

**Netherlands-Amsterdam: Monitoring of Scientific and Medical Literature and the Entry of Relevant Information into EudraVigilance**

OJ S 66/2021 06/04/2021

Contract notice

Services

**Legal Basis:**

Regulation (EU, Euratom) No 2018/1046

**Section I: Contracting authority**

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**I.1. Name and addresses**

Official name: European Medicines Agency

Postal address: Domenico Scarlattilaan 6

Town: Amsterdam

NUTS code: NL1 Noord-Nederland

Postal code: 1083 HS

Country: Netherlands

E-mail: [procurement@ema.europa.eu](mailto:procurement@ema.europa.eu)**Internet address(es):**Main address: <https://www.ema.europa.eu/>Address of the buyer profile: <https://www.ema.europa.eu/en/about-us/procurement>**I.3. Communication**The procurement documents are available for unrestricted and full direct access, free of charge, at: <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=7639>

Additional information can be obtained from the abovementioned address

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

**I.4. Type of the contracting authority**

European institution/agency or international organisation

**I.5. Main activity**

General public services

**Section II: Object**

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**II.1. Scope of the procurement****II.1.1. Title**

Monitoring of Scientific and Medical Literature and the Entry of Relevant Information into EudraVigilance

Reference number: EMA/2020/17/TDA

**II.1.2. Main CPV code**

73000000 Research and development services and related consultancy services

**II.1.3. Type of contract**

Services

**II.1.4. Short description**

Provision of monitoring of scientific and medical literature and the entry of relevant information into EudraVigilance required by Article 27 of Regulation (EC) No 726/2004.

#### **II.1.5. Estimated total value**

#### **II.1.6. Information about lots**

This contract is divided into lots: no

### **II.2. Description**

#### **II.2.2. Additional CPV code(s)**

72314000 Data collection and collation services

#### **II.2.3. Place of performance**

NUTS code: NL1 Noord-Nederland

Main site or place of performance: Contractor's premises.

#### **II.2.4. Description of the procurement**

Provision of monitoring of scientific and medical literature and the entry of relevant information into EudraVigilance required by Article 27 of Regulation (EC) No 726/2004.

#### **II.2.5. Award criteria**

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

#### **II.2.6. Estimated value**

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

Duration in months: 72

This contract is subject to renewal: yes

Description of renewals:

The contract will be concluded for an initial period of 12 months with the possibility of five renewals each of 1 year (maximum contract duration is 6 years).

#### **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.2.14. Additional information**

The estimated contract volume will initially be for substance groups 1-309 and herbal substance groups 1-100.

The Agency may use the negotiated procedure under point 11.1.e of Annex 1 to the General Financial Regulation to procure new services from the contractors up to a maximum of 50 % of the initial framework contract ceiling.

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

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#### **III.1. Conditions for participation**

### **III.1.1. Suitability to pursue the professional activity, including requirements relating to enrolment on professional or trade registers**

List and brief description of conditions:

See internet address provided in section I.3).

### **III.1.2. Economic and financial standing**

Selection criteria as stated in the procurement documents

### **III.1.3. Technical and professional ability**

Selection criteria as stated in the procurement documents

## **Section IV: Procedure**

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

This service creates and transmits data to Marketing Authorisation Holders and national Competent Authorities. There is a large investment required by the contractor (both organisational and financial) in the set-up of the services, which would take about 6 months. Thus, to reduce the incumbency advantage and ensure a level playing-field for all bidders, the Agency is offering a six year contract.

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

The procurement is covered by the Government Procurement Agreement: no

### **IV.2. Administrative information**

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

Date: 19/05/2021 Local time: 12:00

#### **IV.2.3. Estimated date of dispatch of invitations to tender or to participate to selected candidates**

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

Bulgarian, Czech, Danish, German, Greek, English, Spanish, Estonian, Finnish, French, Irish, Croatian, Hungarian, Italian, Lithuanian, Latvian, Maltese, Dutch, Polish, Portuguese, Romanian, Slovak, Slovenian, Swedish

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

Duration in months: 9 (from the date stated for receipt of tender)

#### **IV.2.7. Conditions for opening of tenders**

Date: 20/05/2021 Local time: 10:00

Place:

Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands.

Information about authorised persons and opening procedure: See internet address provided in section I.3).

## Section VI: Complementary information

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### VI.1. Information about recurrence

This is a recurrent procurement: no

### VI.3. Additional information

### VI.4. Procedures for review

#### VI.4.1. Review body

Official name: General Court

Postal address: rue du Fort Niedergrünwald

Town: Luxembourg

Postal code: L-2925

Country: Luxembourg

E-mail: [generalcourt.registry@curia.europa.eu](mailto:generalcourt.registry@curia.europa.eu)

Telephone: +352 4303-1

Fax: +352 4303-2100

Internet address: <http://curia.europa.eu>

#### VI.4.4. Service from which information about the review procedure may be obtained

Official name: European Medicines Agency

Postal address: Domenico Scarlattilaan 6

Town: Amsterdam

Postal code: 1083 HS

Country: Netherlands

E-mail: [info@ema.europa.eu](mailto:info@ema.europa.eu)

Telephone: +31 887816000

Internet address: <http://www.ema.europa.eu>

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

30/03/2021