# Document no.4

**Invitation to Offer for the Supply, Storage, and Management of Intravenous Fluids**

**Offer reference number: CM/EMI/22/C103602**

**Period of Agreement: 28th July 2023 to 27th July 2025**

**Specification**

1. Background
   1. The Authority’s intention in carrying out this procurement exercise is to enter into a Contract(s) for the supply, storage, and management of the Goods as a Stockpile by the Supplier, with the Supplier being responsible for rotating the stock so that the Goods in the Stockpile have a minimum agreed Shelf Life of 18 months throughout the Term. The purpose of the Stockpile is to have the Goods that are routinely used in the NHS available for release into the UK supply chain in the event of an Emergency. The Goods procured will be used in the NHS including within the devolved administrations of Scotland, Wales and Northern Ireland. As ownership of the Stockpiled Goods lies with the Authority, and the Storage Facilities will be listed on the Authority’s Wholesale Distribution Authorisation, the Authority requires that all Storage Facilities will be located within Great Britain.
   2. From the Commencement Date, the Supplier shall be required to build up the Stockpile for each Good listed in Table A to the Quantity Required.
   3. In the period leading up to expiry of the Contract, the Supplier shall be required, through an agreed Exit Plan, to buy back the Stockpiled Goods. Title to the Stockpiled Goods (prior to any buy back) will remain with the Authority, but the Supplier must store the Stockpiled Goods at their own risk and manage it, to include regular reporting and review meetings with the Authority.
2. Licensing Requirements
   1. The Goods must be Licensed for use in the United Kingdom (Great Britain and Northern Ireland).
   2. The Supplier must have at all times, the requisite Wholesale Distribution Authorisation (H) licence and/or a MIA licence, sufficient for the supply of the Goods and Storage Services in accordance with the terms of the Contract.
3. Packaging and Labelling
   1. The pack design must comply with the principles of the “MHRA Best Practice Guidance on Labelling and Packaging”[[1]](#footnote-2) and the “National Patient Safety Agency Guidelines on Packaging and Labelling”[[2]](#footnote-3).
   2. The name of the medicine expressed on the packaging must be the same as that which is registered in the Summary of Product Characteristics approved by the MHRA. This will be the brand name for a proprietary product, but the generic name must also be clearly expressed. Abbreviations must not be used.
   3. All critical information must be present, namely:

* the generic name of the medicine;
* the strength of the medicine;
* the form of the medicine;
* the route of administration;
* posology; and
* warnings.
  1. All packs must include a Patient Information Leaflet in English Language in the form approved by the MHRA. The Patient Information Leaflet must comply with current regulatory requirements.
  2. The batch number and expiry date must be clearly present and easily legible. Where embossing is used for this purpose then the batch number and expiry date must be clearly discernible under normal reading conditions. The expiry date must be unambiguously expressed.
  3. Temperature storage conditions must be clearly stated on both the primary and secondary packaging.
  4. Outer boxes must be robust and provide adequate protection to the inner Good containers.
  5. **Shelf** **Life**
  6. There must be a minimum of 18 months’ Shelf Life remaining on the Goods in the Stockpile at all times.
  7. **Delivery** **and Storage**
  8. The Supplier will be required to transport the Goods from the manufacturer’s(s’) site(s), and deliver them to the Storage Facilities. The Supplier shall also be required to provide details of location(s) where the Goods are to be stored. Such details will include:

Name of storage location

Address of storage location

Wholesale Distribution Authorisation (H) number

Wholesale Distribution Authorisation (H) date

WDA(H) Licence Number - Site number (this number is of the facility where the Goods will be stored)

Name of the Supplier’s Responsible Person (this should be filled in even if contracting to a third-party storage location)

Name of Responsible Person within the proposed storage location (if different from above i.e. the stock is being held at a third-party location)

Name of medicine being supplied and confirmation that the medicine shall be stored at the storage location in ambient storage conditions

* 1. Except in the case of an Authorised Release, the Supplier shall ensure that it maintains the Quantity Required of the Stockpiled Goods.
  2. The Authority is permitted by the Supplier to visit the Supplier’s Storage Facilities for any inspection at agreed scheduled intervals.
  3. **Authority Responsibilities**
  4. The Authority will appoint a Contract Manager to manage the relationship with the Supplier under the Contract.
  5. **Supplier Responsibilities**
  6. The Supplier shall appoint a Contract Manager to oversee the work and liaise with/report to the Authority’s Contract Manager.
  7. **Reporting and Contract Management**
  8. Contract review meetings between the Supplier and Authority will take place at least once every six months and at such other times as reasonably requested by the Authority from time to time.
  9. Any reports required for the purposes of performing or managing this Contract shall be provided to the Authority by the Supplier in accordance with the Contract or at intervals agreed with the Supplier in writing from time to time.
  10. Further instructions and obligations on the Supplier are set out in Schedule 2 (General Terms and Conditions) of the Conditions of Contract.

Table A

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | 1. Volume per Authority's pack\*1 size (E) | |
| 1. Lot | 1. Medicine | 1. Presentation | 1. Units | 1. Quantity Required (Units) |
| 1. Lot 1 | 1. Sodium Lactate | 1. Compound Sodium lactate 1 litre iv infusion | 1. Single bag of fluid | 1. 1,856,463 |
| 1. Lot 2 | 1. Sodium Lactate | 1. Compound Sodium lactate 500ml iv infusion | 1. Single bag of fluid | 1. 339,303 |
| 1. Lot 3 | 1. Glucose | 1. Glucose/Sodium chloride 4%/0.18% 1 litre iv infusion | 1. Single bag of fluid | 1. 79,697 |
| 1. Lot 4 | 1. Glucose | 1. Glucose/Sodium chloride 5%/0.45% 500ml iv infusion | 1. Single bag of fluid | 1. 26,278 |
| 1. Lot 5 | 1. Glucose | 1. Glucose 5% / Sodium chloride 0.9% 500ml iv infusion | 1. Single bag of fluid | 1. 52,986 |
| 1. Lot 6 | 1. Glucose | 1. Glucose 10% - 500ml iv infusion | 1. Single bag of fluid | 1. 117,245 |
| 1. Lot 7 | 1. Glucose | 1. Glucose 50% - 500ml iv infusion | 1. Single bag of fluid | 1. 10,592 |
| 1. Lot 8 | 1. Glucose | 1. Glucose 5% - 1 litre iv infusion | 1. Single bag of fluid | 1. 137,458 |
| 1. Lot 9 | 1. Glucose | 1. Glucose 5% - 500ml iv infusion | 1. Single bag of fluid | 1. 123,058 |
| 1. Lot 10 | 1. Glucose | 1. Glucose 5% - 100ml iv infusion | 1. Single bag of fluid | 1. 357,350 |
| 1. Lot 11 | 1. Sodium Chloride | 1. Sodium Chloride 0.9% - 1 litre iv infusion | 1. Single bag of fluid | 1. 1,962,323 |

1. Available online at < <https://www.gov.uk/government/publications/best-practice-in-the-labelling-and-packaging-of-medicines> [↑](#footnote-ref-2)
2. Available online at <https://www.gov.uk/guidance/medicines-packaging-labelling-and-patient-information-leaflets> [↑](#footnote-ref-3)