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Not applicable

Supply of 18F-DOPA Radionuclide tracer to NHS England Centres

NHS England Specialised Commissioning

F14: Notice for changes or additional information

Notice identifier: 2022/S 000-002427

Procurement identifier (OCID): ocids-h6vhtk-03054e

Published 27 January 2022, 2:23pm

Section I: Contracting authority/entity

I.1) Name and addresses

NHS England Specialised Commissioning

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Internet address(es)

Main address

<https://www.england.nhs.uk/commissioning/spec-services/>

Buyer's address

<https://uk.eu-supply.com/ctm/Company/CompanyInformation/Index/68205>

Section II: Object

II.1) Scope of the procurement

II.1.1) Title

Supply of 18F-DOPA Radionuclide tracer to NHS England Centres

Reference number

48184

II.1.2) Main CPV code

- 85000000 - Health and social work services

II.1.3) Type of contract

Services

II.1.4) Short description

NHS Arden and Greater East Midlands Commissioning Support Unit (AGCSU), on behalf of NHS England (referred to as the Commissioner) is inviting suitably qualified and experienced suppliers to express an interest in delivering the supply of 18F-DOPA radiotracer.

18F-DOPA PET-CT scans are integral to the clinical pathway, as set out in the service specification. The 18F-DOPA PET-CT scan is used to identify patients who have the focal (rather than diffuse) form of congenital hyperinsulinism (CHI), who would benefit from surgery and the precise location of the focal lesions so that they can be removed.

Section VI. Complementary information

VI.6) Original notice reference

Notice number: [2021/S 000-032215](#)

Section VII. Changes

VII.1.2) Text to be corrected in the original notice

Section number

II.2.4

Instead of

Text

Please note that an online Webinar will be held on 01.02.22, further details will be shared in due course

Read

Text

NHS Arden and Greater East Midlands Commissioning Support Unit (AGCSU), on behalf of NHS England (referred to as the Commissioner) is inviting suitably qualified and experienced suppliers to express an interest in delivering the supply of 18F-DOPA radiotracer.

18F-DOPA PET-CT scans are integral to the clinical pathway, as set out in the service specification. The 18F-DOPA PET-CT scan is used to identify patients who have the focal (rather than diffuse) form of congenital hyperinsulinism (CHI), who would benefit from surgery and the precise location of the focal lesions so that they can be removed.

18F-DOPA PET-CT scans are only performed at Institute of Nuclear medicine, University College London Hospitals NHS Foundation Trust and Manchester University NHS Foundation Trust. At present, about ten 18F-DOPA PET-CT scans are performed annually. NHS England is looking to gauge the potential market interest for providing the 18F- DOPA radiotracer to the two CHI scanning centres in England.

Requirements

The supplier will be required to manufacture, quality assure and control and deliver 18F-

DOPA as required (circa ten doses per year). The supplier will need to be flexible in its scheduling of the production of ^{18}F -DOPA to meet the service needs of the scan providers at University College London Hospital and Manchester University NHS Foundation Trust. The tracer will need to be manufactured and transported to the scan provider in a quantity that ensures that there is sufficient activity in the product to carry out an effective scan.

The supplier will need to hold:

a valid manufacturer's licence

a valid marketing authorisation or a Manufacturer's Specials

Licence as applicable issued by the Medicines and Healthcare products Regulatory Agency (MHRA) for the manufacture of the tracer, such licences being subject to renewal following satisfactory MHRA inspection.

The supplier will need to demonstrate that the manufacture and supply of the radiotracer will meet the requirements of the Law and related guidance including:

Good Manufacturing Practice (GMP) as defined in Commission Directive 2003/94/EC (principles and European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009; and

European Pharmaceutical standards for the Quality Control Analysis.

Interested parties are encouraged to register their interest and participate in the market questionnaire which will provide feedback to commissioners. Please note that this is not a call for competition although the commissioner would encourage all potential providers to respond to this market engagement exercise. It is possible that, as a result of this exercise, a formal tender process may not be required but instead a simpler supplier selection process may be considered. The outcome of this market engagement will help inform commissioners of the current and future capacity and capability of the market and will be considered with other evidence to inform the commissioning approach.

The market engagement includes a clear outline of the service requirements along with a questionnaire for bidders to respond to, including the key requirements to ascertain the capability of providers.

The contract duration for this supply is 5 years with an option to extend for a further two years.

The response deadline is 12:00 hrs midday on 18.02.22

To respond to the market engagement exercise please follow this link <https://uk.eu-supply.com/ctm/supplier/publictenders?B=UK> and either login or register on EU Supply and search from ID number 48184

The original Market Engagement webinar was due to be held on the 01.02.22. Due to unforeseen circumstances this webinar has now been rescheduled and will be held on the 08.02.22.

The Market engagement event will be held via Microsoft Teams at 10:30AM on Tuesday the 8th February 2022. If you would like to participate in this event or if you are unable to attend the session but wish to receive the details provided during the webinar, please email josselin.canevet@nhs.net by 12pm on Monday 7th February 2021.