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Tender

NP42824 Unlicensed Imported Medicines

NHS Scotland

F02: Contract notice

Notice identifier: 2023/S 000-035894

Procurement identifier (OCID): ocds-h6vhtk-042204

Published 6 December 2023, 10:21am

Section I: Contracting authority

I.1) Name and addresses

NHS Scotland

Gyle Square (NSS Head Office), 1 South Gyle Crescent

Edinburgh

EH12 9EB

Contact

Nadia Crockett

Email

Nadia.Crockett@nhs.scot

Country

United Kingdom

NUTS code

UKM - Scotland

Internet address(es)

Main address

<http://www.nss.nhs.scot/browse/procurement-and-logistics>

Buyer's address

https://www.publiccontractsscotland.gov.uk/search/Search_AuthProfile.aspx?ID=AA11883

I.2) Information about joint procurement

The contract is awarded by a central purchasing body

I.3) Communication

The procurement documents are available for unrestricted and full direct access, free of charge, at

<https://www.publictendersscotland.publiccontractsscotland.gov.uk/web/login.html>

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

<https://www.publictendersscotland.publiccontractsscotland.gov.uk/web/login.html>

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

NP42824 Unlicensed Imported Medicines

II.1.2) Main CPV code

- 33600000 - Pharmaceutical products

II.1.3) Type of contract

Supplies

II.1.4) Short description

The supply of unlicensed imported medicines to NHS Scotland.

II.1.5) Estimated total value

Value excluding VAT: £8,692,952

II.1.6) Information about lots

This contract is divided into lots: Yes

Tenders may be submitted for all lots

II.2) Description

II.2.1) Title

Additional Unlicensed Imported Medicines

Lot No

2

II.2.2) Additional CPV code(s)

- 33600000 - Pharmaceutical products

II.2.3) Place of performance

NUTS codes

- UKM - Scotland

Main site or place of performance

All entities constituted pursuant to the National Health Service (Scotland) Act 1978, and any Integrated Joint Boards established pursuant to the new Public Bodies (Joint Working) Scotland Act 2014.

II.2.4) Description of the procurement

Supply of additional unlicensed imported medicines incorporating an over labelling and translation service to meet any future requirements as identified by the authority. The scope of these products is unknown at this stage.

The Authority intends to award this framework as an unranked multi-supplier framework with all framework participants who pass the selection criteria receiving the opportunity to participate in Lot 2, regardless if successful or unsuccessful on Lot 1. The mechanism for adding goods to this lot will be described in the ITT.

II.2.5) Award criteria

Price is not the only award criterion and all criteria are stated only in the procurement documents

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

Duration in months

24

This contract is subject to renewal

Yes

Description of renewals

This framework includes the option to extend for any number of periods, up to a maximum overall period of forty-eight (48) months upon giving not less than three (3) months written notice, such notice to expire no later than the date the Framework Agreement is due to expire.

II.2.10) Information about variants

Variants will be accepted: No

II.2.11) Information about options

Options: No

II.2.13) Information about European Union Funds

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

II.2) Description

II.2.1) Title

Unlicensed Imported Medicines

Lot No

1

II.2.2) Additional CPV code(s)

- 33600000 - Pharmaceutical products

II.2.3) Place of performance

NUTS codes

- UKM - Scotland

Main site or place of performance

All entities constituted pursuant to the National Health Service (Scotland) Act 1978, and any Integrated Joint Boards established pursuant to the new Public Bodies (Joint Working) Scotland Act 2014.

II.2.4) Description of the procurement

Supply of Unlicensed Imported Medicines to NHS Scotland. The Authority intends to award this Lot as a single supplier per product line. Full details of Goods and volumes can be found within the ITT documents.

II.2.5) Award criteria

Quality criterion - Name: Quality — sourcing process / Weighting: 16

Quality criterion - Name: Quality — over labelling and translation service / Weighting: 24

Quality criterion - Name: Logistics — delivery and stock capability / Weighting: 7

Quality criterion - Name: Logistics - minimum order quantity and value / Weighting: 3

Price - Weighting: 50

II.2.6) Estimated value

Value excluding VAT: £8,692,952

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

Duration in months

24

This contract is subject to renewal

Yes

Description of renewals

This framework includes the option to extend for any number of periods, up to a maximum overall period of forty-eight (48) months upon giving not less than three (3) months written notice, such notice to expire no later than the date the Framework Agreement is due to expire.

II.2.10) Information about variants

Variants will be accepted: No

II.2.11) Information about options

Options: No

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 III. Legal, economic, financial and technical information

III.1) Conditions for participation

III.1.3) Technical and professional ability

List and brief description of selection criteria

(a) All goods supplied under the framework agreement must be stored in and distributed from a site holding an MHRA wholesale distribution authorisation (WDA) valid for import and handling unlicensed relevant medicinal products issued by the MHRA and for import from outside of the EEA, a manufacturer's 'specials' licence (MS) valid for import;

(b) Potential Framework Participants must be able to demonstrate that all devices tendered and associated ancillaries under this Framework Agreement comply with Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and have an appropriate declaration of conformity and display a valid CE, CE UKNI or UKCA mark.

(c) Potential framework participants and/or sub-contractor(s) must offer a product overlabelling service to meet the NHS pharmaceutical quality assurance committee 'Packaging and labelling for safety: unlicensed imported medicines — guidance for the overlabelling and provision of translated information, edition 2 December 2018' guidance where original packaging is not in English;

(d) Potential framework participants and/or any sub-contractor(s) must offer a translation service for the translation of the SPC, labels and PIL's. Translations must be performed to ISO 17100 for translation services standard or equivalent;

(e) Potential framework participants and any sub-contractor(s) must possess valid certification of BS EN ISO9001 or equivalent.

Minimum level(s) of standards possibly required

(a) Potential Framework Participants must provide confirmation of a current and valid Wholesale Distribution Authorisation (WDA) valid for importing and handling unlicensed relevant medicinal products issued by the MHRA and for import from outside of the EEA, a Manufacturer's Specials' (Licence) MS valid for import;

(b) Confirmation that all devices tendered and associated ancillaries which are classed as medical devices will carry the appropriate declaration of conformity for the UK market and display a valid CE, CE UKNI or UKCA mark prior to the start date of the Framework Agreement.

Confirmation for (a) and (b) at the date of submission of the tender should be stated in the

Qualification Envelope of the ITT under Part 4C: Quality Control.

(c) Potential framework participants must provide confirmation they can offer a product overlabelling service to meet the NHS Pharmaceutical Quality Assurance Committee 'Packaging and labelling for safety: unlicensed imported medicines — guidance for the overlabelling and provision of translated information, edition 2 December 2018' guidance where original packaging is not in English;

(d) Potential framework participants and/or any sub-contractor(s) must provide confirmation they can offer at translation service for the translation of the SPC, labels and PIL's. Translations must be performed to ISO 17100 for translation services standard or equivalent;

(e) Confirmation of the existence of valid certification of BS EN ISO 9001 or equivalent.

Confirmation for (c), (d) and (e) at the date of submission of the tender should be stated in the Qualification Envelope of the ITT under Part 4D: Quality Assurance Schemes.

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Open procedure

IV.1.3) Information about a framework agreement or a dynamic purchasing system

The procurement involves the establishment of a framework agreement

Framework agreement with several operators

Envisaged maximum number of participants to the framework agreement: 15

In the case of framework agreements, provide justification for any duration exceeding 4 years:

Specialised area of medicines with a limited supply base able to meet the minimum criteria required for supplying unlicensed imported medicines.

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: Yes

IV.2) Administrative information

IV.2.2) Time limit for receipt of tenders or requests to participate

Date

19 January 2024

Local time

12:00pm

IV.2.4) Languages in which tenders or requests to participate may be submitted

English

IV.2.6) Minimum time frame during which the tenderer must maintain the tender

Duration in months: 3 (from the date stated for receipt of tender)

IV.2.7) Conditions for opening of tenders

Date

19 January 2024

Local time

12:00pm

Section VI. Complementary information

VI.1) Information about recurrence

This is a recurrent procurement: No

VI.2) Information about electronic workflows

Electronic ordering will be used

Electronic invoicing will be accepted

Electronic payment will be used

VI.3) Additional information

The buyer is using PCS-Tender to conduct this ITT exercise. The Project code is 25719. For more information see:

<http://www.publiccontractsscotland.gov.uk/info/InfoCentre.aspx?ID=2343>

A sub-contract clause has been included in this contract. For more information see:

<http://www.publiccontractsscotland.gov.uk/info/InfoCentre.aspx?ID=2363>

Community benefits are included in this requirement. For more information see:

<https://www.gov.scot/policies/public-sector-procurement/community-benefits-in-procurement/>

A summary of the expected community benefits has been provided as follows:

It is a mandatory requirement that potential framework participants/contractors agree to support the concept, provision, and ongoing development of community benefits provision in relation to this framework/contract.

Potential framework participants/contractors are required to agree to this mandatory requirement. They are also requested to provide a summary of the community benefits that have recently been delivered within Scotland, if at all, and what impact and outcomes these have achieved.

Potential framework participants/contractors are required to summarise any proposed community benefits that will be developed and delivered as part of this framework/contract if successful or, alternatively, potential framework participants/contractors confirm that they will engage with the NHS Scotland's Community Benefits Gateway (CBG). This gateway, developed through requests from suppliers seeking opportunities to support the

delivery of community benefits within the contracting region, provides information on community benefit opportunities. The CBG is a free and easy to use online service that connects NHS Scotland suppliers with third sector community organisations within Scotland and will be used for tracking and reporting and is an approved compliant route to the realisation of community benefits.

For further information please visit NHSS Community Benefit Gateway (<https://www.nss.nhs.scot/procurement-and-logistics/sustainability/access-our-community-benefit-gateway/>).

(SC Ref:751547)

VI.4) Procedures for review

VI.4.1) Review body

Sheriff Court House

27 Chambers Street

Edinburgh

EH1 1LB

Email

edinburgh@scotcourts.gov.uk

Telephone

+44 1312252525

Country

United Kingdom

Internet address

<https://scotcourts.gov.uk/the-courts/sheriff-court/about-sheriff-courts>

VI.4.3) Review procedure

Precise information on deadline(s) for review procedures

Authority will notify economic operators who submitted a tender or (where no deselection

notification has previously been made) applied to be selected to tender, of its decision to award the framework agreement which notification will contain among other information, a summary of the reasons why the economic operators was unsuccessful. The notification will incorporate a 'standstill period' of a minimum of 10 clear calendar days (or a minimum of 15 if the communication method used is not electronic) between the date on which the Authority dispatches the notice(s) and the date on which the Authority proposes to conclude the relevant framework agreement. The bringing of court proceedings against the Authority during the standstill period will automatically continue the prohibition on entering into the framework agreement until the court proceedings are determined, discontinued, or disposed of, or the court, by interim order, brings to an end the prohibition. The remedies that may be awarded by the courts before the framework agreement has been entered into include the setting aside of the decision to award the framework agreement to the winning tenderer(s). The bringing of court proceedings against the Authority after the framework agreement has been entered into will not affect the framework agreement unless grounds for the imposition of special penalties under the Public Contracts (Scotland) Regulations 2015 can be established. Otherwise, the remedies that may be awarded by the courts where the framework agreement has been entered into are limited to the award of damages.