This notice is for information only and provides an update with regards to the tender for the Storage & Distribution of Human Medicines, Vaccines & Associated Medical Products for the UK Health Security Agency (UKHSA).

**Description**

UKHSA is seeking to establish a contractual agreement 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 is needed 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 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.

The requirement is critical to UKHSA in order to allow the uninterrupted and continued service 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 a best endeavours target of 5 hours in support of a healthcare emergency in the UK

The overall need of UKHSA is to ensure that requirements and outputs are managed in a way that:

• continues to provide a high-quality flexible service that can adapt to suit changing needs;

• drives maximum savings;

• increases UKHSA efficiency;

• promotes the use of ‘best practice’ in line with Good Distribution Practice (GDP), and Medicines and Healthcare products Regulatory Agency (MHRA) regulatory requirements; and

• provides full transparency of reporting and record keeping

**Description of the 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 <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 despatch 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 dependant on numerous factors such as the impact of other potential pandemics and infectious disease outbreaks.

**Updates**

This opportunity is still in development and will be progressing through the necessary governance processes. It is anticipated that this opportunity will be advertised in early 2025 under the Public Contracts Regulations 2015 . The contract will be based upon the Cabinet Office’s Model Services Contract as amended to suit the needs of the Authority. More information can be found at: [Model Services Contract](https://www.gov.uk/government/collections/model-services-contract#the-model-services-contract---core-terms-(england-&-wales)).

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. Current estimates anticipate that service transition will commence in late 2026.

The following licensing 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
1. Current Good Distribution Practice (GDP) Certificate with MHRA
2. 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 licensing 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 06/20](https://www.gov.uk/government/publications/procurement-policy-note-0620-taking-account-of-social-value-in-the-award-of-central-government-contracts), 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 06/21](https://www.gov.uk/government/publications/procurement-policy-note-0621-taking-account-of-carbon-reduction-plans-in-the-procurement-of-major-government-contracts)) and tackling modern slavery in supply chains ([PPN 02/23](https://www.gov.uk/government/publications/ppn-0223-tackling-modern-slavery-in-government-supply-chains)) will also be assessed.

**Previous notices associated with this opportunity**

A Prior Information Notice was issued in September 2023 and although the response window for this PIN has now closed, more information regarding the potential requirements can be found  at the following link: [Market Engagement for Storage & Distribution of Human Medicines, Vaccines & Associated Medical Products - Find a Tender (find-tender.service.gov.uk)](https://www.find-tender.service.gov.uk/Notice/026501-2023).

Please note that although the information contained in this notice is correct as at the date of publication it is possible that subsequent developments, events and circumstances may necessitate further changes to the Authority’s requirements and to the details of the proposed procurement.