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Planning

Storage & Distribution of Human Medicines, Vaccines & Associated Medical Products

UK Health Security Agency

UK2: Preliminary market engagement notice - Procurement Act 2023 - <u>view information</u> <u>about notice types</u>

Notice identifier: 2025/S 000-015899

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Changes to notice

This notice has been edited. The <u>previous version</u> is still available.

Scope

Reference

C208046

Description

Background

The UK Health Security Agency (UKHSA) wishes to establish a contract with a pharmaceutical wholesaler for human medicines who can act as a third party on behalf of the Agency for the UK storage and distribution of the Agency's vaccines, other medicines and associated medical products (ownership remains with the UKHSA).

A new storage and distribution contract, to commence from September 2027, is required to ensure that storage and distribution of UKHSA-owned goods, including, but not exclusively limited to, consumables, pharmaceutical goods including controlled drugs (CDs), medical devices, immunoglobulins, antitoxins, antivenoms and vaccines, can continue to be safely received from manufacturers, stored, and distributed to the NHS and other specified recipients under appropriate conditions as per licence requirements. The products require specialist storage and distribution to ensure that they are not damaged, both physically and biologically. To support this, effective stock management and audit systems are essential in accordance with Good Distribution Practice (GDP) requirements.

The proposed requirement is to provide ambient temperature controlled (ie. below 15C to 25C), chilled (ie. 2C to 8C), frozen (ie. -15C to -50C) and ultra-low temperature (eg. -60C to -90C) warehousing, distribution and management services across the UK (including Northern Ireland and Crown Dependencies) for the supply of human medicines, vaccines and associated medical products, covering a multi-tiered response level (including scheduled routine deliveries and urgent same-day service levels). Prior to the operational service commencement date, the provider should also have the capability for repack and thaw activities in compliance with its Manufacturing Specials (MS) Licence.

This is a critical contract to ensure that the UKHSA can meet its requirements for:

- National Immunisation Programmes the importance of population-based immunisation in protecting public health through minimising/eradicating the incidence and spread of vaccine preventable diseases is well established. The UK has one of the most comprehensive immunisation programmes in the world, with protection throughout the life course starting before birth, continuing into childhood, adolescence and adulthood including older adults.
- Pandemic Preparedness Portfolio (PPP) the stockpiling of medicines, vaccines and associated consumable products in preparedness to respond to a future pandemic.
- Covid Vaccine Programme The UK continues to respond to the threat of COVID-19 through a targeted vaccination programme for those most vulnerable to the virus. This includes older people, people with underlying health conditions, and frontline health and social care workers.

- Emergency Preparedness, Resilience and Response programme (EPRR) the UK has provisions in place for responding to accidental or intentional releases of chemical, biological, radiological or nuclear (CBRN) materials.
- Rapid Deployment Treatments (RDT) includes small volumes of chilled pharmaceutical goods held for rapid deployment and delivery within 5 hours in support of a healthcare emergency in the UK.

Description of Procurement

UKHSA owns stocks of vaccines, pandemic and medical countermeasures which it stores and distributes for use across the UK. It uses a web-based ordering system/platform (ImmForm) to facilitate remote ordering by designated customers.

The service required has the following component parts (this list is not exhaustive):

- Services are to be provided throughout with regulatory compliance to the Human Medicines Regulations 2012 and adherence to Good Distribution Practice for all sites and warehouses used to provide the services.
- The requirements are expected to include long term storage of national stock holdings of circa 60,000 pallets of stock at various temperature regimes including ambient temperature controlled, chilled, frozen and ultra-low temperature. In addition, the capability to undertake repack activity will be required, as well as thaw activity on a weekly basis for circa 4000 packs of stock held at -90°C and -15°C.
- A regular scheduled programme of routine chilled deliveries (next day and scheduled delivery day) for immunisation products amounts to approximately 5,000 deliveries per week covering currently circa 12,000 locations across the UK including Northern Ireland and Crown Dependencies, covering a range of healthcare organisations, including general practices, NHS hospitals, school-aged immunisation services and some community pharmacies. Capability is required to expand the customer base in line with changing NHS-commissioned vaccination providers.
- Be in a ready state for deployment of certain stockpiles in the event of a pandemic or CBRN event. Deployment of the relevant stockpile or part thereof could range from national deployment to predefined locations within England or to specific/restricted geographical deployments that could be anywhere in the UK.
- Rapid Deployment Treatment medicines for same-day deliveries for specific products, within 5 hours in response to an emergency situation (generally less than 1000 per year). RDT covers the UK the majority of products will require delivery to acute healthcare trusts, with a small number of products potentially requiring deployment to any postcode location in the UK in response to a biological incident. This should be supported with 24

hour follow-on dispatch of replenishment goods from the stockpile to strategically located distribution hubs where needed.

- A seasonal programme of frozen and ultra-low temperature (ULT) deliveries which amounts to approximately 6 ULT deliveries per week and 30 frozen deliveries a week to circa 1000 locations (UK and Crown Dependencies).
- Service is expected to operate 24 hours/365 days per year uninterrupted.
- Facility to expand chilled storage and distribution capacity in GB and Northern Ireland in response to a pandemic or other major health incident/national emergency required (reserve capacity).
- Be scalable to encompass future services, e.g., including but not limited to, frozen storage and distribution, or significant thaw capability with chilled distribution, for vaccines used within the national immunisation programme as vaccine platform technology develops.
- Capacity to manufacture "Specials" required. An MS licence will be needed for packing down and labelling activities of unlicensed medicines. The importation of the unlicensed medicines from third countries and from EU/EEA will be carried out through the Authority's MS licence.
- Provider's warehouse management system will need to be able to interface with the Agency's bespoke web-based ordering system/platform (ImmForm) to facilitate remote ordering by designated customers.
- Routine record-keeping and reporting relating to receipt, storage and deployment of stock held will be required.

Please note that estimated volumes are provided for information purposes and are based on current information, and therefore may be subject to fluctuations dependent on numerous factors such as the impact of other potential pandemics and infectious disease outbreaks.

Procurement Process

This opportunity will be advertised under the new Procurement Act 2023 regulations. The contract will be based upon the Cabinet Office's Model Services Contract as amended to suit the needs of the Authority.

This opportunity will be advertised as one lot and awarded to one supplier. The contract term will consist of a transition period of up to 12 months, with an operational services period of approximately 6 years with possible extensions.

The following licence requirements are identified as essential:

- 1. Wholesale Dealers Authorisation (Human) WDA(H) for holding and distribution for the following categories:
- Wholesale distribution Operations: Holding and Supply.
- Medicinal Products: With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorization, a certificate of registration or traditional herbal registration). -Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market
- Medicinal Products with Additional Requirements: Narcotic or psychotropic products, Medicinal products derived from blood, Immunological medicinal product, Cold chain products (requiring low temperature handling)
- Categories of products handled at the site: Prescription Only Medicines, -Pharmacy
- 2. Current Good Distribution Practice (GDP) Certificate with MHRA
- 3. Home Office Controlled Drug (CD) Licence; covering the following Schedules/Authorisation of Activity for CDs; Schedule 2 (possess, supply), Schedule 3 (possess, supply), Schedule 4 part 1 (possess, supply) and Schedule 5 (supply)

The following licence requirements are required to be obtained during the transition period of up to 12 months prior to the operational service commencement date:

- 1. Manufacturing Specials (MS) licence
- 2. Current Good Manufacturing Practice (GMP) Certificate with MHRA

Social Value, NET Zero and Modern Slavery

In line with the UK Government's Policy Procurement Note, PPN 002, 10% of the scored element of this tender will be attributed to social value. This will focus on:

- Tackling Economic Equality
- Fighting Climate Change
- Equal opportunity
- Wellbeing

Carbon reduction plans in line with NET zero (PPN 006) and tackling modern slavery in supply chains (PPN 009) will also be assessed.

Total value (estimated)

- £545,712,000 excluding VAT
- £654,854,400 including VAT

Above the relevant threshold

Contract dates (estimated)

- 1 October 2027 to 30 September 2033
- Possible extension to 30 September 2037
- 10 years

Main procurement category

Services

CPV classifications

• 63120000 - Storage and warehousing services

Contract locations

- UK United Kingdom
- GG Guernsey
- IM Isle of Man

• JE - Jersey

Engagement

Engagement deadline

13 May 2025

Engagement process description

The Agency invites interested parties to attend a virtual market engagement event at 10-11am on Tuesday 13 May 2025.

The purpose of the event is to:

- Share the new vision of the contract with the market and highlight the changes against the incumbent contract:
- Gather market intelligence to frame the procurement delivery model and tender documentation;
- Demonstrate the Agency's aspiration for the contract to prepare the market for the upcoming tender;
- Allow the market to share their thoughts on the requirement and ask questions.

Please follow this link to access the registration form:

https://forms.office.com/pages/responsepage.aspx?id=mRRO7jVKLkutR188-d6GZrhfnUtb KuNJkJxL8TF0NgFUMExJVTVHVFZCOU4zSIRMMFFKVjdJS0ZZUy4u&route=shorturl

Previous market engagement

In September 2023 and 2024, UKHSA issued Prior Information Notices (PIN) for this opportunity to gather information on the capacity of the market to deliver the requirement, inform potential delivery timescales and to better under the feasibility of the requirement.

Although the response windows for both PINs have now closed, more information regarding the requirement can be found at the following links:

2023 PIN - https://www.find-tender.service.gov.uk/Notice/026501-2023

2024 PIN - https://www.find-tender.service.gov.uk/Notice/030308-2024

Submission

Publication date of tender notice (estimated)

16 June 2025

Contracting authority

UK Health Security Agency

NHS Organisation Data Service: U6N4T

Public Procurement Organisation Number: PBMQ-7576-DVGW

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