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Planning

non-DEHP Blood Pack Validation

NHS Blood and Transplant

F01: Prior information notice

Prior information only

Notice identifier: 2024/S 000-004554

Procurement identifier (OCID): ocids-h6vhtk-043925

Published 12 February 2024, 9:07am

Section I: Contracting authority

I.1) Name and addresses

NHS Blood and Transplant

500 North Bristol Park

Bristol

BS34 7QH

Contact

Samantha Rix

Email

samantha.rix@nhsbt.nhs.uk

Telephone

+44 7385972251

Country

United Kingdom

Region code

UKK11 - Bristol, City of

Internet address(es)

Main address

<https://www.nhsbt.nhs.uk/>

Buyer's address

<https://www.nhsbt.nhs.uk/>

I.3) Communication

Additional information can be obtained from the above-mentioned address

Electronic communication requires the use of tools and devices that are not generally available. Unrestricted and full direct access to these tools and devices is possible, free of charge, at

<https://health-family.force.com/s/Welcome>

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**

non-DEHP Blood Pack Validation

Reference number

C238220

II.1.2) Main CPV code

- 33141613 - Blood bags

II.1.3) Type of contract

Supplies

II.1.4) Short description

Following a change in EU legislation, DEHP plasticiser will be removed from medical devices, including blood packs. NHSBT wishes to commence a validation process in early 2024 for non-DEHP primary collection and ancillary blood packs. The project will have a duration of 2 calendar years from commencement.

Primary collection systems are for the collection of whole blood in two configurations ('bottom and top' and 'top and top').

Ancillary systems are for secondary manufacturing processes and subsequent storage, such as for pooled platelet concentrates or small volume neonatal components.

II.1.5) Estimated total value

Value excluding VAT: £48,000

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

Main site or place of performance

United Kingdom, Europe and World Wide

II.2.4) Description of the procurement

Please note that this is not the start of a procurement process. A separate contract notice will be published to cover this requirement. The purpose of this Prior Information Notice (PIN) is to inform the market of prospective requirements, as far as the details are known at this time.

This PIN is being published by NHSBT on behalf of itself and potentially in collaboration with other Blood Services.

NHSBT seeks to understand the market's ability to supply non-DEHP primary and ancillary blood packs and to validate these packs in order to support a potential future tender.

Subject to satisfactory agreements, the validation may be in collaboration with other Blood Services, potentially within the European Blood Alliance (EBA) or the Alliance of Blood Operators (ABO). To support validation of the blood packs and avoid duplication across multiple Blood Services, NHSBT will participate in the European Blood Alliance data sharing agreements, and will adopt the published EBA validation strategy as a framework for its own validation activities.

NHSBT intends to validate all non-DEHP blood pack systems that have received CE marking under EU MDR, or which have a credible application and timeline for receipt of the accreditation within the timeline of this validation project. Validation will consist of phase 0 and phase 1 activities. No components will be issued to patients.

Suppliers should contact Samantha Rix, samantha.rix@nhsbt.nhs.uk by 14 March 2024 to express their interest or for further information, should the Supplier have (or is likely to have) non-DEHP primary and ancillary blood packs which meet the criteria and timescales stated above.

II.2.14) Additional information

Validation Project Timeline - April 2024 to March 2026

Phase 0 = Physical examination of pack

Phase 1 = small scale product/pack tests

II.3) Estimated date of publication of contract notice

24 January 2024

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: No