

**United Kingdom-Bristol: Nuclear, biological, chemical and radiological protection equipment**

OJ S 106/2020 03/06/2020

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: YEW 3a, #1342, MOD Abbey Wood

Town: Bristol

Postal code: BS34 8JH

Country: United Kingdom

Contact person: George Pritchard

E-mail: [George.Pritchard112@mod.gov.uk](mailto:George.Pritchard112@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>

Address of the buyer profile: <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**

Provision of an Auto-Injector Partner

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

Supplies

Purchase

Main site or place of performance: Gloucestershire, Wiltshire and Bristol/Bath area.

**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)**

Nuclear, biological, chemical and radiological protection equipment, medical specialist services, pharmaceutical products, pharmaceutical articles, medical equipments, pharmaceuticals and personal care products, miscellaneous medical devices and products, medical consumables, chemical products, specialised chemical products, medical equipments, medical needles. The UK Ministry of Defence (UK MOD) has an identified and likely future requirement for the production of single and triple therapy auto-injector devices for intramuscular administration. The auto-injectors should be capable of storing up to three active pharmaceutical ingredients in a single, dual or triple chambered device. Full operating capability will require the final drug product to be submitted to Regulatory Agencies in the EU and the United Kingdom with the intent for full licensure/marketing authorisation (MA). The chemical biological radiological nuclear team (CBRN) is therefore seeking to appoint a partner to manufacture current auto-injector requirements with future options to manufacture other similar devices as they arise throughout the contractual period.

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

35113200 Nuclear, biological, chemical and radiological protection equipment, 85121200 Medical specialist services, 33600000 Pharmaceutical products, 33680000 Pharmaceutical articles, 33000000 Medical equipments, pharmaceuticals and personal care products, 33190000 Miscellaneous medical devices and products, 33140000 Medical consumables, 24000000 Chemical products, 24950000 Specialised chemical products, 33100000 Medical equipments, 33141320 Medical needles

**II.1.7. Information about subcontracting**

**II.1.8. Lots**

This contract is divided into lots: no

**II.1.9. Information about variants**

Variants will be accepted: yes

**II.2. Scope of the procurement**

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

The supplier will be responsible for:

- 1) demonstrating of wet or wet/dry storage capability in an existing auto-injector. The maximum capacities of chamber will be no more than 3 ml or 1.5 ml per chamber if dual chamber;
- 2) protocols for, and results of, forced degradation studies of Midazolam, atropine and 2PAM, using previously validated analytical methods demonstrated to qualify and quantify known degradants of each API;
- 3) documentation of the processes and validated test methods describing the manufacturing and performance of the active auto-injector/drug product;
- 4) demonstration of stability of active auto-injectors, and of the active pharmaceutical ingredients stored within the active auto-injector;
- 5) demonstration of wet storage capability in an auto-injector i.e. within the cartridge or the device. The maximum capacities of the chamber will be no more than 3 ml, or 1.5 ml if dual

- chamber (and sufficient if dual chamber for separated API);
- 6) demonstration of technical and performance (including safety). Testing described in ISO 11608 and the quality systems of ISO13485 and the requirements of the Medical Devices Regulations (MDR) should be considered. Distribution robustness should be modelled and tested to ensure the product remains intact under operational transport stresses;
  - 7) demonstration of robustness (stress testing) of the tertiary packaging of the assembled auto-injector in its proposed tertiary packaging, and suitability of the packaging for military use;
  - 8) provision of the specification documentation for the active auto-injector device, the APIs and the processes and test methods describing the manufacturing and performance of the active auto-injector device;
  - 9) demonstration of the consistency of manufacturing of the active auto-injector device through process validation activities according to ICH Q8 R2 Part 1;
  - 10) provision of training auto-injector devices and instructions for use;
  - 11) protocols for, and results (in interim and final Reports) of ICH and GxP-compliant stability studies. Stability studies for up to 5 years;
  - 12) certification of the auto-injector to CE standard, meeting the requirements of the Medical Device Regulation 2017/745, as amended, and manufactured to ISO 13485:2016 (or current version);
  - 13) documentation and data review to populate a common technical document prior to marketing authorisation application, including a paediatric investigation plan waiver;
  - 14) manufacture product in accordance with current good manufacturing practice (cGMP) standards as defined by the International Conference on Harmonisation and regulated by the national competent Authority's in Europe and Canada;
  - 15) storage of the finished product and all product movement between qualified person (QP) release and receipt will be carried out in accordance with the requirements of good distribution practice (GDP) and the guidelines on GDP on medicinal products for human use (2013/C 343 /01) or as subsequently amended.

Estimated value excluding VAT:

Range: between 20 000 000 and 100 000 000 GBP

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

Options: yes

Description of options: Option period 1 — continued support from October 2023 to October 2035.

Provisional timetable for recourse to these options:  
in months: 144 (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**

This will be detailed in the ITN.

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

This will be detailed in the ITN.

**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 detailed in the ITN.

**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 detailed in the ITN.

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

Candidates which do not yet hold security clearance may obtain such clearance until:  
1.10.2035

**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: This will be detailed in the ITN.

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

List and brief description of conditions: This will be detailed in the ITN.

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

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

List and brief description of conditions: (c) where appropriate, a statement, covering the 3 previous financial years of the economic operator, of:

(i) the overall turnover of the business of the economic operator; and

(ii) where appropriate, the turnover in respect of the work, works, goods or services which are of a similar type to the subject matter of the contract.

This will be detailed in the ITN.

Minimum level(s) of standards possibly required: This will be detailed in the ITN.

**Criteria regarding the economic and financial standing of subcontractors (that may lead to their rejection)**

List and brief description of conditions: This will be detailed in the ITN.

Minimum level(s) of standards possibly required: This will be detailed in the ITN.

**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)**

List and brief description of conditions:

This will be detailed in the ITN.

Minimum level(s) of standards possibly required

This will be detailed in the ITN.

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

List and brief description of conditions:

This will be detailed in the ITN.

Minimum level(s) of standards possibly required

This will be detailed in the ITN.

**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**

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/AIP

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

no

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

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

30.6.2020 - 12:00

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

31.7.2020

#### **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: yes

Estimated timing for further notices to be published: 2033

## 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 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 instructions on safeguarding classified information (e.g. a Security Aspects Letter), the Authority reserves the right to amend the terms of these instructions 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-UMXB85VX).

### 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 deliverables 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 fully complete the pre-qualification questionnaire (PQQ) to answer all questions and 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
- ( ) 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), if you score below 2 (Satisfactory) 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>.

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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: FK85P6K285.

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 Telephone 0800 282 324.

Go reference: GO-2020529-DCB-16647297

#### **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: [George.Pritchard112@mod.gov.uk](mailto:George.Pritchard112@mod.gov.uk)

Telephone: +44 3067933663

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

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

Town: Bristol

Country: United Kingdom

E-mail: [George.Pritchard112@mod.gov.uk](mailto:George.Pritchard112@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, ISTAR, Chemical, Biological, Radiological and Nuclear Delivery Team (CBRN DT)

Town: Bristol

Country: United Kingdom

E-mail: [George.Pritchard112@mod.gov.uk](mailto:George.Pritchard112@mod.gov.uk)

Telephone: +44 3067933663

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

29.5.2020