**Title: Market Engagement with pharmaceutical pre-wholesaler/wholesalers for storage and distribution of human medicines, vaccines, and associated medical products**

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).

We expect to conduct a tender exercise in accordance with the Public Contracts Regulations 2015 within the next twelve months.

**Background**

UK Health Security Agency (UKHSA) is an executive agency of the Department of Health and Social Care which operates as an integral part of the public health system and national security infrastructure, utilising state-of-the-art technologies and ground-breaking capabilities in data analytics and genomic surveillance to tackle coronavirus (COVID-19) and future threats locally, nationally, and globally.

UKHSA provides intellectual, scientific and operational leadership at national and local levels, as well as on the global stage, to make the nation’s health secure. It is responsible for protecting every member of every community from the impact of infectious diseases, chemical, biological, radiological and nuclear incidents and other health threats.

The Vaccines and Countermeasures response team is part of the Commercial Directorate within UKHSA. We are responsible for the business and procurement functions for vaccines and countermeasures. These functions support the efficient delivery of National immunisation programmes, and preparation for the effective response to a pandemic; an accidental or malicious chemical, biological, radiological or nuclear release; and incidents involving certain venoms and toxins.

**Scope of the procurement**

A new storage and distribution contract is needed to ensure that storage and distribution of UKHSA procured vaccines, immunoglobulins, antibiotics, medical consumables, antitoxins and antivenoms can continue to be safely received from manufacturers, stored, and distributed to the NHS and other specified recipients under controlled conditions. 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.

The requirement is critical to UKHSA 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, adulthood including older adults.
* **Pandemic Preparedness Portfolio (PPP)** – the stockpiling of medicines and vaccines, and associated consumable products in preparedness to respond to a future pandemic.
* **Covid 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. The vaccination programme has been highly successful in protecting people from severe disease, hospitalisation, and death. In the UK, the vaccines have been estimated to have prevented over 14,000 deaths and over 42,000 hospitalisations; and
* **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 materials.

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

#### **Short description**

The proposed requirement is to provide ambient temperature controlled, chilled, frozen and ultra-low temperature 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. The provider should also have the capability for repack and thaw activities.

**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 2012 Human Medicines Regulations 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, chill (+2°C to +8°C), frozen (-20°C) and ultra-low temperature (-75°C). In addition, capability to undertake repack activity required, as well as thaw activity on a weekly basis circa 4000 packs of stock held at -75°C and -20°C.
* A regular scheduled programme of routine chill deliveries (next day and scheduled delivery day) for vaccinations 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 health care 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 same-day deliveries for specific products, within 5 hours in response to an emergency situation (generally <1000 per year). Rapid Deployment 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 post code 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 (-20°C) and ultra-low temperature (-75°C) deliveries which amounts to approximately 6 deliveries per week at -75°C and 30 deliveries a week at -20°C to circa 1000 locations (UK and Crown Dependencies).
* Service is expected to operate 24 hour/365 days per year uninterrupted.
* Facility to expand chill 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, -20°C storage and distribution, or significant thaw capability with chill distribution, for vaccines used within the national immunisation programme as vaccine platform technology develops;
* Capacity to manufacture "Specials” required.
* 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.

We are approaching you regarding the potential requirement for the national chilled storage and distribution of vaccines, other medicines and associated medical products and as such are seeking further information on your company’s ability and capacity to meet our requirements outlined above.

**Supplier Response**

**Can you please provide details of your company name and contact details below:**

**Company Name:**

**Contact Name:**

**Role:**

**Questions**

1. **Pharmaceutical Licencing requirements (these will be required at the point of tendering):**
	1. **Do you hold a Wholesale Dealers Authorisation (Human) WDA (H) for holding & distribution?**

**Yes/No**

* 1. **Do you hold a current Good Distribution Practice GDP Certificate with MHRA?**

**Yes/No**

* 1. **Do you hold a Manufacturing Specials (MS) licence?**

**Yes/No**

1. **Do you hold a licence for the manufacture/importation of licensed medicinal products for human use (MIA)??**

**Yes/No**

1. **Do you hold a licence for the manufacture/importation of investigational medicinal products (MIA IMP)?**

**Yes/No**

1. **Do you hold a current Good Manufacturing Practice GMP Certificate with MHRA?**

**Yes/No**

1. **Holding and distribution – Please provide details on your current ability to provide a temperature controlled distribution chain of -75°C to ambient temperature controlled and any limitations with regards to your ability to provide -75°C storage which may need to be considered**

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1. **Capacity - Please indicate what your average daily/weekly capacity would be for the various aspects of this requirement including details of how your organisation could provide a fully flexible service which can adapt to the needs of UKHSA in a timely manner**

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1. **Capability - Can your Warehouse Management System Interface orders from the Authority and provide information to the Authority’s system on Order status, Delivery information, Stock levels?**

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1. **Please provide an indication of mobilisation/implementation timescales or range of timescales (including recruitment considerations etc) regarding the transition required to move stock and services from an existing incumbent**

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1. **Please provide details of a mobilisation plan regarding the transition required to move stock and services from an existing incumbent and the factors it would take into consideration if you were awarded the contract**

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1. **What is your organisation’s deployment ‘reach’ ie. number of sites currently delivered to, their localities (geographical spread), and how frequently these deliveries are made. What information can your organisation provide on how you plan to increase the deployment reach to meet the Authority’s needs, and timescales associated with this.**

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1. **Would your organisation need to, and be willing to, invest and expand your business to be able to meet the Authority’s needs? If so, what are the implementation timescales associated with this?**

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1. **What is the minimum length of contract term that would make the tender attractive to your organisation?**

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1. **At further competition stage UKHSA aims to provide a reasonably comprehensive data set regarding requirements. Aside from this, what additional information would you expect to be made available as part of the tendering activity?**

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1. **Are there any observations or feedback, based on the scope and information contained within the brief that you would like to advise on?**

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UKHSA appreciates you taking the time to review this Capability Assessment.

**Upon completion, can you please return the form to** **Logisticsandto@ukhsa.gov.uk** **by 3:00 pm on Thursday 28th September**