec;

(r) "HQ Process" shall have the meaning given to it in Section 6.2;

(s) "Health Canada" means Her Majesty the Queen in right of Canada as represented by the federal Minister of Health being the regulator of Products in Canada;

(t) "Improvement" means a change to the Fractionation Services which enhances the safety, efficacy, identity, potency or purity of the Product(s);

HQ

(u) [redacted]

(v) "Inventory System" means the supply management system used by HQ for inventory management of plasma protein products;

(w) "Licensed Product" means a pharmaceutical product licensed by Health Canada for sale or distribution in Canada;

(x) "Plasma" shall have the meaning given in Schedule C 'Quality Agreement';

(y) [redacted]

(z) "Plasma Volume Forecast" shall have the meaning given to it in Section 4.1;

(aa) "Plasma Intermediates" means any by-product produced during the fractionation of Plasma by Supplier;

(bb) "Product(s)" means the following products manufactured by Supplier:

[redacted]

(cc) "Proposal" shall have the meaning given to it at Section 10.5;

(dd) "Recall" means any action ordered by a governmental or regulatory authority to remove permanently or temporarily a Product from further distribution or use;

(ee) "Rejected Plasma and Products" shall have the meaning given to it at Section 2.10(a);

(ff) "Relevant IP" shall have the meaning given to it at Section 12.1;

(gg) "Replacement Product" shall have the meaning given to it at Section 5.6;

HQ

(hh) "Samples" means HQ Plasma collected in small tubes which is used to test HQ Plasma before fractionation;

(ii)

(jj)

(kk)

(ll)

(mm) "Withdrawal" means any action ordered by any Party, in accordance with the terms of this Fractionation and Supply Agreement, to remove permanently or temporarily a Product from distribution or use.

1.2 Schedules

The following are the schedules which are referred to and which form part of this Fractionation and Supply Agreement:

Schedule "A" – Products Prices and HQ Target Inventory Level

Schedule "B" – Products Specifications

Schedule "C" – Quality Agreement
Appendix "1" to Schedule "C"

Schedule "D" – Quality Requirements
Appendix "1" to Schedule "D"
Appendix "2" to Schedule "D"

Schedule "E" – Delivery Requirements
Appendix "1" to Schedule "E"

Schedule "F" – Key Performance Indicators Program

Schedule "G" – Test Methodology

1.3 Precedence

In the event of contradictions or discrepancies between the documents cited in Section 1.2 the order of precedence shall be this Fractionation and Supply Agreement followed by the above-mentioned schedules in the order listed at Section 1.2.

HQ

2. HQ PLASMA COLLECTION AND PROCESSING

2.1 HQ Plasma Collection

HQ represents and warrants that all HQ Plasma provided to Supplier for Fractionation shall be collected and stored by HQ and (if transported by HQ) transported in accordance with (i) the *Food and Drugs Act (Canada)* (including the regulations thereto) and the Drugs Directorate Good Manufacturing Practices (GMP) for Schedule D Drugs, Part 2, Human Blood and Blood Components, 1999, (ii) the specifications set out in Schedule "C"-- Quality Agreement, Schedule "D"-- Quality Requirement, and Schedule "E"-- Delivery Requirements, and (iii) any applicable laws and regulations.

2.2 Responsibility for HQ Plasma in HQ's Possession

HQ shall be responsible for and shall bear all risk of loss or damage to the HQ Plasma until picked up by Supplier or its agents, including but not limited to any loss or damage resulting from the improper storage, handling, packing, crating, blocking and/or transportation of the HQ Plasma at the collection sites.

2.3 Notice Period for HQ Plasma Pickup by Supplier

Supplier shall arrange for pickup of HQ Plasma from HQ's collection sites in Québec listed in Appendix "1" to Schedule "C". The HQ Plasma collection schedule and additional HQ collection sites, if any, shall be settled by the Parties at least six (6) months prior to Supplier's first pickup of HQ plasma.

Supplier shall provide HQ with reasonable advance notice of the time of pickup of HQ Plasma from HQ's collection sites (during normal business hours), such advance notice being not less than 48 hours.

An annual HQ Plasma pickup schedule for each Agreement Year shall be agreed upon between the Parties. In preparing such schedule the Parties shall take into account the quantity of HQ Plasma to be collected, HQ storage capabilities and HQ procurement plans. Such schedule is to serve as a guideline and may be amended from time to time by HQ or Supplier upon reasonable notice. Depending on the volume of plasma to be collected, HQ and Supplier may mutually agree to cancel some scheduled pickups.

2.4 Packaging and Storage of HQ Plasma

Supplier shall provide HQ, at its own cost, with boxes for the collection of HQ Plasma and Samples. HQ shall provide, at its own cost, Sample tubes and Sample holders (clamshells) that conform to the Delivery Requirements which shall be specified in Schedule "E". The Delivery Requirements shall be agreed between the Parties at least six (6) months prior to Supplier's first pickup of HQ plasma.

HQ

Supplier shall arrange storage for HQ Plasma before onward transfer to Supplier. Supplier shall select and make all arrangements for carriage and storage of the HQ Plasma, in its sole discretion.

HQ shall cooperate with Supplier and provide such documentation as may be reasonably required to assist relevant activities.

2.5 Segregation of Plasma

HQ acknowledges and agrees that should any plasma be held by HQ for transportation to a fractionator other than Supplier, then HQ must ensure that:

(a) plasma destined for a third party fractionator shall not be handled by Supplier;
(b) boxes, bags or other containers of Supplier are never used to store or transport plasma destined for a third party fractionator; and
(c) any plasma to be sent to a third party fractionator be clearly marked at the HQ collection site as destined for such third party fractionator.

The Supplier shall ensure that pools of Plasma to be fractionated into Products shall only contain HQ supplied Plasma unless otherwise specifically agreed in writing by HQ ("Plasma Segregation").

2.6 Shipping Documents for HQ Plasma

Prior to each pickup of HQ Plasma by Supplier, HQ shall provide Supplier with a copy of the production site HQ Plasma shipment summaries. Donation detailed listings (plasma unit sheets listing testing and acceptance) shall be sent directly to Supplier concurrent with the consolidated HQ Plasma shipment. All the requirements of documentation shall be specified in Schedule "E"--Delivery Requirement.

2.7 Responsibility for HQ Plasma in the Possession of Supplier

Supplier shall be responsible for and shall bear all risk of loss or damage to the HQ Plasma while it is in its possession or in the possession of Supplier's carriers, storage facilities, or agents. Except as otherwise provided for herein, this responsibility includes, but is not limited to, any loss or damage resulting from the improper storage, handling, loading, packing, blocking and/or transportation of the HQ Plasma once it departs HQ's collection sites. Supplier shall take all reasonable steps to ensure that HQ Plasma and Fractionation Products are appropriately segregated and not intermingled with other raw materials or products.

2.8 Supplier to Inspect HQ Plasma

Immediately prior to the fractionation of HQ Plasma at Supplier's fractionation facility, Supplier shall inspect the HQ Plasma and any associated documentation received by Supplier for visual defects, temperature excursions, shortage or damage.

HQ

For greater certainty, Supplier has no duty to test the HQ Plasma under this Section 2.8 and this Section 2.8 does not apply to latent defects in the HQ Plasma.

2.9 HQ Determines HQ Plasma Delivered to Supplier is Unsuitable

If, after any HQ Plasma has been picked up by Supplier, HQ determines, acting reasonably, that any of the HQ Plasma is unsuitable or poses a reasonable likelihood of adverse risk to the safety or quality of any of the Fractionation Products or Plasma Intermediates, HQ shall immediately notify Supplier. For routine look backs, HQ shall provide notification according to terms of Schedule "C"-- Quality Agreement and Schedule "D"-- Quality Requirements. For more serious issues, HQ shall immediately notify Supplier by telephone and facsimile transmission or electronic mail and shall work with Supplier to mutually agree on a course of action to be taken regarding the impacted HQ Plasma, Plasma Intermediates, or Fractionation Products.

2.10 Right of Supplier to Reject HQ Plasma

(a) In addition to its other rights herein, Supplier shall have the right, at any time while the HQ Plasma is in its possession during the fractionation process, to reject any HQ Plasma, Plasma pools which contain the rejected HQ Plasma pursuant to this Section 2.10(a), resulting Plasma Intermediates or Fractionation Products("**Rejected Plasma and Products**") which:

(i) do not meet the standards set out in Section 2.1;
(ii) originate from an HQ Collection Site that has not been qualified by Supplier;
(iii) are determined to be deficient by HQ, with notice of any such deficiency to be provided to Supplier pursuant to Section 2.9;
(iv) are otherwise damaged, or possibly contaminated, or subject to temperature excursion, or are improperly packaged, labeled, stored, or improperly documented; or
(v) are, in the opinion of Supplier, acting reasonably, unsuitable or pose a likely risk to the safety, quality, purity, potency or efficacy of any resulting Fractionation Products.

(b) Supplier shall immediately notify HQ by telephone followed by facsimile transmission or electronic mail of any rejection by Supplier pursuant to Subsection 2.10(a). HQ shall co-operate with Supplier in any efforts to correct any deficiencies attributable to HQ Plasma. Upon mutual agreement and appropriate regulatory approvals, if applicable, Supplier shall retest, reprocess, destroy or return the HQ Plasma, the resulting Plasma Intermediates or Fractionation Products at the sole cost and expense of HQ unless the HQ Plasma, the Plasma Intermediates or Fractionation Products was rejected as a result of a breach by Supplier of any of its obligations under this Fractionation and Supply Agreement pertaining to the handling, storage or transport of the HQ Plasma. Notwithstanding anything to the contrary herein, all damages, charges, losses, liabilities, cost or expense resulting from any Rejected Plasma and Products by Supplier pursuant to Subsection 2.10(a) shall be borne by HQ,

HQ

including but not limited to: (i) cleaning cost; [redacted] provided however that such Rejected Plasma and Products is not the result of any omission, negligence or deviation from the Supplier's approved manufacturing processes. All Rejected Plasma and Products shall be held at the relevant Supplier facility until HQ and Supplier have mutually agreed on their disposal, the cost of which shall be borne by HQ.

2.11 Plasma Rendered Unsuitable Due to Breach by Supplier

If any HQ Plasma is rendered unsuitable through no fault of HQ but rather as a result of a breach by Supplier of any of its obligations under this Fractionation and Supply Agreement pertaining to the processing, handling, storage, or transport of the HQ Plasma, then Supplier shall replace Fractionation Products that were to result from the fractionation of such HQ Plasma with equivalent products manufactured by Supplier. Supplier shall supply and deliver the Fractionation Products on the date scheduled for the delivery of said Fractionation Products. In the event Supplier is unable to supply Fractionation Products pursuant to Schedule A, HQ shall be entitled to proceed with the purchase of Replacement Products from alternate suppliers pursuant to the provisions of Section 10.5.

2.12 Change to HQ Standard Operating Procedures

In the event HQ wishes to materially alter any of its standard operating procedures affecting the collection of HQ Plasma to be used for Fractionation Services during the Term, HQ must inform Supplier of the proposed change at least sixty (60) days in advance of implementing such change or, if change imposed by Health Canada is to take effect within a shorter time frame, then HQ shall notify Supplier as soon as reasonably possible. HQ shall work with Supplier to evaluate the consequences of any such change on the Fractionation Services. To the extent such change results in an increase or a decrease in cost, Supplier shall notify promptly HQ in writing and the Parties agree to negotiate, in good faith, the applicable price adjustment.

2.13 Records

Supplier shall maintain accurate records of all recordable events commencing with the pickup of HQ Plasma by Supplier, including but not limited to, as applicable, records of the HQ Plasma, Plasma Intermediates and Fractionation Products during acceptance, processing and storage, as well as laboratory testing reports, assays, correspondence and other documents concerning lot processing, tracking plasma units throughout the fractionation process and releases. Such records shall be duly kept by Supplier for the applicable period prescribed by Health Canada. Such records shall be made available for examination by duly authorized representatives of HQ upon reasonable request.

2.14 ISBT 128 Compliance

Supplier shall have systems and procedures to receive and process HQ Plasma using ISBT 128 barcode system.

HQ

2.15 Yield

Supplier's yield for Fractionation Products fabricated from HQ Plasma by Supplier shall be agreed upon between the Parties

During the production process Supplier shall test HQ Plasma for protein and IgG content. The test methodology shall be as further described in Schedule "H" hereto. The test results shall, absent manifest error, be binding on the Parties.

3. FRACTIONATION SERVICES AND PURCHASE OF PRODUCTS

3.1 Fractionation Services and purchase of Products

The Parties recognize and acknowledge that a certain volume of plasma will be fractionated by a third party fractionator.

HQ

During [redacted] this Fractionation and Supply Agreement:

(a) HQ :

(i) shall provide to the Supplier [redacted] liters of HQ Plasma;

(ii) shall provide to the Supplier [redacted] liters of HQ Plasma [redacted], the timing of which shall be at HQ discretion;

(iii) shall test HQ Plasma delivered to the Supplier for fractionation on individual samples;

(iv) shall purchase from the Supplier [redacted] manufactured by the Supplier [redacted]

(v) [redacted]

(vi) [redacted]

(vii) [redacted]

(b) Supplier shall:

(i) process HQ Plasma into Fractionation Products for human therapeutic use only. Supplier may not sell or otherwise transfer HQ Plasma to another party or customer without a written authorization from HQ;

(ii) shall test HQ Plasma delivered to the Supplier for fractionation. Testing will be performed by the Supplier on a batch or lot basis rather than on individual Samples;

(iii) [redacted] sell on an exclusive basis to HQ all the Fractionation Products manufactured from the HQ Plasma. Such sales to be made at the prices set forth in Schedule "A"; and

(iv) take direction from HQ from time to time on the final disposal of Plasma Intermediates that are not used for Fractionation Products. If HQ does not give direction on the final disposal for more than one (1) year from the time when Plasma Intermediates were produced, Supplier may, at its discretion, return the Plasma Intermediates to HQ or destroy them. The cost of destroying the Plasma Intermediates by Supplier shall be borne by Supplier on the condition that HQ meets all the obligations of supply and purchase on the above Subsection 3.1(a).

HQ

(c)

(d)

(e)

(f) If Supplier is unable to supply HQ with Fractionation Services and/or to supply Products as set forth in Section 3.1(a)

(g) If Supplier s unable to supply HQ with Fractionation Services and/or to supply Products as set forth in Section 3.1(a),

4. FORECASTING AND ORDERS

4.1 Plasma Forecasting

By April 1 of each Agreement Year, HQ shall provide Supplier with a twelve (12) month forecast of the projected monthly supply of HQ Plasma available for fractionation ("**Plasma Volume Forecast**"). The Plasma Volume Forecast shall be updated by HQ and provided to Supplier on a semi-annual basis. If the Plasma Volume Forecast is not provided or updated by HQ as indicated above, the preceding Plasma Volume Forecast shall stand.

HQ

4.2 Products Volume and Forecast

[redacted]

While developing the Delivery Schedule, Supplier acknowledges that Products cannot be made available for delivery until released by Health Canada and made available, in Supplier's warehouse, for distribution.

The quantities, vial sizes and delivery date for Products are as indicated in the Plasma Volume Forecast. For each shipment, Supplier must plan the delivery by assessing the available quantity [redacted] needed to meet the Products Delivery Schedule (ref: Article 5.2).

[redacted]

4.3 Continued Obligations after Termination

Notwithstanding the expiry or termination of this Fractionation and Supply Agreement, any HQ Plasma picked up by Supplier from HQ prior to the termination or expiration of this Fractionation and Supply Agreement shall be fractionated by Supplier into Fractionation Products and sold to HQ pursuant to this Fractionation and Supply Agreement, and any Plasma Intermediates produced therefrom must similarly be either purchased by HQ, returned or destroyed on the terms and conditions set forth in Subsection 3(b)(iii) hereof. Said rights and obligations of the Parties shall survive the expiration or termination of this Fractionation and Supply Agreement.

5. PRODUCT SPECIFICATIONS AND DELIVERY OF PRODUCTS

5.1 Product Specifications

Supplier shall provide Products in accordance with the Product Specification of Schedule 'B' to this Fractionation and Supply Agreement.

5.2 Finished Products Delivery Schedules

Each Agreement Year delivery schedule of Products, including quantity and vial sizes, ("**Delivery Schedule**") shall be decided by the Parties at least six (6) months prior to Supplier's first pickup of HQ Plasma for Fractionation Services. The Delivery Schedule shall take into account the relevant Plasma Volume Forecast, Supplier's available production schedule and HQ's supply and purchasing obligations hereunder. HQ shall provide Supplier with a twelve (12) month forecast

HQ

of the projected monthly delivery of the Products [redacted]. Such forecast shall include the required quantity of each vial size and shall serve as a basis for the preparation of the Delivery Schedule. Delivery Schedules shall be updated by HQ and provided to Supplier on a semi-annual basis and adjusted by mutual agreement. If the Delivery Schedule is not provided or updated by HQ as indicated above, the preceding Delivery Schedule shall stand.

The Delivery Schedule of the first Agreement Year shall be set by both parties at least six (6) months prior to Supplier's first pickup of HQ Plasma for Fractionation Services. Delivery frequency can be as much as once per week.

If HQ's delivery requirements change during the Term, HQ shall provide Supplier with an updated written revision to the Delivery Schedule and both Parties shall use reasonable best efforts to agree to a revised Delivery Schedule.

5.3 Delivery of Products

(a) Each shipment of Products to HQ shall include a packing slip detailing the nature of the Product and the quantity being shipped.

(b) Supplier shall provide documentation satisfactory to HQ to establish that the Products received by HQ were transported under conditions that did not compromise their quality and safety.

(c) Supplier shall transport all Products for HQ using a carrier selected by Supplier, which carrier shall be required to operate in compliance with Supplier's established standard operating procedures. If emergency shipments are required, Supplier may use an alternate carrier subject to meeting the same quality requirements. When Products are ready for shipment to HQ, a shipment notification shall be sent to HQ by Supplier via facsimile or electronic mail at least 24 hours prior to shipment. The notice shall specify the projected delivery date and method, the product code, the lot number, the expiry date and the quantity. The notice must be accompanied by a copy of Health Canada's lot release, the certificate of analysis which includes the date and place of manufacture of the Product and the quality control test results and their acceptable ranges.

5.4 Responsibility for Products

Supplier shall be responsible for and bear all risk of loss or damage to the Products until delivery to HQ's warehouse. Fractionation Products are supplied INCOTERMS 2010 DDP HQ's warehouse in Québec. The warehouse(s) shall be decided later through the Parties' mutual discussions and the agreed warehouse(s) shall be set out in Appendix "1" to Schedule E at least six (6) months prior to Supplier's first pickup of HQ Plasma for Fractionation Services.

HQ

5.5 HQ's Duty of Inspection

(a) HQ shall inspect incoming shipments for external visible damages within three (3) Business Days after delivery of the Products to HQ's warehouse. For greater certainty, HQ has no duty to test the Products and this Section 5.5 does not apply to latent defects or product deficiencies uncovered once the Products are released from the warehouse and put to use.

(b) HQ shall notify Supplier within two (2) days of inspection, in writing, of any visible damage not caused by HQ. Products that are to be returned to Supplier's facility shall be picked up by Supplier at the warehouse. Any such damaged Products shall give rise to a credit note issued by Supplier.

5.6 Late Deliveries

(a) If Supplier becomes aware of any potential delays in meeting the Delivery Schedule, then Supplier shall promptly (but not later than 48 hours after Supplier becomes aware of such potential delay) advise HQ of the reasons for the potential delay and of the date by which Supplier can confirm a revised Delivery Schedule.

(b) As soon as Supplier is able to confirm that it shall not meet the Delivery Schedule, Supplier shall notify HQ in writing, and shall indicate the next anticipated delivery date.

(c) In the event that Supplier's inability to meet one or more deliveries dates on the Delivery Schedule results in an actual or expected shortage in the Inventory System, HQ shall so notify Supplier in writing. Supplier shall have five (5) Business Days from receipt of such notice to make arrangements for the supply of sufficient quantities of Products or of substitutes of Products acceptable to HQ ("Replacement Product") to be delivered to HQ in order to restore the Inventory System to its target level. Failure to do so by Supplier shall entitle HQ to acquire Replacement Products pursuant to Section 10.5.

5.7 Product Shelf Life

Supplier shall ensure that all Products shipped to HQ pursuant to this Fractionation and Supply Agreement shall be in the correct vial sizes and have a remaining minimum shelf life of twelve (12) months from the date of receipt by HQ.

If certain vial sizes or minimum shelf life Products are in short supply at HQ due to the failure of Supplier to meet the Delivery Schedule and Delivery Requirements, then Supplier shall make available to HQ Products in other vial sizes or with shelf lives of not less than six (6) months, the whole subject to the following:

(a) Supplier may subsequently replace the other sized vials with the appropriate vial sizes if HQ's inventory of the other sized vials exceeds HQ's requirements; and

HQ

(b) Products delivered to HQ with less than six (6) months remaining shelf life and still in the Inventory System at the time of outdating may be returned by HQ to Supplier.

All HQ costs relating to vial size replacement or return of Products under this Section 5.7 shall give rise to a credit note issued by Supplier no later than thirty (30) days after demand therefor by HQ.

HQ shall indemnify and hold Supplier harmless from any and all damages, costs and expenses caused by HQ relating to the production, packaging, storage, handling, loading, transportation and destruction by Supplier of (i) any Products in unwanted vial sizes, or (ii) any Products that become outdated.

5.8 Distribution of Products

HQ hereby acknowledges and agrees that the Products are and shall be for distribution by HQ in the Province of Québec, except that nothing herein shall prevent HQ, with the prior written permission of Supplier, which permission shall not be unreasonably withheld, from: (i) donating such Products to organizations outside Canada for charitable purposes and in compliance with all applicable laws and regulations,

6. PRICES, PAYMENT TERMS AND INVOICES

6.1 Price

All prices payable under the Fractionation and Supply Agreement by HQ are set forth in Schedule "A".

All prices are in Canadian currency, and subject to GST and QST, as applicable.

6.2 Price Adjustments

(a)

(b) Improvements Mandated by Regulator – Products

Where Supplier is directed by a regulator with authority to make an Improvement which shall result in a price increase to HQ, Supplier shall

HQ

provide HQ with notice in accordance with Section 9.7 and shall substantiate the proposed price increase and timing. The Parties shall negotiate in good faith the amount and timing of the proposed price increase. If HQ does not agree with the proposed price or timing, the matter shall be referred to the arbitration process pursuant to Article 15.

(c) Improvements Mandated by Supplier –Products

With respect to any Improvement initiated by Supplier, Supplier shall notify HQ in accordance with Section 9.7, and if this Improvement shall increase the price of a Fractionation Product to HQ, or shall require HQ to make a change to its collection, processing, storage or shipping of HQ Plasma ("**HQ Process**"), the Parties shall negotiate in good faith the amount and timing of the proposed price increase. If the Parties cannot agree on the proposed timing and price, the matter shall be referred to the arbitration process pursuant to Article 15.

6.3 Payment Terms/Prompt Payment Discount/Interest on Late Payment

Payment of invoices not disputed shall be net thirty (30) days from the later occurrence of the following events: (i) the date of receipt of the relevant Product by HQ, or (ii) the date of receipt of the invoice by HQ.

6.4 Invoices

Supplier shall issue one invoice per delivery. Invoices shall clearly indicate the invoiced Product(s) and the quantity delivered. Invoices shall be rendered in two (2) copies and must be sent to the following address at the time of each delivery:

Héma-Québec
Comptes à payer
4045, boulevard de la Côte-Vertu
Montréal, arrondissement Saint-Laurent
Québec, CANADA H4R 2W7

7. MEETINGS

The Parties shall meet at least semi-annually for the purpose of discussing matters related to this Fractionation and Supply Agreement, including, but not limited to, operational issues, new processes, procedures and products, inventory levels and regulatory issues. During such meetings, Supplier shall provide to HQ global adverse drug reaction data for Products consumed in the Province of Québec during

HQ

the last six months. Supplier shall provide to HQ a complete reconciliation report of HQ Plasma and Fractionation Products at least two (2) weeks prior to each meeting. Meetings may be cancelled if both HQ and Supplier are in agreement. Either HQ or Supplier may call a meeting by giving written notice to the other Party. Meetings are to be held in Montréal unless otherwise agreed between the Parties. Each of HQ and Supplier agree to have the necessary and appropriate representatives present at such meetings. The name of the attendees shall be communicated well ahead of the meeting scheduled date.

8. KEY PERFORMANCE INDICATORS (KPI)

The performance of Supplier shall be monitored by HQ based on [redacted] The objectives of the KPI program are set out in Schedule "G".

9. REGULATORY AND QUALITY ASSURANCE MATTERS

9.1 Regulatory Condition of Supply

Supplier shall obtain and submit to HQ a copy of the Notice of Compliance issued by Health Canada in order to substantiate that the Fractionation Products being supplied under the Agreement meet the requirements and standards of Health Canada. If the Notice of Compliance is subject to any conditions, then Supplier shall, not less than once per Agreement Year, update HQ on its progress towards satisfying Health Canada requirements, and shall issue a letter to health care providers for the corresponding period describing the original conditions and the progress realized to date.

9.2 Special Access Program

(a) If any Product ceases to be licensed by Health Canada and can be made available only under a special access program, then HQ may require Supplier to supply the Product pursuant to such Special Access Program ("SAP Product"). In order to manage a smooth transition and decrease wastage, Supplier shall be allowed to lower the inventory level during the transition period.

(b) Notwithstanding Subsection 9.2(a), if the applicable legislation or decision of Health Canada requires HQ to move to a product supplied by another manufacturer, HQ may acquire Replacement Products pursuant to the provisions of Section 10.5.

(c) [redacted]

HQ

(d) [redacted]

9.3 Senior Regulatory Officer Information

Supplier shall, upon execution of this Fractionation and Supply Agreement, notify HQ in writing, of the name of its senior regulatory officer(s). In the event of a change in the designated person(s) during the Term, Supplier shall immediately notify HQ, in writing, of such change.

9.4 Communications

Supplier shall disclose to HQ the Fractionation Products manufacturing location, the inspection location, the warehousing location and any other location where the Fractionation Products are processed prior to delivery to HQ. If Supplier is not the prime manufacturer of the Fractionation Products, Supplier shall also provide the above information on third party manufacturing facilities.

Supplier shall promptly notify HQ and shall provide HQ with electronic and hard copies of the following documents in connection with the Fractionation Products supplied under this Fractionation and Supply Agreement:

(a) Supplemental/New Drug Submission and New Drug Submission cover letters only, or if the said letters do not clearly identify the nature of the submission, documentation identifying the nature of the submission;

(b) Health Canada Notices of Compliance;

(c) Printed components, including cartons, labels and package insert with explanation of changes thereto;

(d) Product monographs approved by Health Canada;

(e) Health Canada establishment license and any update on an annual basis;

(f) Health Canada Exit Notices and associated responses;

(g) [redacted]

(h) Quarantine, Recall and Withdrawal notices and correspondence from/to associated regulators;

(i) [redacted] or Notices of Intent issued by Health Canada with respect to premises where Fractionation Products are manufactured; and

HQ

(j) Changes to the telephone numbers to be used by Consumers or healthcare professionals to report adverse drug reactions both during normal business hours and after hours.

Other documents regarding regulatory issues shall be provided to HQ by agreement with Supplier, on a case by case basis.

9.5 Adverse Event Reporting

In accordance with Health Canada regulations, HQ shall promptly notify Supplier by facsimile or electronic mail of any adverse drug reactions potentially associated with the use of the Products reported to it. Supplier shall provide final results on the investigation, in written form, within sixty (60) days of receipt of HQ's written notification.

9.6 Compliance Audit

HQ shall be entitled to audit quality systems, manufacturing processes, warehousing facilities, and the books and records of Supplier in connection with the Fractionation and supply of Products by the Supplier under this Fractionation and Supply Agreement. Where relevant, audit responses including a plan of action for corrective measures to audit observations shall be provided by Supplier to HQ within thirty (30) days of receiving the audit report. Agreed-upon corrective measures shall be implemented within a reasonable time frame.

Additionally, HQ shall be entitled to audit third party facilities and freight carriers, if applicable, with respect to quality assurance matters arising from this Fractionation and Supply Agreement. Such audit rights shall include the right to inspect associated books and records with respect to quality assurance matters. In such audits, Supplier shall liaise with the third party warehouse facility or freight carrier on behalf of HQ and shall require such third party vendors to provide audit responses within thirty (30) days of receiving the audit report. Supplier shall further require third party vendors to implement any agreed-upon corrective actions within a reasonable period of time.

Conditions for all quality assurance audits:

(a) Each Party shall be responsible for its own costs;

(b) The audit is conducted at a reasonable time with adequate prior notice;

(c) The audit occur not more frequently than once per Agreement Year, provided that there are no risks to revocation of Health Canada licensure, in which case an audit may be performed immediately, and in compliance with this Section 9.6; and

HQ

(d) Results for all audits shall be maintained as confidential information and shall be used for the purposes of and as contemplated by this Fractionation and Supply Agreement or as otherwise required by law.

9.7 Improvements

(a) If Supplier plans to make an Improvement to a Fractionation Product, Supplier shall advise HQ of such planned Improvement at least three (3) months prior to implementing any such Improvement, except that under exceptional circumstances, including patient safety, the notification period may be shorter. Updates shall be provided by Supplier at the semi-annual meetings mentioned at Section 7.

(b) If a regulator with authority notifies Supplier that it requires an Improvement in a shorter time frame, Supplier shall notify HQ within five (5) Business Days of receipt of notice by Supplier of such required change.

(c) If Supplier introduces any Improvement in the United States or in Europe, the Supplier shall, unless the Parties agree otherwise, use all reasonable efforts to incorporate such Improvement in the relevant Fractionation Product supplied under this Agreement, subject to the price adjustment provisions of Section 6.2.

(d) For Improvements that require approval by Health Canada, Supplier shall at the time of filing the submission for the Improvement, or within a reasonable period thereafter, apply for Health Canada's approval. Should the Improvement not be permitted due to Health Canada requirements, Supplier shall advise HQ.

(e) If an Improvement requires approval by Health Canada, Supplier shall notify HQ within five (5) Business Days of the date the application is filed with Health Canada.

(f) If an Improvement requires a HQ Process change, Supplier shall provide HQ with reasonable advance notice so that HQ can process the change, perform validation and apply to Health Canada for an amendment to its license.

(g) No Party shall be responsible for, or incur any liability in connection with, any delay in obtaining any Health Canada approval to the extent such delay is caused by Health Canada or results from the failure to meet any requirements imposed or administered by Health Canada.

10. PRODUCT WITHDRAWALS/RECALLS

10.1 Supplier Determines Products are Unsuitable

(a) If Supplier determines, in its reasonable discretion, after any Products have been delivered to HQ, that such Products are unsuitable or defective in any manner, and that such unsuitability or defect creates a reasonable likelihood of adverse risk to the safety or quality of any Products, Supplier shall give immediate notice to HQ by telephone of any such occurrence, followed by

HQ

facsimile transmission or electronic mail to HQ. If Supplier, acting reasonably, places Products under quarantine, or recalls or withdrawing any Products, or takes any other action to remedy any deficiencies in Products, and HQ has been asked to co-operate in any such quarantine, Recall or Withdrawal or remedial action (which request shall not be made unreasonably), HQ shall reasonably co-operate in any such quarantine, Recall or Withdrawal, or remedial action as is reasonably required by Supplier to remedy any deficiency in the Products.

(b) The costs of such actions, including the cost of making good to or replacing any defective Products, shall be paid by the Party to whom causation is attributable.

10.2 HQ Determines Products are Unsuitable

(a) If HQ determines, in its reasonable discretion, that any Product fails to meet the specifications in Schedule "B", and that such failure creates a reasonable likelihood of an adverse risk to the safety or quality of the Product, HQ shall immediately notify Supplier by telephone of such occurrence, followed by facsimile transmission or electronic mail. If HQ, acting reasonably, notifies Supplier that it is placing the said Product in quarantine, or recalling or withdrawing such Product, or is taking any other remedial action, then Supplier shall reasonably co-operate in any such actions as is required by HQ to deal with the failure of the Product to meet the specifications in Schedule "B".

(b) The costs of such actions, including the cost of making good to or replacing any defective Products, shall be paid by the Party to whom causation is attributable. For greater certainty, HQ is not required to notify Supplier of any defect or possible defect caused by HQ while the Product is in HQ's care and control and where there is no impact on Supplier under this Fractionation and Supply Agreement, unless otherwise required by any regulatory authority or by law.

(c) If HQ initiated the quarantine, Recall or Withdrawal of a Product pursuant to Subsection 10.2(a), and it is subsequently determined that the Product does not create a reasonable likelihood of risk to the safety or quality of the Product, as determined by Health Canada, HQ shall be required to return the Product to the market or remove the quarantine, recall or withdrawal, as applicable, as its sole cost and expense.

10.3 Recall / Withdrawal

(a) Before the first delivery of the Products to HQ, Supplier shall notify HQ of Supplier's toll-free telephone number and contact name(s) for customers' enquiries or questions.

(b) Supplier must provide supporting information or documentation to HQ for dissemination immediately and not later than twenty-four (24) hours by telephone, facsimile and electronic mail of a decision to quarantine, Recall or Withdraw any of the Products.

HQ

(c) If a Product quarantine, Recall or Withdrawal is initiated by Supplier, Supplier shall call HQ's Stable Products & Logistics department support telephone line. Such call must be followed by a facsimile and/or electronic mail to HQ.

(d) Supplier shall appoint a spokesperson who shall be responsible for the communication on the specifics of the quarantine, Recall or Withdrawal unless the quarantine, Recall or Withdrawal is initiated by HQ.

(e) Any news release or disclosure relating to a removal from the market, quarantine, Recall or Withdrawal of a Product which references Supplier or HQ must be mutually reviewed and approved by the Parties prior to release.

10.4 Product Quarantined, Recalled, Withdrawn

HQ shall be entitled to purchase Replacement Products in accordance with Section 10.5 if (i) a quarantine, Recall or Withdrawal of a Product results in a shortage which is not attributable to HQ, or (ii) Health Canada or other governmental authority determines that a Product may not be distributed or used in Canada and such determination results in a shortage which is not attributable to HQ.

10.5 Procedures and Remedies - Alternate Sourcing

(a) Should HQ be able to purchase a Replacement Product pursuant to Section 2.11, 5.6, 9.2 or 10.4, then Supplier shall respond in writing to HQ within two (2) Business Days (in the case of Section 5.6 such delay shall be calculated from the end of the five (5) Business Day period stipulated in Section 5.6) or such longer time period as may be agreed by the Parties, confirming whether Supplier can provide the Replacement Product. If Supplier notifies HQ that it can provide Replacement Product then it shall provide comprehensive specifications and proposed delivery schedule for such Replacement Products (the "**Proposal**"). HQ shall advise Supplier in writing whether or not the Proposal is acceptable. If the proposed Replacement Product is acceptable to HQ, then Supplier shall provide such Replacement Product to HQ for the price of the Product being replaced and under the terms and conditions of this Fractionation and Supply Agreement.

(b) If HQ, acting reasonably, rejects the Proposal or if no Proposal is offered within the stipulated or agreed time frame, and provided that Section 17.16 is not operative, HQ may proceed to locate a Replacement Product from a third party supplier selected by HQ. The quantity of Replacement Product purchased by HQ pursuant to this Section 10.5 shall be limited to the quantity necessary to avert a shortage. Supplier acknowledges that HQ has the right to purchase sufficient Replacement Product to re-establish its target level inventory.

(c) Supplier shall compensate HQ for the difference in price between the price of the Replacement Product and that of the Product. Such compensation shall be due and payable by Supplier within fifteen (15) days of delivery by HQ of an invoice therefor.

HQ

10.6 Replacement Products

Any Replacement Products proposed by Supplier under Sections 2.11, 5.6, 9.2 and 10.5 must be licensed by Health Canada or if no Replacement Products are licensed by Health Canada, such Replacement Products must be approved by Health Canada under a special access program.

10.7 Patient Notification System

Supplier understands that the Patient Notification System was created to provide a fast, confidential method to provide information to Consumers on quarantine, Recall or Withdrawal events. Supplier agrees, at its own cost, to participate in the Patient Notification System as a subscriber and to provide all information regarding quarantine, Recalls or Withdrawals to the Patient Notification System at the same time as the information is provided to Health Canada and HQ.

11. REPRESENTATIONS AND WARRANTIES

11.1 Representations and Warranties of the Parties

Each of the Parties represents and warrants to the other that at the time of entering into this Fractionation and Supply Agreement:

(a) It is duly organized, validly existing and is in good standing under the laws of its jurisdiction of incorporation, and is qualified to do business and in the case of HQ to carry on its activities, and is in good standing in each jurisdiction in which the performance of its obligations hereunder requires such qualification (except where such failure to qualify would not have a material adverse effect) and has all requisite power and authority, corporate or otherwise, to conduct its business as now being conducted, to own, lease and operate its properties and to execute, deliver and perform this Fractionation and Supply Agreement;

(b) Subject to Section 1.1(a)(i), the execution, delivery and performance by it of this Fractionation and Supply Agreement have been duly authorized by all necessary corporate or other legal action and do not and shall not:

(i) require any consent or approval of its shareholders, members or other stakeholders as the case may be;
(ii) violate any provision of any law, rule, regulation, order, writ, judgment, injunction, decree, determination or award presently in effect having applicability to it and known to it or any provision of its charter documents; or
(iii) result in a breach of or constitute a default under any material agreement, mortgage, lease, license, permit or other instrument or obligation to which it is a party or by which it or its properties may be bound or affected.

HQ

(c) This Fractionation and Supply Agreement is a legal, valid and binding obligation of it enforceable against it in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws and regulations affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);

(d) It is not under any obligation to any person, or entity, contractual or otherwise, that is conflicting or inconsistent in any respect with the terms of this Fractionation and Supply Agreement or that would impede the diligent and complete fulfillment of its obligations;

(e) It has good and marketable title to or valid leases or licenses for all its properties, rights and assets necessary for the completion of its responsibilities under this Fractionation and Supply Agreement, subject only to the claim of any relevant lessor or licensor; and

(f) There are no legal or arbitral proceedings, or any proceedings by or before any governmental or regulatory authority or agency, now pending or (to its knowledge) threatened against it that, if adversely determined could (either individually or in the aggregate) have a material adverse effect on its ability to perform its obligations under this Fractionation and Supply Agreement.

11.2 Supplier's representations and warranties with respect to the Fractionation Products

(a) Supplier covenants to HQ that the Products shall:

(i) be manufactured, stored, released and transported in accordance with:

- Canadian laws and regulations (including, but not limited to, Drugs Directorate Good Manufacturing Practices stipulated under the *Food and Drug Act (Canada)*); and
- Supplier's Quality Assurance and Quality Control processes;

(ii) Comply with the certificates of analysis;
(iii) Conform to any and all specifications described in Schedule "B" and descriptions or designs furnished by Supplier in any product inserts or labeling; and
(iv) be transported to HQ in a manner in which their quality, safety and efficacy are not otherwise compromised.

(b) Supplier further represents and warrants that, if required, valid Health Canada approvals for the Products shall have been issued and be in good standing at the time of delivery of any Product to HQ. Supplier shall notify HQ immediately upon any notice of deficiencies or requests for submissions with respect to any of the Products supplied under this Fractionation and Supply Agreement.

HQ

11.3 HQ Representations and Warranties

HQ represents and warrants to Supplier that it shall transport, store and distribute the Products in accordance with the terms of this Fractionation and Supply Agreement and in accordance with applicable laws and regulations.

11.4 Current Information

Supplier represents and warrants to HQ that the information currently provided to HQ and which shall, from time to time, be amended or further provided with the Products, including without limitation, any regulatory filings, circulars and package inserts, are current, accurate and fulfill any regulatory requirements for the Products.

11.5 No Waiver

Each of the foregoing representations and warranties shall not be (nor shall the same be deemed to be) waived, in whole or in part, as a result of any audit or pre-testing conducted by or on behalf of HQ or any third party, except as expressly provided for herein.

11.6 Survival of Representations and Warranties

All representations and warranties made or provided herein or in any document delivered pursuant hereto or incorporated by reference herein, whether expressed or implied by law or otherwise, shall survive inspection and acceptance thereof and payment thereunder and shall inure to the benefit of the Parties notwithstanding the termination or expiration of this Fractionation and Supply Agreement.

12. INTELLECTUAL PROPERTY

12.1 Grant under Supplier's Intellectual Property

Supplier hereby grants to HQ under all Relevant IP [redacted]. "**Relevant IP**" means all intellectual property, including, but not limited to, domestic and foreign trade-marks, patents, designs and copyright, whether registered or not.

12.2 Non Infringement

Supplier hereby represents and warrants to HQ that to the best of its knowledge as of the Effective Date, none of the Products or processes related to the provision of Fractionation Services or any component thereof infringe or shall constitute an infringement of any Relevant IP when Products are used according to approved uses.

HQ

12.3 Potential infringement of a third party intellectual property right

If one of the Parties learns of a potential infringement of third party intellectual property related to the manufacture, use, or distribution of the Fractionation Products, such Party shall notify the other Party in writing of such potential infringement, including any known details or supporting information, to the extent such details and information may be lawfully disclosed.

13. INSURANCE AND INDEMNIFICATION

13.1 Supplier's Insurance

(a) Supplier shall provide and maintain during each Agreement Year, at its own expense, the following insurance coverage:

No such policies shall provide for subrogation against HQ when liability is legally determined to rest entirely with Supplier. Supplier shall provide HQ with proof of valid insurance coverage. A certificate of insurance issued by the insurer shall be acceptable to HQ as proof of coverage. All of the aforementioned certificates provided by the insurer to Supplier shall certify the following:

(i) that the required insurance policies are valid and the coverage specified in this Section 13.1, is in effect; and
(ii) the insurer shall provide notice of amendments or cancellation to HQ.

(b) Supplier shall provide HQ with at least fifteen (15) days advance written notice of any change in the amount of coverage or type of insurance stipulated. In no case shall Supplier materially alter, cancel or allow to lapse any stipulated insurance while HQ is receiving Fractionation Products pursuant to this Agreement. For greater clarity, Supplier may engage different insurers for the foregoing insurance coverage, so long as the foregoing insurance requirements are maintained.

(c) The foregoing insurance provisions shall not limit the amount or type of insurance otherwise required by law. It shall be the sole responsibility of Supplier to determine what additional insurance coverage, if any, is necessary and advisable for its own protection or to fulfill its obligations under this Fractionation and Supply Agreement. Any such additional insurance shall be provided and maintained by Supplier at its own cost and expense.

(d) Supplier warrants to HQ that as of the Effective Date, it has not done or shall not do anything which would cause the stipulated insurance policy or policies to be suspended, impaired, cancelled or otherwise adversely affected by the respective insurers.

HQ

(e) In the event that one of the Parties is notified of a proceeding, claim or demand brought or made against the other Party in relation to this Fractionation and Supply Agreement, the recipient party must immediately notify the other Party in writing.

13.2 Indemnification by Supplier

(a) Supplier shall indemnify and hold harmless HQ and its directors, officers and employees from and against

(b) Supplier hereby agrees to indemnify and hold harmless HQ and its directors, officers and employees harmless from and against

13.3 Indemnification by HQ

(a) HQ shall indemnify and hold harmless Supplier and its respective directors, officers and employees from and against

HQ

(b) HQ hereby further agrees to indemnify and hold harmless Supplier and its directors, officers and employees harmless from and against all

13.4 Notice, cooperation and survival

(a) In the event that a Party (the "**Indemnitee**") becomes aware of any action, claim or demand in respect of which the other Party (the "**Indemnitor**") is liable to indemnify Indemnitee pursuant to this Fractionation and Supply Agreement, the Indemnitee shall promptly notify the Indemnitor thereof. The Indemnitor shall at all times have the right at its sole expense to dispute and contest in the name of the Indemnitee or otherwise any such action, claim or demand. The Indemnitee, at its own expense, shall fully co-operate with the Indemnitor and its counsel in any proceedings with respect to any such action, claim or demand.

(b) The provisions contained in Sections 13.2 and 13.3 shall survive the termination of this Fractionation and Supply Agreement and shall be in addition to and shall not affect any other indemnification provisions contained herein.

13.5 Approval of Counsel

The Indemnitee reserves the right to approve or reject (acting reasonably) the selection of counsel for any lawsuit or proceeding for which any claim for indemnification may be made against the Indemnitor. In the event of any such suit no Party nor their representatives shall make any public disclosure or comment (other than as part of the actual legal proceedings) without the prior written consent of the other Party.

14. TERMINATION

14.1 Termination of Fractionation and Supply Agreement

Any Party may, without prejudice to any other right or remedy it may have, immediately terminate this Fractionation and Supply Agreement or suspend its obligations hereunder if an event of default (as defined in Section 14.2 or 14.3 as a "**Supplier Event of Default**" or an "**HQ Event of Default**") occurs and the other Party does not cure such Events of Default within thirty (30) days, upon receiving written notice thereof. If such termination or suspension occurs, the terminating party shall be relieved of any further obligations under this Fractionation and Supply Agreement, other than obligations that are intended to survive termination and payment of any outstanding invoices or obligations previously incurred.

14.2 Supplier Event of Default

A "**Supplier Event of Default**" shall mean:

(a) the failure by Supplier to meet the claims, representations or warranties made (i) in labeled promotional material distributed by Supplier in connection with Products, (ii) in Product information distributed by Supplier, or (iii) on labeled Products;

(b) any misrepresentation herein contained having a material adverse effect on HQ or any material breach by Supplier of any provision of this Fractionation and Supply Agreement. It is acknowledged and agreed that persistent or repeated minor breaches can amount to a material breach if they have a material adverse effect on HQ;

(c) a seizure is made of all or substantially all of the property or assets of Supplier and such seizure is not dismissed within fifteen (15) days unless otherwise agreed by the Parties;

(d) the making of a general assignment of the property of Supplier for the benefit of its creditors;

(e) the appointment (by court order or otherwise) of a receiver, receiver and manager or a trustee for the benefit of one or more of the creditors of Supplier;

(f) the filing of a voluntary petition in bankruptcy, adjudication as a bankrupt or the filing of an answer or admission seeking relief pursuant to applicable bankruptcy law pertaining to Supplier or any filing by or against Supplier of any proceedings under the Companies' Creditors Arrangement Act, R.S.C. 1985, c. C.-36, as amended; or

(g) the filing of an involuntary petition in bankruptcy pertaining to Supplier which petition is not dismissed, vacated, set aside or stayed within forty-five (45) days.

HQ

For the events described in Subsections 14.2(a) and (b), a Supplier Event of Default shall, unless cured, take effect thirty (30) days after notice given by HQ to Supplier specifying Supplier Event of Default.

14.3 HQ Event of Default

An "**HQ Event of Default**" shall mean:

(a) any misrepresentation herein contained having a material adverse effect on Supplier or any material breach by HQ of any provisions of this Fractionation and Supply Agreement. It is acknowledged and agreed that persistent or repeated minor breaches can amount to a material breach if they have a material adverse effect on Supplier; for greater certainty a breach of Section 3.1(a) shall be deemed a material breach under this Section 14.3;

(b) an seizure is made of all or substantially all of the property or assets of HQ and such seizure is not dismissed within fifteen (15) days unless otherwise agreed by the Parties;

(c) the making of a general assignment of the property of HQ for the benefit of its creditors;

(d) the appointment (by court order or otherwise) of a receiver, receiver/manager or a trustee for the benefit of one or more of the creditors of HQ;

(e) the filing of a voluntary petition in bankruptcy, adjudication as a bankrupt or the filing of an answer or admission seeking relief pursuant to applicable bankruptcy law pertaining to HQ or any filing by or against HQ of any proceedings under the Companies' Creditors Arrangement Act, R.S.C. 1985, c. C.-36, as amended; or

(f) the filing of an involuntary petition in bankruptcy pertaining to HQ which petition is not dismissed, vacated, set aside or stayed within forty-five (45) days.

For the events described in Subsection 14.3(a), an HQ Event of Default shall, unless cured, take effect thirty (30) days after notice given by Supplier to HQ specifying the HQ Event of Default.

14.4 Obligations for Work in Progress, Freight and Testing Upon Termination

Unless the termination is due to a Supplier Event of Default, in the event of termination or expiration of this Fractionation and Supply Agreement, HQ shall be obligated to pay for all work in progress and charges incurred for freight and testing.

14.5 Termination in the Event of Revocation of Health Canada Approvals

In the event that Health Canada revokes any necessary Health Canada approvals for the provision of Products to HQ and Supplier has satisfied itself, acting reasonably,

HQ

that reinstatement of such approvals is unlikely, Supplier shall upon thirty (30) days advance written notice to HQ, terminate this Fractionation and Supply Agreement and in that case all Parties shall be relieved of further obligations hereunder other than the obligations that are intended to survive termination. In the instance where Health Canada has revoked necessary approvals or licenses, and HQ Plasma has not been consumed, then Supplier shall return all such HQ Plasma to HQ. If HQ Plasma has been consumed and has not been provided as Fractionation Products to HQ, Supplier shall reimburse HQ the fair market value of any HQ Plasma within its inventory.

15. DISPUTE RESOLUTION

15.1 Arbitration

(a) The Parties agree that in the event of any dispute or claim arising under or in connection with this Fractionation and Supply Agreement or any instructions issued pursuant to this Fractionation and Supply Agreement, including, but not limited to, the interpretation or application of this Fractionation and Supply Agreement, the Parties shall endeavor to resolve the dispute with diligence and good faith negotiations to be handled between the Parties.

(b) If the Parties have been unable to resolve the dispute, despite diligence and good faith negotiations, such dispute or claim shall be settled by arbitration, as dictated by this Article.

(c) All questions, disputes or differences of opinion involving the interpretation, application, administration, or alleged violation of this Fractionation and Supply Agreement including a question of whether a matter may be subject to arbitration, shall be settled by arbitration.

(d) The arbitration shall take place in the City of Montréal and each party may be represented by counsel at the arbitration.

(e) In the event that the Supplier or HQ requests that a dispute shall be put to arbitration, then such party shall give fifteen (15) days written notice thereof to the other. If Supplier and HQ cannot agree upon arbitrator within fifteen (15) days after demand by either of them for arbitration, then each of HQ and Supplier shall select one (1) arbitrator. The two (2) arbitrators selected shall then choose a third arbitrator in order that the dispute may be finally resolved by a majority of the panel of three (3) arbitrators.

(f) The Parties acknowledge that it would be advantageous to the resolution of disputes if the arbitrators chosen possess relevant scientific, technical or medical knowledge, and they shall endeavor to select arbitrators with the requisite expertise. The expense of the arbitration shall be paid by the Party to whom causation is attributable. Any such arbitration shall be conducted in accordance with the laws of the Province of Québec. The decision of the arbitrators shall be final and binding and any of the Parties may make

HQ

application to a court of competent jurisdiction for the judicial acceptance of the award and an order for enforcement.

(g) The Parties hereby agree that prior to the disclosure of any material in furtherance of this Article, the Parties and the selected arbitrators shall be required to enter into confidentiality agreements to protect information disclosed during the arbitration process and the ruling of the arbitrators.

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17. GENERAL

17.1 Time of the Essence

Time shall be of the essence.

17.2 Extended Meanings

In this Fractionation and Supply Agreement, words importing the singular number include the plural and vice versa.

17.3 Notices

(a) Any notice or demand required or permitted to be given by one party to the other shall be in writing and shall be, unless otherwise specifically stipulated herein:
   (i) personally delivered;
   (ii) sent by courier, prepaid;
   (iii) sent by facsimile; or
   (iv) sent by electronic mail.

(b) The address of each party for any such notice shall be as follows:

To HQ: **HÉMA-QUÉBEC**
4045 Côte-Vertu Blvd.
Saint-Laurent (Québec) H4R 2W7
CANADA

HQ

Operational issues and regulatory issues including quality assurance matters, Product quarantine, Recall or Withdrawal document or correspondence:

Attention: Director of stable products & logistics services
Telephone: 514 832-5000 ext. •
Facsimile: •
e-mail: jean-lapierre@hema-quebec.qc.ca

Contractual matters including formal notice to be given pursuant to the Fractionation and Supply Agreement:

Attention: Director of Purchasing, stores & facilities
Telephone: 514 832-5000 ext. 379
Facsimile: 514 832 1027
e-mail: jean-francois.deschenes@hema-quebec.qc.ca

To Supplier: **GREEN CROSS BIOTHERAPEUTICS INC.**

Technoparc Montréal (Lot 14)
7140 Albert-Einstein, suite 200
Montréal (Québec) H4S 2C1
Attention:
Telephone:
Facsimile:
e-mail:

Any party may from time to time change its address by written notice to the other party given in accordance with the provisions of this Section. Any notice given by personal delivery or courier shall be deemed to be received on the date of delivery. Any notice by facsimile or electronic mail shall be deemed to be received when it is properly sent.

17.4 Assignment

Neither this Fractionation and Supply Agreement nor any of the rights or obligations of any party may be assigned without the prior written consent of the other Party which consent shall not unreasonably be withheld provided that (i) such consent shall not be required for assignment to an "Affiliate" as defined by the *Canada Business Corporations Act*, R.S.C., 1985, c. C-44 as amended nor (ii) if HQ, or its successor, ceases to coordinate or loses the authority to collect HQ Plasma or to distribute the Fractionation Products in the Province of Québec and this Fractionation and Supply Agreement is assigned to a successor.

17.5 Independent Contractors

HQ and Supplier are contractors independent of each other and neither HQ nor Supplier has the authority to bind the other to any third person or otherwise to act in any way as the representative of the other unless otherwise expressly agreed to in writing by the other. Neither HQ nor Supplier shall hold itself out as having, any

HQ

right, power or authority to create any contract or obligation, either express or implied, on behalf of, in the name of or binding upon the other. It is understood and agreed that no party, their respective shareholders, members, directors, officers, employees, agents, and other legal representatives have, nor are they to be construed to have, any relationship with the others (whether as an employee, agent, partner or otherwise) except that of HQ and Supplier being independent contractors in respect of the matters which are subject of this Fractionation and Supply Agreement.

17.6 Severability

If any provision of this Fractionation and Supply Agreement is determined to be invalid or unenforceable in whole or in part by a court of competent jurisdiction, such invalidity or unenforceability shall attach only to such provision and everything else in this Fractionation and Supply Agreement shall continue in full force and effect.

17.7 Governing Law

This Fractionation and Supply Agreement shall be governed by and construed in accordance with the laws in force in the Province of Québec and shall be treated in all respects as a Québec contract. The Parties submit to the jurisdiction of the Courts of Québec with respect to any dispute, claim or other matter arising under this Fractionation and Supply Agreement and the Courts of Québec shall have exclusive jurisdiction with respect to any such dispute, claim or other matter subject to the provisions of Section 15. The Parties agree that the United Nations Convention on contracts for the International Sale of Goods shall not apply to this Fractionation and Supply Agreement.

17.8 Successors and Assigns

This Fractionation and Supply Agreement shall inure to the benefit of and be binding upon the Parties and their respective heirs, executors, administrators, and permitted successors and assigns.

17.9 Non Waiver

No waiver by any Party of any breach of any of the provisions of this Fractionation and Supply Agreement by another shall take effect or be binding upon the Party unless agreed in writing. Unless otherwise provided therein, a waiver shall not limit or affect the rights of the Party granting the waiver with respect to any other breach.

17.10 Remedies Cumulative

Except as otherwise expressly provided in this Fractionation and Supply Agreement, the rights and remedies of the Parties under this Fractionation and Supply Agreement are cumulative and in addition to and not in substitution for any other rights and remedies available at law or otherwise, and no single or partial exercise by a party of any right or remedy precludes or otherwise affects the exercise of any other right or remedy to which that party may be entitled.

HQ

17.11 Counterparts

This Fractionation and Supply Agreement may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall constitute the Fractionation and Supply Agreement.

17.12 Amendment

This Fractionation and Supply Agreement may not be amended or modified in any way except by the written consent of the Parties hereto.

17.13 Confidential Information

All information pertaining to the technology, business and affairs of any Party obtained as a result of or in respect of this Fractionation and Supply Agreement shall be kept and maintained in confidence and shall not be disclosed to any other person, except:

(a) to the auditors, legal counsel and professional advisors of the Parties hereto provided that the professional advisors have signed a confidentiality agreement with the disclosing party;

(b) if such information enters the public domain otherwise than by a breach of this Fractionation and Supply Agreement or the negligence of a Party; and

(c) if disclosure of such information is required by virtue of any present or future applicable law, regulation or ruling by a relevant government or governmental board, commission, department, bureau or authority to which the relevant party hereto is subject.

17.14 Pricing Information to Customers

HQ may publish within the hospital network the list of tariffs applicable to the purchase of [redacted] products developed by averaging HQ cost of distributing [redacted] products [redacted] to the hospitals. HQ may also publish the estimated total value of the Purchase Agreement entered into with the Supplier for the Term of such Agreement. Unless required by law or by ministerial order, the Supplier's unit prices shall not be disclosed nor discussed with third parties.

17.15 Public Announcements

No public announcement or press release relating in any way to this Fractionation and Supply Agreement shall be made without the prior written consent of HQ in the case of Supplier, and Supplier in the case of HQ, and joint approval of the contents of such announcement or release except where any such announcement is required by law, in which case the announcing Party shall send by facsimile and electronic

HQ

mail the draft announcement to the other Party immediately upon becoming aware of the legal requirement and, in any event, before releasing such announcement.

17.16 Force Majeure

No party hereto shall be deemed in default hereunder for any failure or delay to perform any of its obligations under this Fractionation and Supply Agreement caused or arising out of the following acts (provided the same is not within the control any of Supplier or any of its suppliers providing services hereunder) : acts of God, strikes, lockouts or other industrial disputes, acts of the public enemy, riots, failure of utilities, fire, storm, flood, explosion. If a failure or delay is caused by one of the events above-mentioned, all delays provided for in this Fractionation and Supply Agreement shall be extended for a period commensurate with the period of the delay and, to the extent possible, the said party affected shall take all reasonable steps to remedy the delay caused by the events above-mentioned; provided; however, that nothing contained in this Section 17.16 shall require either party to settle any industrial dispute.

17.17 Entire Agreement

(a) This Fractionation and Supply Agreement, including the attached Schedules, constitutes the entire agreement between the Parties pertaining to its subject matter and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions, whether oral or written, of the Parties. There are no warranties, representations, or other agreements between or among the Parties in connection with its subject matter except as specifically set forth in this Fractionation and Supply Agreement. No supplement, modification, amendment, or waiver of this Fractionation and Supply Agreement shall be binding unless executed in writing by all Parties.

(b) The delivery of any Fractionation Product pursuant to this Fractionation and Supply Agreement shall be governed strictly by the term and conditions of this Fractionation and Supply Agreement.

17.18 Choice of Language

The Parties hereto have expressly required that this Fractionation and Supply Agreement and all documents and notices related thereto and/or resulting therefrom be drawn up in the English language.

Les parties aux présentes ont expressément exigé que la présente convention ainsi que tous les documents et avis s'y rattachant et/ou qui en découleront soient rédigés en langue anglaise.

HQ

IN WITNESS WHEREOF Supplier and HQ have executed this Fractionation and Supply Agreement, each on the date indicated hereunder.

HÉMA-QUÉBEC

By: _____
Name: S.GHIBU
Title: ACTING PRESIDENT
Date: 13-05-2015

GREEN CROSS BIOTHERAPEUTICS INC.

By: _____
Name:
Title:
Date:

HQ

SCHEDULE "A" –PRODUCTS PRICES AND HQ TARGET INVENTORY LEVEL

HQ

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SCHEDULE "B" - PRODUCT SPECIFICATIONS

Product(s)	Specifications Product Monograph, Date, Version
●	Product Monograph Date of Revision: ● Date of Approval: ● Control #: ●

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SCHEDULE "C" – QUALITY AGREEMENT
APPENDIX "1" to SCHEDULE "C"
HQ PLASMA COLLECTION SCHEDULE AND COLLECTION SITES

HQ

SCHEDULE "D" – QUALITY REQUIREMENTS

APPENDIX 1 to SCHEDULE "D"

General Information for All Test Kits

APPENDIX 2 to SCHEDULE "D"

Temperature Deviations

HQ

SCHEDULE "E" – DELIVERY REQUIREMENTS

HQ

SCHEDULE "F" – KEY PERFORMANCE INDICATORS PROGRAM

Extended performance measurement program

Objective:

The extended performance measurement program has been created to measure and document HQ's supplier performance for different aspects related to Products with the goal of optimizing performance and ensuring maximum efficiency.

Key Performance Indicators (KPI):

The extended performance measurement is based on four indicators:

(a) Delivery performance (20%)
(b) Product conformance (15%)
(c) Contract – partnership
    1. Regulatory documentation (15%)
    2. Inventory level (20%)
(d) Customer service (30%)

Supplier's undertaking:

- Supplier is required to maintain a delivery performance rating of [ ] and an inventory level rating of [ ] or more as measured by HQ each month.

- With respect to the overall performance including delivery performance, product conformance, contract partnership and customer service indicators, Supplier agree to use its best reasonable efforts to meet the target level of [ ]

(a) Delivery performance (20%)

Delivery performance is based on three criteria:

- Quantity;
- Delivery date;
- Documentation.

A global result is calculated based on the number of line items respecting all three criteria

Formula:	Number of line items respecting all 3 criteria Total number of line items

The results compiled by criteria are, however, not in direct relation to the global result.

HQ

For each measurement criteria, there are three possibilities:

- Respect;
- Non-respect; or
- Not received.

Respect: The criteria is considered as "in respect" if:

- The criteria is respected;
- HQ is notified of a change and if HQ is in acceptance of the change.

Non-respect: The criteria is considered as "non respect" if:

- The criteria is not respected or is erroneous;
- A change is not notified to HQ;
- A change is notified to but not accepted by HQ for a delay within the same month.

Not received: The criteria is considered as "not received" if:

- The criteria is not fulfilled in the current month;
- A change is notified to but not accepted by HQ and which in consequence entails a delivery delay to a subsequent month.

Note: Any change that is affected within the rolling forecast and is accepted by Parties is measured according to the established criteria based on the updated requirement.

Quantity criteria:

- A line item delivered at outside ± 10% is considered as a "non-respect" if a change in quantity has not been confirmed to HQ stable products department;
- A pre-shipment notification must be provided to HQ prior to delivery, confirming the exact quantity/quantities to be shipped. Upon receipt, should the quantity for any line item differ from the quantity confirmed, the applicable line item shall be considered as a "non-respect";
- If the total quantity for a line item shall not be received in a single delivery and if the HQ stable products department has accepted the split delivery, a new line item shall be created to reflect the subsequent delivery and shall in consequence be measured according to the updated information.

Delivery date criteria:

- Supplier must supply a written pre-shipment notification confirming the precise delivery date for each line item. If the actual receipt date differs from the confirmed date, the applicable line item(s) shall be considered as "non-respect". However, if the actual receipt date differs from the confirmed date as a result of a situation beyond the reasonable control of Supplier as defined in Section 17.7, supplier shall be considered to have met the criteria;

HQ

- A line item which is delivered in a month other than the current month and for which HQ fractionation department has not accepted the schedule change, the line item shall be considered as "not received".

Documentation criteria:

The documentation criteria includes two types of documentation :

- Pre-shipment notification
- Documentation at the time of receipt

Pre-shipment notification:

- Includes all necessary documentation required for the receipt and the Quality Assurance release for each line item. These documents are required by HQ minimum one (1) business day prior to the receipt. Any documentation containing erroneous information shall constitute a 'non-respect'.
- Documentation requirements : Pre-shipment notification
- Lot release letter issued by Health Canada (if applicable)*
- Certificate of analysis*

* Note: The lot release letter and the certificate of analysis are required only prior to the first receipt of any given lot to HQ.

Documentation at the time of receipt:

- The packing slip must be included with the shipment and received by HQ at the time of receipt. If any pertinent information included therein is erroneous, the documentation criteria shall be considered as 'non-respect'.
- For example:
  - HQ purchase order number & line item
  - HQ item number
  - Quantity
  - Expiry date

(b) Product conformance (15%)

Non-exhaustive list of elements to be measured (when applicable):

- Integrity of packaging
- Temperature excursion
- Missing product
- Labeling or printing issues (lot number, expiry date)

HQ

(c) Contract – Partnership

Regulatory documentation (15%)

Timely receipt of documentation pursuant to Section 9. Non-exhaustive list of elements to be measured (when applicable):

- Notice of Supplemental/New drug Submission
- Notice of compliance
- Product Monographs
- Health Canada Exit Notices
-
- Quarantine, Recall or Withdrawal
- Warning Letters

Inventory level (20%)

If a supplier inventory is mandatory, the respect of Supplier inventory level is evaluated for a security of supply and a customer service standpoint (availability of all formats of products from supplier).

Method of calculation:

- Monthly average of weekly level supplier inventory
- Should the inventory level of a format fall below 50% of the target level during the month, supplier shall need to inform HQ, on the first working day following the end month, of the number of days that such product was under 50%.
- The inventory performance rating for the month shall be reduced by 2% per working day for each product at less than 50% of the target level during that month.

(d) Customer service (30%)

Timely response: Non-exhaustive list of elements to be measured (when applicable): 10%

- Specific questions about product(s)
- Questions of a general nature
- Request for documentation or missing information
- Complaints
- Adverse event reporting
- SAP management by Supplier

Quality of information: Non-exhaustive list of elements to be measured (when applicable): 10%

- Information received is clear and complete
- Information received meets the request of HQ
- Information received is accurate

HQ

Quality of support / service: non-exhaustive list of elements to be measured (when applicable): 10%

- Accessibility of appropriate personnel
- Pro activity
- Responsiveness to HQ requests

Evaluation

HQ evaluates each indicator/criterion on a scale from 20% to 100% (with the exception of delivery performance and inventory level)

- 100% : Perfect performance
- 95% : Good, consistent
- 80% : Acceptable Effort, but should be more steadfast
- 60% : Poor, negligent
- 20% : Unacceptable
- Each indicator/criterion is attributed a weighting (%).

An overall performance of is considered as:

Excellent performance: 96% +
The performance of Supplier largely and constantly exceeds all the criteria sets out in the stable products key performance indicators program.

Good performance: 90% - 95%

Supplier's performance is good based on the criteria set out in stable products key performance indicators program. However, efforts are expected in order to improve results on a few criteria.

Improvements are required: Less than 90%:

The performance of Supplier is not meeting the objective(s) of the stable products key performance indicators program. Improvements are required on several criteria of the program.

Reporting:

- On a monthly basis, HQ shall identify any incidents that were documented during the preceding month.
- Supplier is encouraged to instate corrective action in order to improve performance rating for appropriate indicator/criterion.
- A preliminary report shall be presented to supplier after the first 6 months.
- A final report shall be presented to supplier at each Agreement Year end.

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SCHEDULE "G" – TEST METHODOLOGY

HQ