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Planning

Clinical Trials Drug Supply in Primary Care for COVID-19

Department of Health and Social Care

F01: Prior information notice

Reducing time limits for receipt of tenders

Notice identifier: 2021/S 000-018348

Procurement identifier (OCID): ocds-h6vhtk-02cf1a

Published 2 August 2021, 8:21am

Section I: Contracting authority

I.1) Name and addresses

Department of Health and Social Care

39 Victoria Street

London

SW1H 0EU

Contact

Marjia Monsur

Email

AntiviralsTaskforce@dhsc.gov.uk

Country

United Kingdom

NUTS code

UKI32 - Westminster

Internet address(es)

Main address

<https://www.gov.uk/government/organisations/department-of-health-and-social-care>

Buyer's address

<https://www.gov.uk/government/organisations/department-of-health-and-social-care>

I.3) Communication

Additional information can be obtained from the above-mentioned address

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

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

Clinical Trials Drug Supply in Primary Care for COVID-19

II.1.2) Main CPV code

- 85149000 - Pharmacy services

II.1.3) Type of contract

Services

II.1.4) Short description

Agreement for the re-packing, re-labelling for individual use and distribution of medicines into the community for clinical trials. Some of the drugs will be novel drugs, or unlicensed drugs and others will be off-label drugs.

II.1.6) Information about lots

This contract is divided into lots: No

II.2) Description

II.2.3) Place of performance

NUTS codes

- UK - United Kingdom

II.2.4) Description of the procurement

The purpose of the exercise will be to assess, and potentially award a contract(s), to Distance Selling Pharmacies (DSPs) or online pharmacies, for the distribution of medicines to patients participating in COVID-19 clinical trial(s). It is likely that more than one clinical trial may require the same service. However, the exact number of trials and the number of participants are yet to be finalised. The medicines and their quantities to be distributed are currently unknown, as we await confirmation on which drugs will be included in the clinical trials. These will be shared with suppliers as soon as is practically possible. At the moment, DHSC are working to a scenario whereby 1,000 to 5,000 patients could be recruited into national priority COVID-19 clinical trial(s) per week over a 6-month period. Only one delivery of medication will be required per patient. Manufacturers of the drugs will store and deliver the drugs to the selected DSP or online pharmacy. Notification on what medication needs to be dispatched to trial participants will be provided by the Trial Team, it is essential that the drug is received by the trial participant within 24 hours of the notification. We need to ensure rapid delivery of the drugs to the patients, therefore it would also be beneficial to explore options where the drug can be received by the participants within a 4 hour window of the notification or same day delivery. It is also vital that the trial drugs are stored and dispatched according to ICH GCP guidelines. To note, these figures are planning scenarios based on current estimates so may change as the clinical trials progress and/or expand. Actual volumes of required deliveries may be lower depending on the progression of the pandemic and the uptake of participation in a clinical trial, however, we are currently assessing the capability of suppliers to meet the upper limit of our supply requirements. Any figures shared

throughout the process should not be shared with anybody who is not part of either an Expression of Interest (EOI) or a bid for this work. Therefore, we are asking suppliers to submit an EOI if they are: 1) Able to robustly meet all their prescription nominations in the first instance (i.e. able to easily handle their BAU); and 2) Able to either meet the above delivery demand to distribute Covid-19 treatment courses for clinical trials or be able to ramp up their capacity to meet this demand in the timeframes set out. The expectation is that this will be in place from mid-October 2021 for a minimum period of 6 months. In order to distribute these medicines in accordance with the clinical trial protocols, these medicines may need to be re-packaged down from their manufactured packs to a size that equates to a single treatment course. Even if they don't need to be re-packaged, with the patient information included, they will need to be labelled for individual patient use. With the new label on the pack, they will then need to be distributed throughout the UK (including the Devolved Administrations) to patients who are participating in the clinical trial. This contract is intended to be used for the UK's response to COVID-19, to support clinical trials looking into drug efficacy. The contract will initially be for a 6 month period, with an option to extend as required.

II.2.5) Award criteria

Price

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

Duration in months

6

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.3) Estimated date of publication of contract notice

6 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

The contract agreement would be for the benefit of the contracting authority, NHS bodies and other public bodies responsible for delivery of health-related services in the United Kingdom including, without limitation, the National Assembly for Wales, the Northern Ireland Assembly, and Scottish Ministers, other government departments and non-department public bodies. Although DHSC are issuing a PIN, this is in no way a commitment to proceed with a procurement, it is merely an indication that the Department would like to engage with the market around a potential specification. The Expression of Interest (EOI) needs to be in the form of an email to the following address AntiviralsTaskforce@dhsc.gov.uk stating your interest and the names and contact details of those that will be in attendance or should be contacted. An EOI, of no longer than two A4 pages, should be returned in response to this PIN. In the EOI please set out why you are well placed to complete this work and some high-level costings to undertake this work for the initial 6 month period. The engagement with the market will take the form of a one-to-one call with suppliers who provide an EOI and have an ability to meet the upper limit of our requirement. If a larger number of suppliers submit an EOI, we may set-up an initial webinar to take suppliers through the requirement and the key questions. The date and time for this webinar will be confirmed once we have received responses to the PIN. To organise sessions or a webinar, we will send details out to the contacts identified in the EOI. In addition to this not forming a commitment to proceed with a procurement, not engaging with DHSC via the EOI does not exclude any organisation from participating in any formal commercial process which may follow. Please note that by participating in this EOI, records of 1:1 conversations and Q&As may be kept in order to ensure a clearly auditable decision-making trail and for FOI requests.

VI.4) Procedures for review

VI.4.1) Review body

The High Court

Strand

London

WC2A 2LL

Country

United Kingdom

Internet address

<https://www.gov.uk/courts-tribunals>