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Award

Supply and Manufacture of Investigational Medicinal Products (IMPs) for the Clinical Trial: "Examining Antibiotics for Ulcerated Skin Cancer Surgical Excision"

NHS Wales Shared Services Partnership (NWSSP) - Procurement Services

F15: Voluntary ex ante transparency notice

Notice identifier: 2025/S 000-001841

Procurement identifier (OCID): ocds-h6vhtk-04d494

Published 20 January 2025, 12:02pm

Section I: Contracting authority/entity

I.1) Name and addresses

NHS Wales Shared Services Partnership (NWSSP) - Procurement Services

Woodland House, 2nd Floor, Maes-Y-Coed Road

Cardiff

CF14 4HH

Contact

Nia Price

Email

nia.price@wales.nhs.uk

Telephone

+44 2921501500

Country

United Kingdom

NUTS code

UK - United Kingdom

Internet address(es)

Main address

<http://nwssp.nhs.wales/ourservices/procurement-services/>

Buyer's address

https://www.sell2wales.gov.wales/search/Search_AuthProfile.aspx?ID=AA0221

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Health

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

Supply and Manufacture of Investigational Medicinal Products (IMPs) for the Clinical Trial:
"Examining Antibiotics for Ulcerated Skin Cancer Surgical Excision"

II.1.2) Main CPV code

- 33000000 - Medical equipments, pharmaceuticals and personal care products

II.1.3) Type of contract

Supplies

II.1.4) Short description

Cardiff and Vale University Health Board (CAVUHB) is undertaking a clinical trial entitled 'Examining Antibiotics for Ulcerated Skin Cancer Surgical Excision', funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (Ref: NIHR 160872). As part of this clinical trial, an Investigational Medicinal Product (IMP) needs to be manufactured and distributed.

II.1.6) Information about lots

This contract is divided into lots: No

II.1.7) Total value of the procurement (excluding VAT)

Value excluding VAT: £116,645

II.2) Description

II.2.2) Additional CPV code(s)

- 33000000 - Medical equipments, pharmaceuticals and personal care products

II.2.3) Place of performance

NUTS codes

- UKL22 - Cardiff and Vale of Glamorgan

II.2.4) Description of the procurement

Supply and Manufacture of Investigational Medicinal Products (IMPs) for the Clinical Trial: "Examining Antibiotics for Ulcerated Skin Cancer Surgical Excision"

Cardiff and Vale University Health Board (CAVUHB) is undertaking a clinical trial entitled 'Examining Antibiotics for Ulcerated Skin Cancer Surgical Excision', funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (Ref: NIHR 160872). As part of this clinical trial, an Investigational Medicinal Product (IMP) needs to be manufactured and distributed. The IMPs required are:

-Flucloxacillin 2 x 500mg capsules, over encapsulated

-A matching placebo of inert filler, over encapsulated to match flucloxacillin 2 x 500mg capsules.

The successful supplier will be responsible for the manufacture, packaging, labelling, Quality Assurance (QA) certification, storage, shipment, and regulatory compliance (CTIMP regulations) associated with the trial's IMPs.

After extensive market research and consultations with multiple suppliers, it has been concluded that only one supplier, Simbec-Orion, has the capability to fulfil the full scope of the contract requirements. This includes:

- Over encapsulation of flucloxacillin and matching placebo
- Packaging and labelling of the final product
- Compliance with clinical trial regulations (CTIMP)
- Storage and shipment logistics to participating NHS sites
- QA certification and regulatory compliance for blinded clinical trials

Simbec-Orion will also source the bulk IMP (4 lots of flucloxacillin, 1 lot of placebos), over encapsulate the product, and ensure all necessary documentation and quality assurance procedures are met.

Simbec-Orion is uniquely positioned to meet the requirements of the clinical trial due to its established capabilities in the manufacture and regulatory compliance of Investigational Medicinal Products (IMPs). No other supplier was found to be able to offer the complete set of services required for this project.

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

Section IV. Procedure

IV.1) Description

IV.1.1) Type of procedure

Negotiated without a prior call for competition

- The products involved are manufactured purely for the purpose of research, experiment, study or development

Explanation:

The products involved are manufactured purely for the purpose of research. In addition, Simbec-Orion is positioned to meet the requirements of the clinical trial. No other supplier was found to be able to offer the complete set of services required for this project.

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

The procurement is covered by the Government Procurement Agreement: Yes

Section V. Award of contract/concession

Contract No

CAV-VEA (24-25) 169

A contract/lot is awarded: Yes

V.2) Award of contract/concession

V.2.1) Date of conclusion of the contract

1 January 2025

V.2.2) Information about tenders

The contract has been awarded to a group of economic operators: No

V.2.3) Name and address of the contractor/concessionaire

SIMBEC RESEARCH LIMITED

Simbec House Merthyr Tydfil Industrial Park, Pentrebach

Merthyr Tydfil

CF484DR

Telephone

+44 1753944092

Country

United Kingdom

NUTS code

- UKL - Wales

The contractor/concessionaire is an SME

Yes

V.2.4) Information on value of contract/lot/concession (excluding VAT)

Total value of the contract/lot/concession: £116,645

Section VI. Complementary information

VI.3) Additional information

NHS Wales Shared Services Partnership are publishing this notice on behalf of;

Cardiff and Vale University Health Board

Woodland House

Maes-y-Coed Road

Cardiff

CF14 4HH

A standstill period of 10 calendar days from publication of this notice will be observed by the authority prior to entering into a contract.

NOTE: To register your interest in this notice and obtain any additional information please visit the Sell2Wales Web Site at

https://www.sell2wales.gov.wales/Search/Search_Switch.aspx?ID=147495.

(WA Ref:147495)

VI.4) Procedures for review

VI.4.1) Review body

High Court

Royal Courts of Justice, The Strand

London

WC2A 2LL

Telephone

+44 2079477501

Country

United Kingdom

