**Document No. 04a - Contract Technical Specification**

**NHS National Framework Agreement for the supply of Recombinant Factor IX products for the treatment of Haemophilia B**

**Offer reference number: CM/PHS/17/5534**

**Period of contract: 1st March 2019 to 28th February 2021 with options to extend up to a further 24 months. The total maximum framework period including any extensions will be no more than 48 months**

# Terms of the Framework and Product Specification

## The framework will cover the supply of recombinant factor IX (rFIX) products for the treatment of Haemophilia B.

## The framework agreement will cover England, Northern Ireland, Scotland and Wales.

## The length of this framework is 24 months with options to extend up to a further 24 months. The total maximum framework agreement period including extensions will be no more than 48 months.

## The anticipated approximate annual usage in International Units (IU) of rFIX is 82,000,000 IUs; this figure is based on 12 month sales data from July 2017 to June 2018, see table below for information on the volume split by vial size.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Recombinant Factor IX - Vial Size Annual Volume Split (IU)** | | | | | |
| **250** | **500** | **1000** | **1500** | **2000** | **3000** |
| 3027 | 1514 | 757 | 0 | 378 | 252 |

## Any volume estimates provided to Offerors by Authority staff are statements of opinion, provided in good faith and based on past experience and market knowledge, but they should not be relied upon by Offerors in formulating their offers. No commitment is made by the Commercial Medicines Unit (CMU) on its own behalf or on behalf of Participating Authorities as to the volume of goods which may be purchased by Participating Authorities pursuant to the Framework Agreement.

## These products may be required in vial sizes 250IU, 500IU, 1000IU, 1500IU 2000IU and 3000IU as requested locally and all preparations and sizes being tendered should be listed in your offer.

## All products will be required to be supplied complete with appropriate diluents and devices for administration.

## Additional products to this framework will only be considered by CMU where additional products are new SKUs i.e. different presentation size or where one product replaces another i.e. new product holds the same Marketing Authorisation as the product it is replacing or it is a direct replacement. Any additional product must be price linked to the awarded product i.e. the same pro-rata price for a different vial size or an identical price where one product replaces another. CMU will not consider any additional products offered at an unrelated price to the offer price nor any “enhanced” products. For more detail on ADDITIONAL GOODS refer to Document No.03 – Framework Agreement and Terms and Conditions, Schedule 1 (section 12).

## Offerors should note that any volumes indicated in this Invitation to Offer are based on historical data unless otherwise stated. No commitment is made by the CMU on its own behalf or on behalf of Participating Authorities as to the volume of goods which may be purchased by Participating Authorities pursuant to the Framework Agreement.

## If more than one product is awarded to a product line, the initial call off of product will be from the framework provider ranked one. If the product ranked one is unsuitable to meet the requirements of the patient then product from the framework provider ranked second maybe called off. If this product is also unsuitable to meet the requirements of the patient then product from the Framework Provider ranked third maybe called off and so on.

# Outline

## As part of this ITT Offerors are required to complete Document No. 05a - rFIX - Offer Schedule.

## Offerors must provide 15 product demonstration kits for reconstitution AND any other equipment needed to reconstitute or mix vials to give a 750IU dose. All samples must be delivered by the tender closing date using the address label provided at the end of this document. Failure to provide samples will result in a non-compliant bid.

## Prices are to be submitted using Document No. 05a - rFIX - Offer Schedule - Product Information.

## Prices will be fixed for 24 months; if the framework is extended then prices may be reviewed at this point.

## Offerors are required to provide their offer price(s) per unit of issue (excluding VAT).

## Offerors are required to provide the minimum annual volume that will be made available for this framework in Document No. 05a - rFIX - Offer Schedule - Product Information.

# Award Criteria

## The award of this framework will be based on the most economically advantageous tender (MEAT).

## Award criteria for this framework are:

|  |  |
| --- | --- |
| **Criteria** | **Weighting** |
| Eligibility | Pass / Fail |
| Price | 80% |
| Security of supply | 5% |
| Ease of use | 15% |

## For information of how each of the award criteria will be evaluated and scored please see the table below and also see Document No. 05b - rFIX - Scoring Methodology.

|  |  |  |
| --- | --- | --- |
| **Award Criteria** | **Description** | **Weighting** |
| 1. **Eligibility** | Mandatory Requirements of Framework:   * Technical merit/safety * Terms and conditions * Service levels | **Pass**  **or**  **Fail** |
| 1. **Price** | The lowest price will score a maximum of 10 with the following price brackets being scored as follows:   |  |  | | --- | --- | |  | **Score** | | Offer price more than 0.0001% higher and equal to/less than 5% higher | **9** | | Offer price more than 5.0001% higher and equal to/less than 10% higher | **8** | | Offer price more than 10.0001% higher and equal to/less than 15% higher | **7** | | Offer price more than 15.0001% higher and equal to/less than 20% higher | **6** | | Offer price more than 20.0001% higher and equal to/less than 25% higher | **5** | | Offer price more than 25.0001% higher and equal to/less than 30% higher | **4** | | Offer price more than 30.0001% higher and equal to/less than 35% higher | **3** | | Offer price more than 35.0001% higher and equal to/less than 40% higher | **2** | | Offer price more than 40.0001% higher than lowest offer price | **1** | | No bid | **0** | | **80%** |
| 1. **Security of Supply** | Offerors will be evaluated on the capacity of supply for the product being offered:  *If requested suppliers must provide evidence supporting their answer for this section*  **Drug substance manufacture** (*preparation of substances to be used in the manufacture of the final drug)*   |  |  | | --- | --- | |  | **Score** | | Multiple geographic locations with facilities | **5** | | Two geographic locations with facilities | **4** | | One geographic location with two or more facilities | **2** | | One facility at one geographic location | **1** |     **Production of drug** (*the manufacture of the final drug)*   |  |  | | --- | --- | |  | **Score** | | Multiple geographic locations with facilities | **5** | | Two geographic locations with facilities | **4** | | One geographic location with two or more facilities | **2** | | One facility at one geographic location | **1** |   **Packaging and labelling** *(enclosing and labelling products for distribution, storage, sale and safe use)*   |  |  | | --- | --- | |  | **Score** | | Multiple geographic locations with facilities | **5** | | Two geographic locations with facilities | **4** | | One geographic location with two or more facilities | **2** | | One facility at one geographic location | **1** |   **Stock holding facility/warehouse** *(facility for storing finished product which is ready for distribution to end user)*   |  |  | | --- | --- | |  | **Score** | | Multiple geographic locations with facilities | **5** | | Two geographic locations with facilities | **4** | | One geographic location with two or more facilities | **2** | | One facility at one geographic location | **1** | | **5%** |
| 1. **Ease of Use** | Under ease of use offerors will be evaluated on the following:  Does ancillary pack allow for sterile administrations via portacath with a syringe which is 10ml or greater?   |  |  | | --- | --- | |  | **Score** | | Yes | **4** | | No | **0** |   Does ancillary pack allow for administration of multiple vials with one syringe?   |  |  | | --- | --- | |  | **Score** | | Yes | **2** | | No but extra syringe can be provided | **1** | | No | **0** |   Is there an option to add an ancillary pack to the purchase order without packs automatically being supplied?   |  |  | | --- | --- | |  | **Score** | | Yes | **4** | | No | **0** |   Does packaging contain bar-code?   |  |  | | --- | --- | |  | **Score** | | Yes | **5** | | No | **0** |   How environmentally friendly is packaging i.e. amount of packaging, plastic v cardboard, bulkiness of packaging?   |  |  | | --- | --- | |  | **Score** | | Least amount of waste all of which is recyclable | 8 | | Bulky waste which includes all recyclable material | 5 | | Bulky waste which includes some non-recycling material | 2 | | Bulky waste which includes all non-recycling material | 0 |   How many steps are required to prepare product for administration?  **FOR EXAMPLE: 1**-open box / **2**-take individual components out of box / **3**-taking bottle tops off / **4**-open the swabs / **5**-clean the top(s) / **6**-taking off the syringe lid / **7**-screw the pre-filled syringe plunger into barrel of syringe device (if applicable) OR connect water and factor devices / **8**-fit syringe into transfer device / **9**-draw factor into syringe / **10**-remove factor vial / **11**-open butterfly needle / **12**-remove needle cap / **13**-put needle on syringe / **14**-remove needle sheath   |  |  | | --- | --- | |  | **Score** | | Least steps | 10 | | Second least number of steps | 9 | | Third least number of steps | 8 | | Fourth least number of steps | 7 | | Fifth least number of steps | 6 | | Sixth least number of steps | 5 | | Seventh least number of steps | 4 | | Eighth least number of steps | 3 | | Ninth least number of steps | 2 | | Tenth least number of steps | 1 | | Most number of steps | 0 |   How easily can a 750 IU dose be prepared and infused   |  |  | | --- | --- | |  | **Score** | | Very Easy | **4** | | Easy | **3** | | Difficult | **1** | | Very Difficult | **0** |   Diluent volume supplied with 250 - 1000 IU vial   |  |  | | --- | --- | |  | **Score** | | <3ml | **7** | | 3-4ml | **5** | | 5ml | **3** | | >5ml | **1** |   Diluent volume supplied with 1500 - 3000 IU vial   |  |  | | --- | --- | |  | **Score** | | <3ml | **7** | | 3-4ml | **5** | | 5ml | **3** | | >5ml | **1** |   Can unconstituted product be stored at room temperature?   |  |  | | --- | --- | |  | **Score** | | Yes | **5** | | No | **0** |   How long can unconstituted product be stored at room temperature?   |  |  | | --- | --- | |  | **Score** | | >12 months | **5** | | 9-12 months | **4** | | 6-9 months | **3** | | 3-6 months | **2** | | <3 months | **1** | | No room temp storage | **0** |   Age range of license indication   |  |  | | --- | --- | |  | **Score** | | > 12 years only | **3** | | 2 – 12 years  > 12 years | **6** | | < 2 years  2 – 12 years  > 12 years | **10** |   Total number of infusions required per week per adult with severe Haemophilia B as per SmPC   |  |  | | --- | --- | |  | **Score** | | Once or less per week | **10** | | 1 – 2 per week | **7** | | 2 – 3 per week | **5** | | More than three times a week | **1** |   Number of vials available:   |  |  |  |  | | --- | --- | --- | --- | | **Vial size (IU)** | **Score** | **Total no. of vials** | **Score** | | 250 | **2** | 6 | **2** | | 500 | **2** | 5 | **2** | | 1000 | **1** | 4 | **1** | | 1500 | **1** | 3 | **1** | | 2000 | **1** | 2 | **1** | | 3000 | **1** | 1 | **1** | | **15%** |

# Eligibility

All the points listed within section 4 of this document are mandatory requirements of the framework, for a supplier to be awarded onto the framework the supplier MUST meet all the points listed within this section:

## **Technical Merit/Safety**

### All products must have a valid UK Marketing Authorisation awarded by the MHRA or EMA applicable to all categories of products offered at the award date of the framework which is anticipated to be 1st February 2019.

### Offerors must have product available for delivery to customers at the framework go-live date which is the 1st March 2019.

## **Terms and Conditions**

### Full acceptance of the CMU terms and conditions. No legal or commercial alterations or substitutions can be proposed.

## **Service Levels**

### With effect from the commencement of the framework, the supplier must maintain a level of stock holding sufficient to meet 12 weeks’ anticipated demand. The stock holding figure will be calculated using indicative annual volumes obtained from treatment centres. The CMU will monitor monthly volumes and adjust the required stock holding figure in line with actual volumes. Any amends will be done on a quarterly basis and in conjunction with the supplier.

### Where any products are supplied under this framework the period of time between the date of supply of these goods to the Participating Authority and the expiry date shown on the goods ("the shelf life") shall be not less than 12 months. Supply of any product with a shelf life less than 12 months must be agreed with the Participating Authority prior to delivery. In the event that the supplier supplies product with a shelf life of less than 12 months (or such other period as the Participating Authority must have agreed), the Supplier shall, upon request by the Participating Authority and at no cost to the Participating Authority, replace any product the Participating Authority is unable to use within the product’s remaining shelf life period. Any replacement product must have a shelf life greater than 12 months unless otherwise agreed with the Participating Authority prior to delivery. Alternatively, CMU shall be entitled to terminate this framework agreement with immediate effect on giving written notice to the supplier.

### The supplier must be responsible for ensuring security of delivery to the appropriate delivery point.

### No delivery charges for standard deliveries will be accepted within this framework agreement.

### The supplier must notify CMU of any disruptions to supply and of the contingency arrangements being employed to mitigate and resolve the supply restriction. Notification must be given by contacting the Specialised Pharmaceuticals team by email – [specialisedpharma@dh.gsi.gov.uk](mailto:specialisedpharma@dh.gsi.gov.uk) **and** the relevant CMU Contract Manager.

### The supplier must deliver to third party homecare suppliers on current and any future national framework agreements for the home delivery of products covered in this framework. Any orders placed by third party homecare suppliers as of the 1st March 2019 will be subject to the framework awarded prices.

# Contract Pricing

## Offerors are required to submit prices in Document No. 05a - rFIX - Offer Schedule - Product Information; these prices will be fixed for the framework length of 24 months unless stated otherwise, if the framework is extended then prices may be reviewed at this point. Any price reviews will be made in-line with the Framework Agreement Price Variation Clause which can be found in Document No. 03 – Framework Agreement and Terms and Conditions, Schedule 1 (section 11).

## Prices submitted must be exclusive of VAT.

# General Requirements – Products, Packaging and Stock Holding

## Offerors are required to provide details of their contingency arrangements with their offer i.e. details of any business continuity accreditation or procedure e.g. ISO 22301 in Document No. 05a - rFIX - Offer Schedule - Additional Information.

## “Stock holding” refers to product held in the UK and available for despatch within 24 hours, to meet fluctuation in demand, stocks held elsewhere may be used providing delivery is made in line with the stated delivery lead-time given in Doc No. 5a - rFIX - Offer Schedule - Additional Information.

## The supplier must notify CMU within 24 hours if the stock holding drops below 12 weeks’ average sales.

## The supplier must notify CMU within 4 hours if the stock holding drops below eight weeks average sales.

## The supplier must notify CMU of any stock holding issues by contacting the Specialised Pharmaceuticals team by emailing [specialisedpharma@dh.gsi.gov.uk](mailto:specialisedpharma@dh.gsi.gov.uk) **and** the CMU Contract Manager responsible for this framework.

## If stock levels fall below the required minimum level, suppliers are expected to take action to rectify the issue; failure to do so may lead to termination of the framework agreement with the supplier.

## Where a supplier is unable to meet the delivery requirements of locally agreed contractual arrangements, the supplier shall be liable for any incurred or additional costs incurred by the customer resulting from the requirement to source a suitable product from an alternative supplier.

## The supplier shall on request by CMU provide without delay certificates of analysis (including, without limitation, certificates confirming B.P, E.P. or B.P.C. conformity) in such form as CMU may reasonably require) for such products as CMU may specify.

## Each party’s rights and obligations arising in connection with this order shall be suspended unless and until the contractor can demonstrate to CMU satisfaction that:

### the products have a valid UK Marketing Authorisation awarded by the MHRA or EMEA applicable to all categories of the products at the award date of the framework which is anticipated to be 1st February 2019 and have product available for delivery to customers at the framework go-live date which is the 1st March 2019; and

### the goods have been supplied in accordance with current legislation and if such goods are medical devices that they are CE marked; and

### should the appropriate Marketing Authorisation not have been obtained by the award date of the framework which is anticipated to be 1st February 2019 or product be unavailable for delivery to customers on 1st March 2019, CMU will disregard any offer or terminate any subsequent awarded framework and re-distribute the award accordingly.

## In the event of the goods being recalled, initiated by the manufacturer of the goods, the Secretary of State for Health or the MHRA (or any such similar regulatory body), the supplier shall, without delay and at its own expense, arrange for the collection of such goods and credit the Participating Authority for any goods delivered but unused by the Participating Authority including part used packs.

## Offerors are required to upload information onto PharmaQC no later than the go live date of 1st March 2019 (see Document No. 05a - rFIX - Offer Schedule - Additional Information, Document No. 07a - Quality control technical sheet and Document No. 07b - Guidance for performing a risk assessment of licensed medicines for the NHS for further information). If Offerors have already supplied product information on PharmaQC it is essential the Offeror ensures the information contained on PharmaQC for their product(s) is up to date.

# Local Issues

## Certain issues will need to be considered at a local level and have therefore been excluded from this framework agreement. Successful Offerors will be required to discuss and agree with individual Participating Authorities protocols on areas such as the following:

* Training associated with the supply and use of the product by patients or healthcare professionals
* Delivery requirements, delivery notes, times, etc.
* Research and clinical trials
* The provision of Quality Assurance / Quality Control procedures, certificates, analyses, etc.
* KPIs
* Compliance with the appropriate Authority policies
* Home delivery of product in accordance with Participating Authority’s home delivery arrangements. From the go-live date of the framework agreement – 1st March 2019, the awarded framework prices will be the prices that apply to the product element of any Participating Authority’s home delivery arrangement.

# Homecare and Extension of NHS Terms and Conditions and Pricing to Defined Beneficiaries

## Where the NHS has delegated to defined beneficiaries certain responsibilities, such as delivery of products to patients’ homes, the CMU framework agreement terms and pricing are to be extended to the defined beneficiaries.

## The suppliers/manufacturers awarded onto this framework agreement are expected to work with the home delivery providers awarded onto the CMU NHS National Framework Agreement for the Homecare Delivery Service of products for the treatment of bleeding disorders in England, Wales and Northern Ireland (CM/MSR/15/5480) and with suppliers awarded onto any future CMU Home Delivery Service framework agreements for products for the treatment of bleeding disorders.

## In preparation for the transition of the new framework the suppliers/manufacturers awarded onto the framework are responsible for ensuring that the home delivery providers are aware of the new framework prices well in advance of the framework go-live date of the 1st March 2019. Up to date details for home delivery providers awarded onto the CMU NHS National Framework Agreement for the Homecare Delivery Service of products for the treatment of bleeding disorders in England, Wales and Northern Ireland (CM/MSR/15/5480) can be obtained from [lynne.newall@nhs.net](mailto:lynne.newall@nhs.net)

## Suppliers/manufacturers are responsible for ensuring home delivery providers have updated framework prices throughout the duration of this framework period. Where relevant, the suppliers/manufacturers will inform the home delivery provider well in advance of any start dates of new prices.

## Home delivery providers are responsible for updating their pricing information accordingly. The home delivery provider will invoice the Purchasing Authority at the agreed framework prices for products and medicines from the 1st March 2019.

# Improving Patient Care and Lifestyle

## Successful Offerors will be required to attend regular meetings to discuss and review proposals for innovative delivery of products covered by this framework. Parties present at such meetings may include representatives from CMU, the UKHCDO, Haemophilia CRG and NHS England Commissioning. The purpose of such meetings will be to provide an opportunity for discussion about such things as new prescribing regimes and improving patient care and lifestyle in a cost effective way. Frequency and dates for meetings will be agreed with the successful Offerors.

# Framework Monitoring including Management Information

## The supplier will comply with all ad-hoc requests by the Department of Health, NHS England, the UKHCDO and CMU for management data to be provided in respect of the products supplied under this framework agreement. This information is to be provided within 10 working days for adhoc requests.

## Offerors are required to provide a named contact in Document No. 05a - rFIX - Offer Schedule - Supplier Information who will be responsible for the provision of management information.

## Management information must be submitted in accordance with Document No. 04b – Management Information Schedule.

# Supplier Performance Management

## CMU will continually monitor the successful suppliers’ performance for this framework during the course of the contract period, as a minimum CMU will use a supplier scorecard process which will monitor:

* Volume of product supplied
* Quantity of stock held
* Number of complaints received in relation to number of orders received
* Receipt of monthly MI by the required date and in the required format

### Each of these areas will be given a score on a monthly basis and these scores are used to obtain a quarterly score for the supplier.

### Suppliers are required to score above a minimum score of 80% for each area. Supplier’s scores will be discussed in supplier review meetings which will be held on a regular basis throughout the term of the framework.

### Further details on the supplier scorecard can be viewed in the Excel spreadsheet attached below.



## CMU will operate a Customer Complaints procedure and all customer complaints will be recorded. This procedure will assist CMU in monitoring supplier performance, any such complaints will be taken up with the supplier and a resolution to the issue sought.

## CMU will conduct review meetings with suppliers and expect successful Offerors to attend such meetings.

## Individual Participating Authorities may set individual SLAs with successful Offerors to monitor supplier performance.

## Successful Offerors are required to operate a customer complaints procedure and have an escalation process in place to deal with customer issues. Both the customer complaints procedure and escalation process must be provided upon request.

## Successful Offerors are required to have a product recall procedure in place. The recall procedure must be provided upon request.

# Participating Authorities

## A list of the Participating Authorities in this framework agreement can be found in Document No. 04d - rFIX - Participating Authorities.

# Supplementary Information

## Offerors are given the opportunity to provide additional information in Document No. 05a - rFIX - Offer Schedule - Additional Information to supplement their offer.

### Such information maybe included by the CMU in the final Stakeholder Briefing Document but will NOT be scored.

### Please ensure any supplementary information is labelled clearly and is included with your offer submission. Please note due to system restrictions each attachment can be no larger than 2MB.

FAO: Liz Carroll

The Haemophilia Society

140-148 Borough High Street

London

SE1 1LB

Supplier Name: ………………………………………………………………………….

**Reference: CM/PHS/17/5534**