

**United Kingdom-Bristol: Pharmaceutical products**

OJ S 224/2019 20/11/2019

Contract notice

Supplies

**Directive 2009/81/EC****Section I: Contracting authority/entity**

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**I.1. Name and addresses**

Official name: Ministry of Defence, ISTAR, Chemical, Biological, Radiological and Nuclear Delivery Team (CBRN DT)

Postal address: MOD Abbey Wood #1342, NH1 Yew 3a

Town: Bristol

Postal code: BS34 8JH

Country: United Kingdom

Contact person: Miss K Wilson

E-mail: [Karen.wilson371@mod.gov.uk](mailto:Karen.wilson371@mod.gov.uk)

Telephone: +44 3067933663

**Internet address(es):**

General address of the contracting authority/entity: <https://www.gov.uk/government/organisations/defence-equipment-and-support>

**Additional information can be obtained from:**

the abovementioned address

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

the abovementioned address

**Tenders or requests to participate must be submitted:** the abovementioned address

**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

**I.4. Contract award on behalf of other contracting authorities/entities**

The contracting authority is purchasing on behalf of other contracting authorities: no

**Section II: Object of the contract**

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**II.1. Description****II.1.1. Title attributed to the contract by the contracting authority**

Procurement for the Supply of Active Pharmaceutical Ingredient — Physostigmine Free Base

**II.1.2. Type of contract and place of performance or delivery**

Supplies

Purchase

Main site or place of performance: UNITED KINGDOM.

NUTS code UK United Kingdom

**II.1.3. Information about framework agreement**

#### **II.1.4. Information about framework agreement**

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

Pharmaceutical products, pharmaceutical articles, medical equipments, pharmaceuticals and personal care products, medical consumables, chemical products, specialised chemical products, nuclear, biological, chemical and radiological protection equipment, the chemical biological radiological and nuclear protection delivery team is inviting expressions of interest in respect of a proposed contract for the development, process validation, manufacture and supply of physostigmine free base as an active pharmaceutical ingredient (API) for use in a Ministry of Defence (MOD) final medicinal product currently under development.

The supplier will be required to develop, scale-up and validate the manufacturing method, define a detailed specification and full characterisation of the API, Physostigmine (also known as eserine; chemical name 1,2,3,3a $\beta$ ,8,8a $\beta$ -hexahydro-1,3a,8-trimethylpyrrolo[2,3-b] indol-5-yl-methylcarbamate; chemical formula C<sub>15</sub>H<sub>21</sub>N<sub>3</sub>O<sub>2</sub>; molecular weight 275,36 g/mol)

The supplier will be required to supply the authority with full information on the manufacture and control of the API as described in Annex I to Directive 2001/83/EC as amended (with particular reference to Part I, Section 3) and elaborated in the notice to applicants (Eudralex Volume 2: [https://ec.europa.eu/health/documents/eudralex/vol-2\\_en](https://ec.europa.eu/health/documents/eudralex/vol-2_en)).

The specification should meet modern standards and best endeavours should be taken to remove processing impurities. The specification should align with current regulatory requirements for active pharmaceutical ingredients (including Ph.Eur). The supplier will also be expected to analyse a sample (as much as is required) of the authority's existing physostigmine API material, to assess the comparability of the 2 (to permit bridging between studies using old versus new material). The authority will review the comparability and determine whether the specification of the new API is acceptable.

The supplier will be required to conduct appropriate stability studies as often as required as per the international conference on harmonisation (standard and accelerated), forced degradation and provide data in the form of a written report (including protocol(s)) to support the shelf life to be applied. A shelf life of at least 3 years under storage conditions 2-8°C is required.

The supplier will prepare a primary reference standard no later than the day of commencement of performance validation batches. This standard will be tested throughout its shelf life to maintain its usability and where necessary replaced with a new standard. This standard must be sufficient for all testing required throughout the life of the contract and the authority reserves the right to request quantities on an ad-hoc basis.

#### **II.1.6. CPV code(s)**

33600000 Pharmaceutical products, 33680000 Pharmaceutical articles, 33000000 Medical equipments, pharmaceuticals and personal care products, 33140000 Medical consumables, 24000000 Chemical products, 24950000 Specialised chemical products, 35113200 Nuclear, biological, chemical and radiological protection equipment

#### **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. Scope of the procurement**

#### **II.2.1. Total quantity or scope**

The supplier will be responsible for delivering a laboratory scale batch within the first year of the contract, by 31.3.2021. Subject to successful completion of laboratory scale manufacture, the supplier will be responsible for a pilot scale up manufacture of an 8-10 kg batch (no less than 8 kg). Physostigmine produced at the pilot scale must be suitable for use in pivotal clinical trials and commercial manufacturing.

During the first option period (years 2 to 5 of the potential contract), the supplier will be responsible for establishing a scalable manufacturing process and delivery schedule capable of manufacturing up to 40 kg annually to meet the authority's requirement, with the minimum requirement being manufacture and delivery of 10 kg.

This requirement includes validation of manufacturing process and analytical assays and the manufacture of 3 validation batches and characterisation of the API.

1) That MOD intends to seek a marketing authorisation for the final medicinal product from the medicines and healthcare products regulatory agency and physostigmine will be required as an active ingredient for the registered medicinal product;

2) 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.

Estimated value excluding VAT:

Range: between 1 000 000 and 10 000 000 GBP

#### **II.2.2. Information about options**

Options: yes

Description of options: First option period (4 years - April 2021 to March 2025), which will become contract years 2, 3, 4 and 5.

Second option period (5 years - April 2025-March 2030), which will become contract years 6, 7, 8, 9 and 10.

Provisional timetable for recourse to these options:  
in months: 6 (from the award of the contract)

#### **II.2.3. Information about renewals**

This contract is subject to renewal: yes

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

## **Section III: Legal, economic, financial and technical information**

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### **III.1. Conditions related to the contract**

#### **III.1.1. Deposits and guarantees required**

#### **III.1.2. Main financing conditions and payment arrangements and/or reference to the relevant provisions governing them**

This will 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**

This will 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**

This will be specified in the invitation to negotiate.

### **III.1.5. Information about security clearance**

## **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**

List and brief description of conditions: The authority will apply all the offences listed in Article 39(1) of Directive 2009/81/EC (implemented as Regulation 23(1) of the Defence and Security Public Contract Regulations (DSPCR) 2011 in the UK) and all of the professional misconducts listed at Article 39(2) of Directive 2009/81/EC (see also Regulation 23(2) in the DSPCR 2011) to the decision of whether a candidate is eligible to be invited to tender.

A full list of the Regulation 23(1) and 23(2) criteria are at <http://www.contracts.mod.uk/delta/project/reasonsForExclusion.html#dspr>

Candidates will be required to sign a declaration confirming whether they do or do not have any of the listed criteria as part of the pre-qualification process.

Candidates who have been convicted of any of the offences under Article 39(1) are ineligible and will not be selected to bid, unless there are overriding requirements in the general interest (including defence and security factors) for doing so.

Candidates who are guilty of any of the offences, circumstances or misconduct under Article 39 (2) may be excluded from being selected to bid at the discretion of the authority.

### **III.2.2. Economic and financial ability**

### **III.2.3. Technical and/or professional capacity**

### **III.2.4. Information about reserved contracts**

## **III.3. Conditions specific to services contracts**

### **III.3.1. Information about a particular profession**

### **III.3.2. Information about staff responsible for the performance of the contract**

## **Section IV: Procedure**

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### **IV.1. Type of procedure**

#### **IV.1.1. Type of procedure**

Negotiated

#### **IV.1.2. Information about the limits on the number of candidates to be invited**

Envisaged minimum number 3 and Maximum number 6

Objective criteria for choosing the limited number of candidates:

#### **IV.1.3.**

## **Information about reduction of the number of solutions or tenders during negotiation or dialogue**

### **IV.2. Award criteria**

#### **IV.2.1. Award criteria**

The most economically advantageous tender in terms of Price is not the only award criterion and all criteria are stated only in the procurement documents

#### **IV.2.2. Information about electronic auction**

An electronic auction has been used: no

### **IV.3. Administrative information**

#### **IV.3.1. File reference number attributed by the contracting authority**

CBRN/00265

#### **IV.3.2. Previous publication concerning this procedure**

no

#### **IV.3.3. Conditions for obtaining specifications and additional documents or descriptive document**

Payable documents: no

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

17.12.2019 - 12:00

#### **IV.3.5. Estimated date of dispatch of invitations to tender or to participate to selected candidates**

16.1.2020

#### **IV.3.6. Languages in which tenders or requests to participate may be submitted**

English.

## **Section VI: Complementary information**

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### **VI.1. Information about recurrence**

This is a recurrent procurement: no

### **VI.2. Information about European Union funds**

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

### **VI.3. Additional information**

The contracting authority considers that this contract may be suitable for economic operators that are small or medium enterprises (SMEs). However, any selection of tenderers will be based solely on the criteria set out for the procurement. The authority reserves the right to amend any condition related to security of information to reflect any changes in national law or government policy.

The authority reserves the right to amend any condition related to security of information to reflect any changes in national law or government policy. If any contract documents are accompanied by a security aspects letter, the authority reserves the right to amend the terms of the security aspects letter to reflect any changes in national law or government policy

whether in respect of the applicable protective marking scheme, specific protective markings given, the aspects to which any protective marking applies or otherwise.

The link below to the Gov.uk website provides information on the Government Security Classification. <https://www.gov.uk/government/publications/government-security-classifications>

Advertising Regime OJEU: this contract opportunity is published in the Official Journal of the European Union (OJEU), the MoD Defence contracts bulletin and [www.contracts.mod.uk](http://www.contracts.mod.uk)

The cyber risk profile for this requirement identified by the cyber risk assessment is very low (Ref No: RAR-GFVY72BG).

#### Electronic trading

Potential suppliers must note the mandatory requirement for electronic trading using the contracting, purchasing and finance (CP&F) electronic procurement tool. All payments for contractor deliverable's under the contract shall only be made via CP&F. You can find details on CP&F at <https://www.gov.uk/government/publications/mod-contracting-purchasing-and-finance-e-procurement-system>.

Interested suppliers are required to complete the pre-qualification questionnaire (PQQ) to provide the authority with information to evaluate the supplier's capacity and capability against the selection criteria.

The authority will use the PQQ response to create a shortlist of tenderers who:

- 1) Are eligible to participate;
- 2) Fulfil any minimum economic, financial, professional and technical standards; and
- 3) Best meet in terms of capacity and capability the selection criteria set out in the PQQ.

Full details of the method for choosing the tenderers will be set out in the PQQ. For all scored questions potential suppliers must achieve a mark of 2 (satisfactory) or above, if you score below 2 (Satisfactory) for question DCO 5.1 or 5.2 the authority reserves the right to eliminate you from the competition.

During the PQQ stage, the intention is to arrive at a short list of a minimum of three (3) and a maximum of six (6) qualified potential suppliers for formal invitation to negotiate.

This list of six (6) qualified potential suppliers will be made up of the top six (6) performing PQQ responses.

Suppliers must read through this set of instructions and follow the process to respond to this opportunity.

The information and/or documents for this opportunity are available on <http://www.contracts.mod.uk>.

You must register on this site to respond, if you are already registered you will not need to register again, simply use your existing username and password. Please note there is a password reminder link on the homepage.

Suppliers must log in, go to your response manager and add the following access code: 43W9T5S6SV.

Please ensure you follow any instruction provided to you here.

The deadline for submitting your response(s) is detailed within this contract notice, you will also have visibility of the deadline date, once you have added the access code via DCO as the opening and closing date is visible within the opportunity.

Please ensure that you allow yourself plenty of time when responding to this opportunity prior to the closing date and time, especially if you have been asked to upload documents.

If you experience any difficulties please refer to the online Frequently asked questions (FAQ's) or the user guides or contact the MOD DCO Helpdesk by emailing [support@contracts.mod.uk](mailto:support@contracts.mod.uk) or tel. 0800 282 324.

Go reference: GO-20191115-DCB-15567326

#### **VI.4. Procedures for review**

##### **VI.4.1. Review body**

Official name: Ministry of Defence, ISTAR, Chemical, Biological, Radiological and Nuclear Delivery Team (CBRN DT)

Town: Bristol

Country: United Kingdom

E-mail: [Karen.wilson371@mod.gov.uk](mailto:Karen.wilson371@mod.gov.uk)

Telephone: +44 3067933663

##### **Body responsible for mediation procedures**

Official name: Ministry of Defence

Town: Bristol

Country: United Kingdom

E-mail: [Karen.wilson371@mod.gov.uk](mailto:Karen.wilson371@mod.gov.uk)

Telephone: +44 3067933663

##### **VI.4.2. Review procedure**

##### **VI.4.3. Service from which information about the review procedure may be obtained**

Official name: Ministry of Defence

Town: Bristol

Country: United Kingdom

E-mail: [Karen.wilson371@mod.gov.uk](mailto:Karen.wilson371@mod.gov.uk)

Telephone: +44 3067933663

##### **VI.5. Date of dispatch of this notice**

15.11.2019