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Tender

## **Provision of Regulatory Affairs services to support with obtaining Marketing Authorisation from the VMD for Cattle BCG and a companion skin test, DST-F**

Defra Network eTendering Portal

F02: Contract notice

Notice identifier: 2021/S 000-028008

Procurement identifier (OCID): ocds-h6vhtk-02d32b

Published 8 November 2021, 10:45pm

### **Section I: Contracting authority**

#### **I.1) Name and addresses**

Defra Network eTendering Portal

17 Nobel House

London

SW1P 3JR

#### **Email**

[colette.newton@defra.gov.uk](mailto:colette.newton@defra.gov.uk)

#### **Telephone**

+44 2072385921

#### **Country**

United Kingdom

**NUTS code**

UK - United Kingdom

**Internet address(es)**

Main address

<http://www.defra.gov.uk>

**I.3) Communication**

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

<https://defra.bravosolution.co.uk>

Additional information can be obtained from the above-mentioned address

Tenders or requests to participate must be submitted electronically via

<https://defra.bravosolution.co.uk>

Tenders or requests to participate must be submitted to the above-mentioned address

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

Ministry or any other national or federal authority

**I.5) Main activity**

Environment

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**Section II: Object****II.1) Scope of the procurement****II.1.1) Title**

Provision of Regulatory Affairs services to support with obtaining Marketing Authorisation from the VMD for Cattle BCG and a companion skin test, DST-F

Reference number

33135

### **II.1.2) Main CPV code**

- 71356000 - Technical services

### **II.1.3) Type of contract**

Services

### **II.1.4) Short description**

Provision of regulatory affairs services for compilation and submission to the UK Veterinary Medicines Directorate of Marketing Authorisation Dossiers for CattleBCG and DST-F as part of the of the UK Government bovine tuberculosis (bTB) eradication programme.

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

This contract is divided into lots: No

## **II.2) Description**

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

- 71356300 - Technical support services

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

NUTS codes

- UK - United Kingdom

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

APHA is seeking a contractor for provision of regulatory services for immunological veterinary medicinal products (IVMPs) to compile two Marketing Authorisation (MA) dossiers and manage the MA submissions CattleBCG and DST-F, a DIVA skin test classified as an IVMP for regulatory purposes.

The contractor will be responsible for collating all relevant documentation and parts of the dossier submission to include summary of the dossier, product quality, safety and efficacy data and bibliographic references. Compiling the dossiers according to the requirements outlined in EurdraLex- Volume 6B & 6C and any additional requirements laid down by the Veterinary Medicines Directorate (VMD) for the content and structure of the dossiers

Services are expected to commence from February 2022, please refer to tender document for more information on service commencement date.

#### **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

36

This contract is subject to renewal

Yes

Description of renewals

Optional 12 month extension. No further renewals expected after this.

#### **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**

A PIN was issued earlier this year is to alert the market to this opportunity and invited interested parties to download the supplier information pack which has further information on this project.

This supplier information pack can be downloaded from Bravo along with the full tender documents.

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

### **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

Please refer to tender documents

#### **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

### **III.2) Conditions related to the contract**

#### **III.2.2) Contract performance conditions**

Please refer to tender documents

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## **Section IV. Procedure**

### **IV.1) Description**

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

Open procedure

#### **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.2.1) Previous publication concerning this procedure**

Notice number: [2021/S 000-019388](#)

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

Date

9 December 2021

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: 4 (from the date stated for receipt of tender)

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

Date

9 December 2021

Local time

12:00pm

Information about authorised persons and opening procedure

Sealed Parallel Opening of Tender Documents via Bravo e-Tendering System

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## **Section VI. Complementary information**

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

This is a recurrent procurement: No

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

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

Defra

London

SW1P 3JR

Country

United Kingdom