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Planning

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

F01: Prior information notice

Prior information only

Notice identifier: 2021/S 000-019388

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

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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

Telephone

+44 2072385921

Country

United Kingdom

NUTS code

UK - United Kingdom

Internet address(es)

Main address

www.defra.gov.uk

I.3) Communication

Additional information can be obtained from the above-mentioned address

I.4) Type of the contracting authority

Ministry or any other national or federal authority

I.5) Main activity

Environment

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 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.1.5) Estimated total value

Value excluding VAT: £210,000

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

VMD for the content and structure of the dossiers

The dossiers will be produced to a high specification with respect to content, format and ease of access for the assessors it will be submitted by the contractor via the VMD portal.

The contractor will be the point of contact between APHA and VMD throughout the MA application process including managing the responses to questions or issues raised by the VMD during the MA application procedure. The contractor will play a critical role ensuring timelines for responses are met and working closely with the experts at the APHA to ensure complete and full responses to address VMD concerns, questions or points of clarification.

APHA estimates that the service is required to commence in January 2022.

Note that the contract specification, to be issued as part of the tender documents, will provide comprehensive information on the mandatory standards and requirements for this contract.

II.2.14) Additional information

The purpose of this PIN is to alert the market to a possible opportunity and invite interested parties to download the supplier information pack which has further information on this project and is available on Defra's e-Sourcing system Bravo (<https://defra.bravosolution.co.uk/>) under Project 33135.

Please note it is free to register on Bravo.

II.3) Estimated date of publication of contract notice

24 September 2021

Section IV. Procedure

IV.1) Description

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

The procurement is covered by the Government Procurement Agreement: Yes

Section VI. Complementary information

VI.3) Additional information

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