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Contract

NHS Framework Agreement for the supply of Human Normal Immunoglobulin and Anti-D Immunoglobulin

NHS England

F20: Modification notice

Notice identifier: 2024/S 000-040318

Procurement identifier (OCID): ocds-h6vhtk-028c7b

Published 13 December 2024, 3:44pm

Section I: Contracting authority/entity

I.1) Name and addresses

NHS England

Wellington House, 133-135 Waterloo Rd

London

SE18UG

Contact

Mark Perkins

Email

mark.perkins@nhs.net

Country

United Kingdom

NUTS code

UKJ1 - Berkshire, Buckinghamshire and Oxfordshire

Internet address(es)

Main address

https://www.england.nhs.uk/

Buyer's address

https://www.england.nhs.uk/

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

NHS Framework Agreement for the supply of Human Normal Immunoglobulin and Anti-D Immunoglobulin

II.1.2) Main CPV code

• 33651520 - Immunoglobulins

II.1.3) Type of contract

Supplies

II.2) Description

II.2.3) Place of performance

NUTS codes

• UK - United Kingdom

II.2.4) Description of the procurement at the time of conclusion of the contract:

National Framework Agreement for the supply of Human Normal Immunoglobulin and Anti-D

Immunoglobulin. The framework will commence on 1 July 2021 for a period of 18 months with an option or options to extend (at the Authority's discretion) for a period or periods up to a total of 30 months. Total maximum framework agreement including extension options will be no more than 48 months. Please refer to the invitation to offer documents for a list of the purchasing points

II.2.7) Duration of the contract, framework agreement, dynamic purchasing system or concession

Start date

1 July 2021

End date

31 March 2025

II.2.13) Information about European Union Funds

The procurement is related to a project and/or programme financed by European Union funds: No

Section IV. Procedure

IV.2) Administrative information

IV.2.1) Contract award notice concerning this contract

Notice number: <u>2021/S 000-017380</u>

Section V. Award of contract/concession

Contract No

2021/S 000-017380

Title

NHS Framework Agreement for the supply of Human Normal Immunoglobulin and Anti-D Immunoglobulin

V.2) Award of contract/concession

V.2.1) Date of conclusion of the contract/concession award decision:

23 June 2021

V.2.2) Information about tenders

The contract/concession has been awarded to a group of economic operators: No

V.2.3) Name and address of the contractor/concessionaire

BIO PRODUCTS LABORATORY LIMITED

C/O Bio Products Laboratory, Dagger Lane, Elstree, Hertfordshire, WD6 3BX

Elstree

WD63BX

Country

United Kingdom

NUTS code

• UK - United Kingdom

National registration number

07343036

Internet address

http://www.bpl.co.uk

The contractor/concessionaire is an SME

No

V.2.4) Information on value of the contract/lot/concession (at the time of conclusion of the contract; excluding VAT)

Total value of the procurement: £1

Section VI. Complementary information

VI.3) Additional information

VII.2.1.1 Nature/Extent of Modifications

This modification notice is to provide notice of a modification of the framework agreement (as defined below) to (i) extend its duration with a limited number of suppliers and (ii) increase the estimated value of the framework agreement across all lots.

This framework agreement was awarded as per publication reference 2021/S 000-017380 in August 2021 (the "Current Framework"). The term of the Current Framework was for an initial period from 1st July 2021 to 31st December 2022 with optional extension periods of up

to 30 months (i.e. to 30th June 2025).

Duration Modification

NHS England has previously exercised its right to extend the Current Framework to 31st March 2025 and recently undertook a new procurement for the award of new framework agreements to commence from 1st April 2025 (the "New Framework") for the supply of the same/similar products. The awarded value of the Current Framework was £1.2bn.

However, there are four suppliers – LFB Biomedicaments (Lots 2 and 6), CSL Behring Ltd (Lots 2, 3, 6 and 7), Bio Products Laboratory (Lot 2, 3, 6 and 7), and Grifols UK Ltd (Lots 1 and 5) - on the Current Framework who have either (i) not been awarded a place on the New Framework or (ii) have been awarded a place on the New Framework as a reserve supplier and therefore have no committed volumes or guarantee of supply (the "Absent Suppliers") in respect of the products that they currently supply under the Current Framework (the "Absent Products"). Some patients are reliant upon Absent Products and will require switching to products supplied by suppliers awarded guaranteed supplies on the New Framework (the "New Products"). Changing a patient from Absent Products to a New Product needs to be appropriately managed. The scale of changes required to patient

treatment resulting from the new procurement are higher than expected and cannot be completed prior to the commencement of the New Framework. In order to safely switch patients, more time will be required than could have been foreseen. This switching process will be undertaken over a period of time as is clinically appropriate considering patients' needs and clinical resources. In order to ensure continuity of supply of medicines from current suppliers during the transition period, NHS England will extend the Current Framework for IVIg products by 6 months and for SCIg products by 9 months. In order to secure continued routine access to Absent Products for a period of time to allow the safe switching of products, NHS England were required to extend the duration of the Current Framework with those Absent Suppliers in respect of the Absent Products for a period of time.

NHS England have exercised their contractual right to extend the Current Framework with the Absent Suppliers for a further 3-months to 30th June 2025 and therefore NHS England are not required to rely on regulation 72 of the Public Contracts Regulations 2015 to extend for that period of time. The value of supply of products during this extended period is estimated to be c.£34,056,162.

However, a further period of time beyond that contractually entitled period was also required. As such, NHS England were required to modify the Current Framework with the Absent Suppliers so as to extend the Current Framework for those Absent Products for a further period of (i) 3-months for IVIg products (Lots 1, 2, 5 and 6) (so to 30th September 2025) and (ii) 6-months for SCIg products (Lots 3 and 7) (so to 31st December 2025) (the "Duration Modification").

The awarded value of the Current Framework was £1.2bn. The Duration Modification will increase the framework value by c.£15,036,879 which is within the allowed 50% threshold.

Value Modification

Additionally, NHS England is required to increase the estimated value of the Current Framework. The estimated awarded value of the Current Framework was £1.2bn. NHS England estimates that the total requirement for purchase of products across the lifetime of the Current Framework up to the expiry of the Current Framework on 31st March 2025 will now be an increased figure of £1.6bn and are therefore increasing the estimated value from £1.2bn to £1.6bn (an increase of 33%) (the "Value Modification"). This increase in value is due to a combination of (i) an increase in demand for products and (ii) increase in pricing of the products as a result of inflation and increase in Voluntary Pricing and Access Scheme ("VPAS") rebate scheme. This also includes the value of the Duration Modification.

VII.2.2.2 Description of reason - Duration Modification

The requirement to extend for that additional period of time has become necessary and is permitted by Regulation 72(1)(b) and or (c) of The Public Contacts Regulations 2015. Namely, the following conditions have been fulfilled: (i) additional supplies of products by the original contractors (i.e. the Absent Suppliers) have become necessary so as to secure

continuity of products to allow the transition of patients to products on the New Framework and were not included in the initial procurement (ii) a change of contractor cannot be made for technical reasons of interchangeability with existing supplies as those patients will require switching between products over a period of time under supervision of clinicians and/or would cause significant inconvenience (iii) the increase in price of the modification does not exceed 50% of the original contract value.

Additionally or alternatively (i) the need for modification has been brought about by circumstances which a diligent contracting authority could not have foreseen (ii) the modification does not alter the overall nature of the contract as it continues to be a framework agreement for supply of the same/similar products and (iii) the increase in price of the modification does not exceed 50% of the original contract value.

Value Modification

The Value Modification has become necessary and is permitted by Regulation 72(1)(b), (c) and/or (e) of the Public Contacts Regulations 2015. Namely, the following conditions have been fulfilled: (i) additional supplies of products by the original contractors (i.e. all of those suppliers appointed on the Current Framework) have become necessary so as to secure continuity of products and were not included in the initial procurement (ii) a change of contractor cannot be made for technical reasons of interchangeability with existing supplies as patients require continuity of supply of the products on the Current Framework until the expiry of the Current Framework and commencement of the New Framework (where save for the Absent Suppliers the majority of the suppliers on the Current Framework are also appointed to the New Framework) (iii) the increase in price of the modification does not exceed 50% of the original contract value.

Additionally or alternatively (i) the need for modification has been brought about by circumstances which a diligent contracting authority could not have foreseen (ii) the modification does not alter the overall nature of the contract as it continues to be a framework agreement for supply of the same/similar products and (iii) the increase in price of the modification does not exceed 50% of the original contract value. Finally, the Value Modification is not substantial (as set out in regulation 72(8)) and therefore is permissible pursuant to regulation 72(1)(e).

VI.4) Procedures for review

VI.4.1) Review body

The High Court

The Strand

London

WC2A 2LL

United Kingdom
Internet address
https://www.judiciary.uk/courts-and-tribunals/high-court/
VI.4.2) Body responsible for mediation procedures
The High Court
The Strand
London
WC2A 2LL
Country
United Kingdom
Internet address
https://www.judiciary.uk/courts-and-tribunals/high-court/
Section VIII. Medifications to the contract/concession

Section VII: Modifications to the contract/concession

VII.1) Description of the procurement after the modifications

VII.1.1) Main CPV code

• 33651520 - Immunoglobulins

VII.1.3) Place of performance

NUTS code

Country

• UK - United Kingdom

VII.1.4) Description of the procurement:

This modification notice is to provide notice of the modification of the framework agreement (as defined below) to (i) extend its duration with a limited number of suppliers and (ii) increase the estimated value of the framework agreement across all lots.

The modification is further described in sections VII.2.1 and VII.2.2 below, but in short NHS England were required to (i) modify the Current Framework with the Absent Suppliers (as defined below) so as to extend the Current Framework for those Absent Products (as defined below) for a further period of (i) 3-months for IVIg products (Lots 1, 2, 5 and 6) (so to 30th September 2025) and (ii) 6-months for SCIg products (Lots 3 and 7) (so to 31st December 2025) and (ii) increase the estimated value of the Current Framework from

VII.1.5) Duration of the contract, framework agreement, dynamic purchasing system or concession
Start date
1 July 2021
End date
31 March 2025
VII.1.6) Information on value of the contract/lot/concession (excluding VAT)
VII.1.6) Information on value of the contract/lot/concession (excluding VAT) Total value of the contract/lot/concession:
Total value of the contract/lot/concession:

C/O Bio Products Laboratory, Dagger Lane, Elstree, Hertfordshire, WD6 3BX

Elstree

WD63BX

Country

United Kingdom

£1.2bn to £1.6bn (an increase of 33%).

NUTS code

• UK - United Kingdom

National registration number

07343036

Internet address

http://www.bpl.co.uk

The contractor/concessionaire is an SME

No

VII.2) Information about modifications

VII.2.1) Description of the modifications

Nature and extent of the modifications (with indication of possible earlier changes to the contract):

Please refer to section VI.3.0.1 Additional information

VII.2.2) Reasons for modification

Need for additional works, services or supplies by the original contractor/concessionaire.

Description of the economic or technical reasons and the inconvenience or duplication of cost preventing a change of contractor:

Please refer to section VI.3.0.1 Additional information

VII.2.3) Increase in price

Updated total contract value before the modifications (taking into account possible earlier contract modifications, price adaptions and average inflation)

Value excluding VAT: £1,200,000,000

Total contract value after the modifications

Value excluding VAT: £1,600,000,000