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Tender

The Development, Validation and Supply of Physostigmine Free Base

Ministry of Defence, Defence Science and Technology Laboratory

F17: Contract notice for contracts in the field of defence and security

Notice identifier: 2023/S 000-009030

Procurement identifier (OCID): ocds-h6vhtk-03b6c1

Published 28 March 2023, 4:22pm

Section I: Contracting authority/entity

I.1) Name, addresses and contact point(s)

Ministry of Defence, Defence Science and Technology Laboratory

Porton Down

Salisbury, Wiltshire

SP4 0JQ

For the attention of

ADP Procurement

Email(s)

ADPProcurement@dstl.gov.uk

Country

United Kingdom

Internet address(es)

Address of the buyer profile

www.contracts.mod.uk

Electronic access to information

www.contracts.mod.uk

Electronic submission of tenders and requests to participate

www.contracts.mod.uk

Further information

Further information can be obtained from the above mentioned contact point(s)

Specifications and additional documents (including documents for competitive dialogue and a dynamic purchasing system) can be obtained from

The above-mentioned contact point(s)

Tenders or requests to participate must be sent to

The above-mentioned contact point(s)

I.2) Type of the contracting authority

Ministry or any other national or federal authority, including their regional or local subdivisions

I.3) Main activity

Defence

Section II: Object of the contract

II.1) Description

II.1.1) Title attributed to the contract by the contracting authority

The Development, Validation and Supply of Physostigmine Free Base

II.1.2) Type of contract and location of works, place of delivery or of performance

Supplies

Purchase

NUTS code

- UK - United Kingdom

II.1.5) Short description of the contract or purchase(s)

The Ministry of Defence (MoD) is inviting expressions of interest for a requirement for the provision of Physostigmine Free Base(also known as eserine; chemical name 1,2,3,3a?,8,8a?-hexahydro-1,3a,8-trimethylpyrrolo[2,3-b] indol-5-yl-methylcarbamate; chemical formula C₁₅H₂₁N₃O₂; molecular weight 275,36 g/mol). as part of an ongoing product development and anticipated commercialisation.

The initial Physostigmine supplied must be suitable for use in a pivotal Phase I clinical setting and the manufacturing process will produce material which does not add additional non-clinical activities to the overall programme, best endeavours should be taken to remove processing impurities.

The Supplier is to develop, scale-up and validate the manufacturing method for Physostigmine Free Base as an Active Pharmaceutical Ingredient (API) for use in a MoD final medicinal product currently under development.

The API must be developed and manufactured according to Good Manufacturing Practice (GMP) and must conform to European Transmissible Spongiform Encephalopathies (TSE) requirements, developed such that Intellectual property (IP) is vested in the Authority.

The Authority intends to seek a Marketing Authorisation for the final medicinal product from the Medicines and Healthcare products Regulatory Agency (MHRA) and Physostigmine will be required as an active ingredient for a future registered medicinal product.

The Supplier is required to provide information necessary for the Authority to complete the Chemistry, Manufacturing and Control (CMC) documentation to support a Clinical Trial Application (CTA) and Marketing Authorisation Application for the final medicinal product and make this documentation available to the MA applicant in an appropriate format for inclusion within CTD Module 3.

The Authority anticipates a Limited Quality by Design (QBD) approach to the manufacturing process as defined by the International Conference on Harmonisation (ICH).

All procurement documents are accessible via www.contracts.mod.uk

II.1.6) Common procurement vocabulary (CPV)

- 33661700 - Other nervous system medicinal products

Additional CPV code(s)

- 33660000 - Medicinal products for the nervous system and sensory organs
- 33690000 - Various medicinal products
- 73300000 - Design and execution of research and development

II.1.7) Information about subcontracting

The tenderer has to indicate in the tender any share of the contract it may intend to subcontract to third parties and any proposed subcontractor, as well as the subject-matter of the subcontracts for which they are proposed

The tenderer has to indicate any change occurring at the level of subcontractors during the execution of the contract

II.1.8) Lots

This contract is divided into lots: No

II.1.9) Information about variants

Variants will be accepted: No

II.2) Quantity or scope of the contract

II.2.1) Total quantity or scope

The Contract has an expected duration of 10 years (120 months), plus 5 option years (60

months). Option years may be taken up consecutively or concurrently (to be determined).

Estimated value excluding VAT:

Range: between £3,000,000 and £10,000,000

II.2.2) Information about options

Options: Yes

Description of these options: Up to 5 optional years in addition to the initial 10 year duration. These option years may be taken up individually for each separate option year or in totality for the whole five year period.

II.2.3) Information about renewals

This contract is subject to renewal: Yes

II.3) Duration of the contract or time limit for completion

Duration in months: 180 (from the award of the contract)

Section III. Legal, economic, financial and technical information

III.1) Conditions relating to the contract

III.1.1) Deposits and guarantees required

To be specified in the Invitation to Negotiate

III.1.3) Legal form to be taken by the group of economic operators to whom the contract is to be awarded

To be specified in the Invitation to Negotiate

III.1.4) Other particular conditions to which the performance of the contract is subject, in particular with regard to security of supply and security of information

To be specified in the Invitation to Negotiate

III.2) Conditions for participation

III.2.1) Personal situation

Criteria regarding the personal situation of economic operators (that may lead to their exclusion) including requirements relating to enrolment on professional or trade registers

Information and formalities necessary for evaluating if the requirements are met: Suppliers Instructions How to Express Interest in this Tender:

1. Register your company on the eSourcing portal (this is only required once)

- Browse to the eSourcing Portal
- Click the "Click here to register" link
- Accept the terms and conditions and click "continue"
- Enter your correct business and user details
- Note the username you chose and click "Save" when complete
- You will shortly receive an email with your unique password (please keep this secure)

2. Express an Interest in the tender

- Login to the portal with the username/password
- Click the "PQQs Open to All Suppliers" link. (These are Pre-Qualification Questionnaires open to any registered supplier)
- Click on the relevant PQQ to access the content.
- Click the "Express Interest" button in the "Actions" box on the left-hand side of the page.
- This will move the PQQ into your "My PQQs" page. (This is a secure area reserved for your projects only)
- Click on the PQQ code, you can now access any attachments by clicking the "Settings and Buyer Attachments" in the "Actions" box

3. Responding to the tender

- You can now choose to "Reply" or "Reject" (please give a reason if rejecting)
- You can now use the 'Messages' function to communicate with the buyer and seek any

clarification

- Note the deadline for completion, then follow the onscreen instructions to complete the PQQ
- There may be a mixture of online & offline actions for you to perform (there is detailed online help available)

If you require any further assistance please consult the online help, or contact the eTendering help desk.

Criteria regarding the personal situation of subcontractors (that may lead to their rejection) including requirements relating to enrolment on professional or trade registers

Information and formalities necessary for evaluating if the requirements are met: Suppliers Instructions How to Express Interest in this Tender:

1. Register your company on the eSourcing portal (this is only required once)

- Browse to the eSourcing Portal
- Click the "Click here to register" link
- Accept the terms and conditions and click "continue"
- Enter your correct business and user details
- Note the username you chose and click "Save" when complete
- You will shortly receive an email with your unique password (please keep this secure)

2. Express an Interest in the tender

- Login to the portal with the username/password
- Click the "PQQs Open to All Suppliers" link. (These are Pre-Qualification Questionnaires open to any registered supplier)
- Click on the relevant PQQ to access the content.
- Click the "Express Interest" button in the "Actions" box on the left-hand side of the page.

- This will move the PQQ into your “My PQQs” page. (This is a secure area reserved for your projects only)
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III.2.2) Economic and financial ability

Criteria regarding the economic and financial standing of economic operators (that may lead to their exclusion)

Information and formalities necessary for evaluating if the requirements are met: See PQQ

III.2.3) Technical and/or professional capacity

Criteria regarding the technical and/or professional ability of economic operators (that may lead to their exclusion)

Information and formalities necessary for evaluating if the requirements are met: See PQQ

Criteria regarding the technical and/or professional ability of subcontractors (that may lead to their rejection)

Information and formalities necessary for evaluating if the requirements are met: See PQQ

Section IV: Procedure

IV.1) Type of procedure

IV.1.1) Type of procedure

Negotiated

IV.1.2) Limitations on the number of operators who will be invited to tender or to participate

Envisaged minimum number 3 and maximum number 6

IV.1.3) Reduction of the number of operators during the negotiation or dialogue

Recourse to staged procedure to gradually reduce the number of solutions to be discussed or tenders to be negotiated: yes

IV.2) Award criteria

IV.2.1) Award criteria

the criteria stated in the specifications, in the invitation to tender or to negotiate or in the descriptive document

IV.2.2) Information about electronic auction

An electronic auction has been used: no

IV.3) Administrative information

IV.3.4) Time limit for receipt of tenders or requests to participate

28 April 2023 - 5:00pm

IV.3.6) Language(s) in which tenders or requests to participate may be drawn up

English

Section VI: Complementary information

VI.2) Information about European Union funds

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

VI.3) Additional information

The Contracting Authority intends to use an e-Tendering system in this procurement exercise, please visit www.contracts.mod.uk for full details and to register your interest in this procurement.

The Cyber Risk Profile for this requirement identified by the Cyber Risk Assessment is Very Low (Reference – RAR-800645056).

VI.4) Procedures for appeal

VI.4.1) Body responsible for appeal procedures

Defence Science and Technology Laboratory

Porton Down

Salisbury

SP4 0JQ

Country

United Kingdom

VI.4.1) Body responsible for mediation procedures

Defence Science and Technology Laboratory

Porton Down

Salisbury

SP4 0JQ