

**ITT SCHEDULE 8**

**SPECIFICATION**

**[NOTE TO TENDERERS: This Specification will form part of the Framework Agreement and should be interpreted in accordance with the definitions therein]**

# **Introduction**

## DHSC has appointed the Supplier to store and/or distribute a range of DHSC-owned goods which may include pharmaceutical products, vaccines, repackaged and relabelled products, medical devices, consumables, reagents and medical equipment (the “**Goods**”).

## The Supplier will receive the Goods from DHSC, or from a third-party supplier or manufacturer on behalf of DHSC, and store and/or distribute the Goods to third parties which may be third-party suppliers to DHSC or directly to DHSC’s customers (the “**End-Users**”) on receipt of an End-User Order as further described in this Specification.

## The Services are divided into the following six (6) main lots:

### Lot 1: Pharmaceutical – Primary Care (general practice, pharmacy, dentists, opticians and care homes);

### Lot 2: Pharmaceutical – Secondary Care (including NHS trusts, healthcare providers as part of hospital outreach, Children and Adolescent Mental Health Services);

### Lot 3: National Vaccine Programme Products;

### Lot 4: High Consequence Infectious Disease (HCID) Vaccine Distribution;

### Lot 5: Repacked and Relabelled Products; and

### Lot 6: Medical Devices, Consumables, Reagents and Equipment.

## Each main lot is sub-divided into two sub-lots – sub-Lot (A) will comprise national Framework Suppliers and sub-Lot (B) will comprise regional Framework Suppliers.

## The specific requirements for each main lot are set out further below in this Specification. The Supplier is appointed to sub-lot(s) [insert on framework agreement award] [for the delivery of the Services in the following regions: xxxx] and only the requirements of those sub-lots will apply to the Supplier.

## This Specification will be interpreted in accordance with Joint Schedule 1 (Definitions) of the Framework Agreement and the Glossary set out in the Annex to this Specification.

# **Statement of Requirements for the Goods**

## DHSC purchases and stockpiles Goods in response to anticipated shortages (both imminent shortages and potential long-term shortages further to DHSC’s risk-mitigation strategy). DHSC identifies potential shortages through a number of routes including from intelligence gained from NHS sources (including NHS England’s Allocation and Distribution Group (the “**ADG**”) in respect of pharmaceutical shortages and shortages in secondary-care) or via its supply chain risk identification processes. Where there is a requirement for Framework Suppliers to store these Goods and/or Goods are required by End-Users, DHSC will issue a Statement of Requirements. The Statement of Requirements may be for Services in England only or may include any or all of Northern Ireland, Wales or Scotland (together the “**Devolved Administrations**”) and will specify any specific requirements as necessary.

## DHSC purchases the Goods directly from the manufacturer and may either ask the manufacturer to deliver the Goods directly to the Supplier or will deliver the Goods itself. Exceptionally, DHSC will receive the Goods directly from the manufacturer and the Supplier will be asked to collect the Goods from identified DHSC warehouses. Where this is the case, DHSC will set this out in the Statement of Requirements.

## When a Supplier accepts a Statement of Requirements and enters into a Call-Off Contract, it will confirm to DHSC, or a third party nominated by DHSC, that it has received the relevant Goods in its possession.

## Where a Supplier is required to deliver Goods to End-Users, End-Users will be notified (by DHSC or a third party such as the ADG) that the Supplier holds the Goods. An End-User can then place an End-User Order with the Supplier in respect of those Goods.

## Where a Supplier is instead required to deliver the Goods to a third-party supplier, the arrangements for this will be set out in the Statement of Requirements.

# **Services**

## DHSC will describe the specific Services required in a Statement of Requirements. Those Services may include one or more of the following:

Long-term storage

## The Supplier may be required to hold Goods in long-term storage prior to an End-User Order (whether that End-User Order is received by a Supplier or a third-party supplier). The Supplier may be required to hold larger consignments for a longer term than under a short-term storage and distribution arrangement as described in paragraph 3.3, the specifics of the longer-term storage arrangements being set out in the Statement of Requirements. The Supplier may be required to deliver the Goods to a third-party supplier, including another Framework Supplier, for delivery to the End-User or may be required to deliver the Goods directly to the End-User. In the case of the latter, the provisions below (Short-term storage and distribution) will apply.

Short-term storage and distribution

## The Supplier may be required to hold Goods in short-term storage and deliver the Goods to an End-User on receipt of an End-User Order. The Supplier will need to ensure that it can meet End-User coverage, register new End-Users and prepare its inventory management system for new Goods prior to receiving the first End-User Order. DHSC may, from time to time, notify the Supplier that it must temporarily cease accepting any End-User Orders for particular Goods in the case of excessive demand and/or where there are potential supply shortages. DHSC will inform the Supplier if this is the case and the Supplier will store the Goods until further notice from DHSC.

## The Supplier must provide a secure and user-friendly ordering system for End-Users which, as a minimum, is only accessible by authorised Supplier Staff via a secure company email address log-in and which complies with the provisions of Framework Schedule 9 (Cyber Essentials Framework), Framework Schedule 10 (Business Continuity and Disaster Recovery) and Joint Schedule 10 (Processing Data). If orders are made by telephone, they must be followed-up and confirmed via email by the Supplier.

## On receipt of an End-User Order, the Supplier must deliver the Goods to the address specified by the End-User within the period set out in the Order Form and/or End-User Order.

Collecting End-User Payments

## The actual supply of Goods and the transfer of ownership in those Goods is between DHSC and End-Users and sits outside the Framework Agreement and any Call-Off Contract. However, while title to the Goods remains with DHSC until receipt by the End-User, DHSC may require the Supplier to act as an agent for DHSC, collecting payments from End-Users in a primary care setting on behalf of DHSC on receipt of the Goods (“**End-User Payment**”).

## In this instance, the Supplier will issue an invoice to the End-User for the End-User Payment, previously agreed between DHSC and the End-User, on behalf of DHSC. The Supplier shall ensure that payment terms require End-Users to pay such invoices within a maximum of thirty (30) days from the date of invoice. The Supplier shall use reasonable endeavours to collect the End-User Payment, using all endeavours that it would to collect debt from its own customers. In the event that such End-User Payment has not been collected within sixty (60) days from the date of invoice, DHSC will relieve the Supplier of its obligation and will collect the End-User Payment directly.

## The Supplier must reimburse DHSC in respect of any End-User Payments in aggregate at the end of each calendar month and the details of this will be more specifically set out in an Order Form.

## If the Supplier is required to provide this Service, DHSC will indicate this in the Statement of Requirements.

Delivery to Devolved Administrations

## The Supplier shall ensure that it has any necessary additional licences and export requirements in place prior to delivering to the Devolved Administrations. A Supplier may be required to either deliver directly to a Devolved Administration’s Government, a designated location specified by the Devolved Administration’s Government and/or directly to End-Users within the territory of that Devolved Administration.

## Where a Supplier is unable to deliver the Goods directly to End-Users in the Devolved Administrations because it does not have, for example, the appropriate licences or distribution partners etc. in place, the Supplier shall notify DHSC and DHSC will put in place arrangements outside of the Framework Agreement to ensure that those Goods are delivered to End-Users and the Supplier shall provide all reasonable assistance to DHSC or a supplier nominated by DHSC to ensure a seamless operation and delivery to End-Users in the Devolved Administration.

# **Storage and Distribution**

## The Supplier must at all times handle, control, store and distribute Medicinal Products in accordance with Good Distribution Practice. This will include (but is not limited to) ensuring that records:

### are kept either in the form of purchase/sales invoices, delivery slips, or on computers or any other form, for any transaction in Medicinal Products received, supplied or brokered;

### include at least the following information: date; name of the Medicinal Product; quantity received, supplied or brokered; name and address of the Supplier, End-User, broker or consignee, as appropriate; and batch number for Medicinal Products bearing the safety features; and

### are made available to the End-User and DHSC on request.

## For all Goods, excluding medical devices in Lot 6, DHSC will put in place a separate Quality Technical Agreement which will be annexed to the Statement of Requirements and will explain the roles of DHSC and the Supplier in terms of complying with Good Distribution Practice as well as setting out the process for stock rotation and shelf-life, for which the standard position will be FEFO for shelf life Goods, or FIFO for Goods that don’t have a shelf life e.g. equipment.

## For all lots, the Supplier’s storage facilities should be sufficient to allow the Goods to be stored and managed in accordance with Good Distribution Practice or equivalent including dedicated receipting and quality assurance spaces, separation of inbound and outbound Goods and adequate ventilation around pallets/packs to avoid temperature hot/cold spots. Facilities should have access controls and temperature/humidity controls suitable for the Goods being stored there, as well as cleaning and infestation control arrangements as approved by Good Distribution Practice.

## The Supplier acknowledges that risk and responsibility in the Goods stays with the Supplier until delivery at the End-User’s designated premises or, in respect of the provision of long-term storage, until delivery at a third-party supplier’s premises.

## The Supplier must have robust audit systems in place to ensure that the Goods are stored and treated separately to the Supplier’s own stock and must be able to provide evidence of this to DHSC within three (3) Working Days of receipt of prior written notice.

# **Delivering and Turnaround Times**

## The Supplier shall meet the range of timescales specified by DHSC in the Statement of Requirements which may include, but are not limited to: pick and despatch times, processing times and delivery and collection times. Although the exact timescales will be set out in the relevant Order Form, for Lots 1 to 5, the delivery time is likely to be next day to End-Users (Pharmacies or Hospitals) if an End-User Order is placed before a specified cut-off time. Longer time-frames (for example day 1 for day 3, or possibly longer) may be permitted for bulk movements (pallet size and above) such as between Framework Suppliers or to a third-party supplier.

## In times of urgent clinical need or exceptional circumstances (e.g. when a failure to deliver Goods would be life-threatening to a patient) a Statement of Requirement may require the Supplier to make deliveries outside of the Supplier’s core delivery hours and delivery timescales. This could, for example, involve the need to engage a courier to deliver within a matter of hours. Except for Lot 4, this will always be by exception and will not be business-as-usual and DHSC does not expect this to always be within capability of the Supplier. In the case of Lot 4, this will still be by exception but DHSC expects that the Supplier will have provisions in place for such deliveries 24/7 if required. In either case, any reasonable additional Costs incurred by the Supplier as a result of deliveries made outside of the core hours will fall to DHSC to pay in addition to the agreed Charges.

## The specific delivery times and turnaround times will be specified in each Statement of Requirement and/or Order Form and/or End-User Order.

# **Supplier Staff**

## The Supplier shall ensure that all Supplier Staff possess the qualifications, experience and competence for the tasks for which they are employed or engaged.

## The Supplier shall ensure that the appropriate number of resources with relevant experience and skills are allocated to each Call-Off Contract and this shall be reviewed and managed throughout the duration of the Call-Off Contract in order to ensure DHSC’s and each End-User’s requirements and timescales are met.

## The Supplier shall ensure that all Supplier Staff comply with security controls, procedures and policies as specified by DHSC and any specific End-User policies.

# **Lot-Specific Requirements**

# **Lot 1: Pharmaceuticals – Primary Care**

## The Supplier will store and/or distribute Medicinal Products to End-Users in primary care including general practice, pharmacy, dentists, opticians and care homes.

## The Supplier will store and/or distribute solid or liquid dose forms of Medicinal Products, which may include large volume parenteral fluids, as well as the following:

### GSL Medicines;

### POMs;

### P Medicines;

### Investigational Medicinal Products (IMP); and

### Schedules 2, 3, 4 Controlled Drugs.

## The Goods must be stored as appropriate using the following temperature guide or as otherwise described in any Medicinal Product’s Summary of the Product Characteristics:

### Ambient temperature between 8°c and less than 25°c;

### Refrigerated temperature between 2°c and 8°c; and

### Freezer less than 0°c.

## The Supplier will hold the following licences/certification:

### Wholesale Dealer’s Licence specifying all premises used for the distribution of Medicinal Products under this Lot 1;

### Home Office Controlled Drugs licence; and

### Good Distribution Practice (GDP) certification.

# **Lot 2: Pharmaceuticals – Secondary Care**

## The Supplier will store and/or distribute Medicinal Products to End-Users in secondary care including NHS Trusts, NHS Foundation Trusts, hospital outreach (healthcare organisations, not patients) and Children and Adolescent Mental Health Services (CAMHS).

## The Supplier will store and/or distribute solid or liquid dose forms of Medicinal Products, which may include large volume parenteral fluids, as well as the following:

### GSL Medicines;

### POMs;

### P Medicines;

### Investigational Medicinal Products; and

### Schedules 2, 3, 4 Controlled Drugs.

## The Goods must be stored as appropriate using the following temperature guide or as otherwise described in any Medicinal Product’s Summary of the Product Characteristics:

### Ambient temperature between 8°c and less than 25°c;

### Refrigerated temperature between 2°c and 8°c; and

### Freezer less than 0°c.

## The Supplier will hold the following licences/certification:

### Wholesale Dealer’s Licence specifying all premises used for the distribution of Medicinal Products under this Lot 2;

### Home Office Controlled Drugs licence; and

### Good Distribution Practice (GDP) certification.

# **Lot 3 - National Vaccine Programme Products**

## The Supplier will store and/or distribute single pack and bulk orders to NHS vaccination centres (which may be in a community, primary or secondary care setting or in a pharmacy), hospitals, GP surgeries and United Kingdom Health Security Agency (UKHSA) teams.

## The Supplier will store and/or distribute small volume, individually packed presentations.

## The Supplier will distribute and supply Vaccines:

### which are Authorised Medicinal Products;

### which are Investigational Medicinal Products;

### which have been authorised for sale or supply by the MHRA pursuant to Regulation 174 of the HMR; and

### which can otherwise be lawfully sold or supplied.

## The Goods must be stored as appropriate using the following temperature guide or as otherwise described in any Medicinal Product’s Summary of the Product Characteristics:

## 

### Ambient temperature controlled between 8°c and less than 25°c;

### Refrigerated temperature between 2°c and 8°c; and

### Freezer down to -80°c.

## The Supplier will hold the following licences/certification:

### Wholesale Dealer’s Licence;

### Home Office Controlled Drugs; and

### Good Distribution Practice (GDP) certification.

# **Lot 4 - High Consequence Infectious Disease (HCID) Vaccine Distribution**

## The Supplier will be able to store and/or distribute small volume, individually packed injectable presentations of Vaccines. The Supplier will deliver single pack and bulk orders to NHS vaccination centres (which may be in a community, primary or secondary care setting or in a pharmacy), GP surgeries and United Kingdom Health Security Agency (UKHSA) teams.

## The Supplier will store and/or distribute medicines that are classed as POMs or Investigational Medicinal Products.

## The Goods must be stored as appropriate using the following temperature guide or as otherwise described in any Medicinal Product’s Summary of the Product Characteristics:

### Ambient temperature controlled between 8°c and less than 25°c;

### Refrigerated temperature between 2°c and 8°c; and

### Freezer down to -80°c.

## The Supplier will hold the following licences/certification:

### Wholesale Dealer’s Licence; and

### Good Distribution Practice (GDP) certification.

# **Lot 5 – Repacked and Relabelled Products**

## The Supplier will store and/or distribute oral, liquid or injectable presentations of Medicinal Products that have been repackaged and relabelled by third parties.

# **Lot 6 – Medical Devices, Consumables, Reagents and Equipment**

## The Supplier will distribute Medical Devices including electrical, non-electrical, plastics, chemical substances, small and large equipment, potentially bulky items, accessories, consumables and reagents.

## The Supplier will hold the following relevant certification:

### International Standards Organisation certification (ISO9000 for warehousing and ISO 9001 for provision of customer-focused activity(or equivalent)); and

### Control of Substances Hazardous to Health (COSHH).

## The Supplier will comply with the international regulations on the transportation of dangerous goods by air, sea, road, rail or inland waterway - <https://www.gov.uk/guidance/moving-dangerous-goods>

## The Supplier will be able to distribute single pack and bulk orders to NHS centres; for example but not limited to; Hospitals, GP surgeries, UKHSA teams.

**Annex: Glossary**

**2001 Directive**means Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use

**Authorised Medicinal Product** means a Medicinal Product covered by a UK Marketing Authorisation, an EU Marketing Authorisation, a Certificate of Registration, a Traditional Herbal Registration or, in the case of a Medicinal Product for sale or supply in Northern Ireland, an Article 126a Authorisation

**Certificate of Registration** means a certificate of registration granted by the MHRA under Part 6 of the HMR

**Clinical Trial Regulations** means the Medicines for Human Use (Clinical Trials) Regulations 2004

**Controlled Drug** has the meaning given to it in s.2 Misuse of Drugs Act 1971 and a reference to a schedule in respect of a Controlled Drug means the relevant schedule of the Misuse of Drugs Regulations 2001

**EU Marketing Authorisation**  means a Marketing Authorisation granted or renewed by the European Commission under Regulation (EC) No 726/2004

**FEFO** first-expiry-first-out

**FIFO** first-in-first-out

**Good Distribution Practice** principles and guidelines of good distribution practice published under, or that apply by virtue of, Regulation C17(1)(c) of the HMR

**GSL Medicine** means a Medicinal Product Subject to General Sale

**HMR** the Human Medicines Regulations 2012 (S.I. 2012/1916)

**Investigational Medicinal Product** has the meaning given to it in the Clinical Trials Regulations

**Medical Device** has the meaning given in Regulation 2 of the Medical Devices Regulations 2022

**Medicinal Product** has the meaning given to it in the HMR[[1]](#footnote-1)

**Medicinal Product Subject to General Sale** has the meaning given to it in the HMR[[2]](#footnote-2)

**MHRA** means the Medicines and Healthcare Products Regulatory Agency

**Pharmacy Medicine** has the meaning given to it in the HMR[[3]](#footnote-3)

**P Medicine** means a Pharmacy Medicine

**POM** means a Prescription Only Medicine

**Prescription Only Medicine** has the meaning given to it in the HMR[[4]](#footnote-4)

**Summary of the Product Characteristics** has the meaning given to it in the HMR[[5]](#footnote-5)

**Traditional Herbal Registration** means a traditional herbal registration granted by the MHRA under the HMR

**UK Marketing Authorisation** means a Marketing Authorisation granted by the MHRA under Part 5 of the HMR or Chapter 4 of Title III to the 2001 Directive

**Vaccine** means an antigenic substance which consists wholly or partly of –

(a) any micro-organisms, viruses or other organisms in any state;

(b) any toxins or microbial origin which have been detoxified (toxoids);

(c) any extracts or derivatives of any micro-organisms or of any viruses, being substances which, when administered to human beings, are used for the prevention of specific diseases;

**Wholesale Dealer’s Licence** has the meaning given to it in Regulation 18(1) of the HMR

1. Regulation 2 [↑](#footnote-ref-1)
2. Regulation 5(1) [↑](#footnote-ref-2)
3. Regulation 5(5) [↑](#footnote-ref-3)
4. Regulation 5(3) [↑](#footnote-ref-4)
5. Regulation 8 [↑](#footnote-ref-5)