 

**Component 1**

Specification

For

Unlicensed Imported Medicines Service and Products

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**1. INSTRUCTIONS**

* 1. This specification comprises of the following:

• Description of Service

• Specification for Technical & Quality

• Specification for Social Value Model

• Appendix 1 Abbreviations

• Appendix 2 Definitions

* 1. This document should be read and completed in conjunction with Document 6 Award Criteria Methodology which includes the Assessment Methodology that the Authority will be using to assess the Suppliers (Offerors) responses.

Further responses are required in Document 8 Specification Tender Response (Component 2)

* 1. This document covers all specification points which are mandated, adjudicated, compliance and for information. Where the point states “Mandated”, “Adjudicated” or “Compliance” a response is required in Document 8 Specification Tender Response (Component 2).
  2. Please note that some adjudication questions require a supporting statement from your Head of Quality (or equivalent). Such statements must be provided as a signed and dated, headed document following the naming protocol as outlined in the instructions for Document 8 Specification Tender Response (Component 2).
  3. Where supporting information is to be provided, please ensure the correct naming protocol is followed. The document provided must have the applicable text highlighted or referenced within the appropriate cell to answer the specification point. Please do not submit documents that do not directly answer the specification point.
  4. Questions are to be answered in English, do not insert logos or other corporate identifiers into the response template as this can destabilise the documents.

Suppliers (Offerors) must provide the required documentary evidence and supporting information e.g. Statements, SOPs, and Policies to allow for a full evaluation against the Award Criteria Methodology. If you are using Sub-Contractor(s) please ensure a fully completed in the Document 8 Specification Tender Response (Component 2) Tab 1 & 2 where applicable.

* 1. Suppliers (Offerors) shall comply with all points in this section to meet the requirements outlined below. Should any documentation be missing, or any clarifications be required, in the first instance advise via the question section on the Atamis e-tendering system <https://health-family.force.com/s/Welcome> .

Tender clarification questions should be submitted by no later than the **7th March 2025**

1. **DESCRIPTION OF SERVICE**
   1. The Supplier (Offeror) will provide an Unlicensed Imported Medicines Service incorporating over labelling of product and translation of documents and labels relevant to services offered. This will involve the supply of approved unlicensed imported medicines awarded to the framework.
   2. The Supplier (Offeror) will be awarded to this Unlicensed Imported Medicines framework agreement for a period of 3 years with the option of a 12-month extension following the process set out in Document 6 Award Criteria Methodology.
   3. Suppliers (Offerors) will be invited to take part in further calls for competition ‘mini competitions’ for specific awarded products. Further calls for competition for adhoc additional products will be defined within the specific Mini Competition documentation. Medicines will include, but are not limited to, standard packs of tablets and capsules, injectable products, oral suspension / solution, topical preparation, eye/ear/nose drops, antibiotics, cytotoxic chemotherapy. Etc.
   4. The Supplier (Offeror) must hold relevant licence(s) and be able to provide proof of MHRA non-objection for the importation of each tendered product.
   5. The Supplier (Offeror) must work with the Participating Authority (PA) towards electronic transmission of ordering and invoicing information through e-procurement technologies.
   6. The Supplier (Offeror) will inform the Authority, in writing of any proposed change to: products, prices, unavailability of product, changes to service or changes which affect any specification points within Document 8 Specification Tender Response (Component 1) and/or Document 8 Specification Tender Response (Component 2) and/or information provided in Document 6b Product Specification Response Form B.
   7. Notification of any proposed changes shall ideally be made three months prior to the implementation date of proposed changes. However it is understood that this level of notification is not always possible in which case notice must be made as far in advance as is reasonably possible.
   8. All changes must be approved by the Authority, on behalf of Participating Authority's before implementation following the change control process. Please refer to the agreed change control process as set out in Document 9a Contract Management.
   9. If the Supplier makes the decision to bring a sub-contracting service back in house, then it is also the Supplier’s responsibility to inform the Authority of this change. The Supplier will give adequate prior notification to the Authority before any changes to sub-contracting arrangements affecting the Service.
   10. Approved products supplied against purchase orders must continue to meet the requirements of the specification and have an appropriate product authorisation e. g. Marketing Authorisation (MA) in country of origin.
   11. The Supplier will not substitute any product ordered (including pack size) unless agreed by the Participating Authority (PA) and the Authority using the agreed change control process set out in Document 9a Contract Management.
   12. Products delivered must have a reasonable proportion of the shelf life left remaining. The term “reasonable” may be interpreted to mean that at least 50% of licensed shelf life is still valid.
   13. If a short shelf-life product is delivered to a Participating Authority (PA) without prior authorisation, the Supplier will place no restrictions on return of these products, if deemed unacceptable by the Participating Authority. Product(s) must be returned using the supplier’s return process.
   14. The Supplier must have a returns policy which, as a minimum, complies with the current guidelines on Good Distribution Practice (cGDP) of medicinal products for human use.
   15. The Supplier (Offeror) will take an active part in the management and distribution of stock in critical shortage situations and work collaboratively with the NHS, the Department of Health, and Social Care (DHSC), the Medicines Procurement and Supply Chain (MPSC), manufacturers and other wholesalers to manage supply or the re-introduction of product into the supply chain in a safe and effective manner.
   16. The Participating Authority (PA) reserves the right to return or reject goods, which, upon inspection after delivery, are found to be in an unusable or unacceptable condition and will be withdrawn and uplifted by the Supplier at the Suppliers' own expense in compliance with Good Distribution Practice (cGDP).
   17. In the event of a product recall the Supplier (Offeror) shall inform the Participating Authority (PA) in a timely manner. The Supplier shall, at its own expense, arrange for the collection of any products delivered but unused, including part packs. Any affected stock held by the Supplier will be quarantined and prohibited from onward supply.
   18. A customer services helpline will be provided Monday to Friday 09:00hrs - 17.00hrs as a minimum.
   19. Contract management information such as Product supply status must be provided every 2 weeks. Key Performance Indicators, sales data, complaints information must be provided by the 10th working day of the following month to the Authority in the format outlined in Document 9a Contract Management Information i.e.

|  |  |  |
| --- | --- | --- |
| Tab | Description | Requirement Frequency |
| 3 | Product Supply Status | Every 2 weeks  *(Week 1 first week of month and Week 3)* |
| 4 | Management Information (Sales Data) | 10th of the month |
| 5 | Complaints A (Authority) | 10th of the month |
| 5.1 | Complaints PA (Participating Authority) | 10th of the month |
| 6 | KPI Definitions | For information only |
| 7 | KPI Data Sheet | 10th of the month |
| 8 | KPI Report | For information only |

The KPI report Document 9 Contract Management Information (Tab 8) provides a worked example of KPI data. If requested, sales data and contract management information should be made available to individual Participating Authorities (PA). Please also refer to Document 9 Contract Management Information (Tab 2) for information around the contract review meetings.

* 1. Indemnity Insurance certificates to be provided for Suppliers and Sub-contractors where applicable as detailed in the Standard Selection Questionnaire within Atamis and section 7 and 7.1 of the Standard Selection Questionnaire award criteria methodology (Document 10)

As a Minimum: -

* + Employer’s liability insurance £5,000,000
  + Public liability insurance £2,000,000
  + Product liability £2,000,000
  + Professional indemnity insurance £5,000,000

**3. SPECIFICATION (TECHNICAL & QUALITY)**

**Standard Selection Questionnaire:**

Assessment of Standard Selection Questionnaire (SQ): Parts 1, 2 and 3 of the SQ must be completed fully with satisfactory answers.

If any part of this Stage 3 Assessment of Standard Selection Questionnaire is not satisfactory the Suppliers will be removed from the tender and not be awarded onto the framework.

**MANDATED Point (Evaluated & Scored) please provide response in Document 8 Parenteral Nutrition (PN) Tender Response (PART B) Tab 1**

**A: Scope**

**A1** Suppliers (Offerors) will confirm they can supply unlicensed imported medicines that conform with all mandated criteria and can provide copies of the appropriate licenses commensurate with services offered (Specification point C4).

For import from within the European Economic Area (EEA):

* An MHRA licence for the Wholesale Distribution Authorisation (Human) of medicinal products for human use, commonly abbreviated to WDA (H) (to include unlicensed medicines obtained from another EEA member state)

([Apply for manufacturer or wholesaler of medicines licences - GOV.UK (www.gov.uk)](https://www.gov.uk/guidance/apply-for-manufacturer-or-wholesaler-of-medicines-licences)

*i.e., WDA license scope - 2.6 Products imported from countries on a list; 2.6a Products certified under Article 51 of Directive 2001/83/EC*

For import from outside of the EEA:

* An MHRA manufacturer’s “Specials” licence (Human) for the manufacture/importation of unlicensed medicinal products for human use, commonly abbreviated to MS i.e., MS license scope 2.1 - Imported medicinal products; 2.1.1 Unlicensed medicinal products are imported from outside then EEA at this site
* An MHRA licence for the manufacture/importation of licensed medicinal products for human use, commonly abbreviated to MIA

*i.e., MIA license scope - 1.2.1 Non-sterile products (all appropriate dosage forms)*

Suppliers (Offerors) shall provide copies of ALL licenses relevant to services offered, please detail the site name, address, and license number against this point (Document 8 Tender Response Component 2, Tab 1) and submit a copy of the license in specification point **C6** (Document 8 Tender Response Component 2 Tab 1).

Where you are utilising multiple sites complete specification point C4 (Document 8 Component 2, Tab 2).

**MANDATED Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**A2** Where service offers over-labelling of imported medicines, additional licensing further to those requested in A1, with appropriate additional permissions, is **mandatory**.

Where service is not offered, select option N/A.

Required if over-labelling service offered:

* An MHRA 'specials' licence for the manufacture/importation of unlicensed medicinal products for human use, commonly abbreviated to MS, with specific permission for over-labelling

*i.e., MS license scope - 1.5 Packaging; 1.5.2 Secondary packaging*

Supplier(s) (Offerors) shall provide copies of ALL licenses relevant to services offered, please detail the site name, address and license number against this point (Document 8 -Tender Response Component 2, Tab 1) and submit a copy of the license in specification point C4 (Document 8 - Component 2, Tab 1).

Where you are utilising multiple sites complete specification point C4 (Document 8 - Component 2, Tab 2).

**MANDATED Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable. Note: N/A can only be selected if over labelling service is NOT offered.**

**A3** All tendered products must be licensed for use as a medicinal product in a “Trusted Country”.

Under the scope of this tender a medicinal product is as defined in MHRA Guidance Note No. 8 ‘A guide to what is a medicinal product’.

<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/872742/GN8_FINAL_10_03_2020__combined_.pdf>

Trusted Countries are:

a) EU-EEA countries:

<https://www.ema.europa.eu/en/medicines/national-registers-authorised-medicines>

b) Countries holding fully operational Mutual Recognition Agreements (MRAs) namely, Australia, New Zealand, and Switzerland.

<https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/mutual-recognition-agreements-mra>

c) Countries holding MRAs with limitations and exclusions namely, Canada, Japan, Israel and United States of America, see link below for details on constraints of cover and therefore for types of medicines not within the scope of this tender:

<https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/mutual-recognition-agreements-mra>

d) Unlicensed medicines made under specials manufacturing licence, medical devices, food supplements and imported medicines **NOT** licensed in one of the countries listed above (point a, b, c) are outside the scope of this tender**.**

**MANDATED Point (Evaluated & Scored) please provide a response in Document 8 Specification Response (Component 2) Tab 1**

**A4** Document 7 NEYPPC Member & Eligible Participating Organisations lists the Participating Authorities with access to the framework pricing. Please note: - Deliveries will be made to Participating Authorities or Stores and not directly to patients. Details of annual historic contract product volumes are provided within the offer documentation although please note that these volumes are indicative and are not guaranteed or a prediction of uptake.

Estimated quantities shall indicate only the probable requirements and the Authority shall not be bound by these figures (unless otherwise agreed). This may differ from future usage as forecasting methods have not been used. Supplier(s) (Offerors) are requested to base their prices on these indicative volumes.

It is envisaged that Participating Authorities will join the agreement on a phased basis. This phasing programme will be agreed between the supplier and the Participating Authority directly.

Participating Authorities must provide the supplier (Offeror) with three months’ notice unless a shorter timeframe is agreed in writing.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in** **Document 8 Specification Tender Response (Component 2) Tab 1**

**B: Capacity and Contingency**

**B1** Supplier(s) (Offerors) must provide details of their Contingency / Business Continuity arrangements, and most recent test results in accordance with NHS Terms and Conditions Schedule 2 (Point 6). This must include details of their contingency arrangements for managing an unexpected interruption to one or more of their warehousing and/or distribution sites, or logistics partner.

The Supplier(s) (Offerors) shall test its Business Continuity Plan at reasonable intervals, at least once every twelve (12) months and provide a summary of the results to The Authority.

Supplier(s) (Offerors) must provide their Contingency / Business Continuity plan and most recent test results including details of all contingency partners that will be used or potentially used under this agreement. Detail is to be provided and relevant document(s) attached using the naming protocol.

If Supplier (Offeror) has ISO 22301 accreditation a copy of their valid certificate must be provided.

Please include details of all contingency partners that will be used or potentially used under this agreement. Detail is to be provided and relevant document(s) attached using the naming protocol

**ADJUDICATED Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**B2** Supplier(s) (Offerors) are required to provide detail of the number and location of any warehouses, over-labelling units, office premises, or distribution centres currently being constructed or planned. Details should also be included of the anticipated capacity of these facilities, the planned date of completion for the site, and the anticipated commencement of services at these location(s).

**For Information only (Not Evaluated & Not Scored)**

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| **Please provide a response below** |
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**C: Warehousing, Processing, Distribution, and Quality Culture**

**C1** Suppliers (Offerors) are required to provide a statement supported by appropriate SOPs to describe the supply chain for the distribution of unlicensed imported medicines, (from procurement thereof to delivery to Participating Authority premises).

Statement should include:

* Interrelationships between the contractor and any transport and distribution partners should also be included in the description
* A brief statement describing the stock control/management system
* A list of provided supporting SOP(s) evidencing that good stock management and control is delivered e.g., Goods Receipt / Goods Return / Non return policies.

Please provide a statement describing the supply chain. Where SOPs provided are referenced, please highlight reference point(s) in the statement.

**ADJUDICATED Point (Evaluated & Scored) please provide a response in Document 8 Document 8 Specification Tender Response (Component 2) Tab 1**

**C2** Suppliers (Offerors) must provide a list detailing the names and addresses of all subcontractors, examples of which are, but not limited to:

* warehousing subcontractors
* distribution and logistics subcontractors
* contingency partners
* overlabelling / translatory services

that will be used or potentially used under this framework agreement. Where a supplier does not subcontract for any aspect of the service, please select the ‘Not Applicable’ option in document 8 component 2.

**MANDATED Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**C3** Where elements of the supply chain are sub-contracted, Quality/Technical Agreements must be in place between the contractor and all sub-suppliers or contingency partners.

Suppliers (Offerors) and Sub-Contractors to be used under this agreement must have an established and robust Quality Management System (QMS) in place. The QMS must be able to demonstrate that procedures are in place to ensure that all imports are of appropriate quality with a robust temperature control throughout the supply chain and delivery process.

Suppliers must provide a copy of the Quality/Technical Agreement between all relevant parties and their supplier/sub-contractor approval policy following the naming protocol.

Where a supplier does not subcontract for any aspect of the service, please select the ‘Not Applicable’ option in document 8 component 2.

**ADJUDICATED Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**C4** Provide the name, address, Wholesale Distribution Authorisation Human (WDA H) and/or MIA and/or MS licence number of the licence holder(s) as applicable and if required.

Suppliers (Offerors) shall provide a copy of their Wholesale Distribution Authorisation - Human (WDA H) licence where applicable, please detail the site name and WDA(H) license number and where you are utilising multiple sites, and with the relevant scope to provide the tendered products.

Suppliers (Offerors) shall provide a copy of their MIA Importer’s licence with the relevant scope to provide the tendered products - where applicable.

Suppliers (Offerors) shall provide a copy of their MHRA Manufacturer's Specials licence (MS) with the relevant scope to provide the tendered products, including overlabelling where offered - where applicable.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**MANDATED Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C5** Suppliers (Offerors) will state the date of their most recent MHRA inspection(s) pertaining to the site(s) being utilised to supply products offered in this tender.

Suppliers (Offerors) will provide a statement from their Head of Quality (or equivalent) summarising the main findings of their most recent MHRA inspection(s) including:

- critical or major findings

- the overall risk rating and inspection frequency

- details of progress made to correct the identified deficiencies.

Suppliers (Offerors) will also provide the closure letter unless this has not yet been received from the MHRA.

Suppliers (Offerors) will state if the licence holder is currently under the management by the Inspection Action Group (IAG) or Compliance Management Team (CMT) or has been referred to the IAG or CMT and provide evidence of progress having been made to correct the identified deficiencies.

Provide the documentary evidence as attachment(s) for this site following the naming protocol.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C6** From the point of tender submission and during the life of the contract, Suppliers (Offerors) agree to provide the Authority with:

* + - the dates of forthcoming MHRA inspections, as soon as they are known to the Supplier (Offeror)
    - a statement from their Head of Quality (or equivalent) summarising the main findings of any subsequent MHRA inspections
    - details of any critical or major deficiencies
    - details of any referral to IAG or CMT including evidence of progress having been made to correct the identified deficiencies.
    - evidence of closure of all MHRA inspections
    - the anticipated date of the next planed MHRA inspection.
    - any further restrictions on capacity enforced by the MHRA

Suppliers (Offerors) will inform the Authority within 10 working days if the licence holders have been referred to either the IAG or CMT.

Suppliers (Offerors) will engage with stakeholders and will provide details of any identified issues applied and their turnaround plans.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C7** Suppliers (Offerors) will provide a statement to confirm they will allow NHS QA Specialists to conduct an NHS QA Audit as required in the future at a time that is practically possible for both parties. This must include additional site(s) or sub-contractor(s) to be used under this agreement.

**For Information only (Not Evaluated & Not Scored)**

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| **Please provide a response below** |
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**C8** Suppliers (Offerors) will provide a copy of their current Good Distribution Practice (GDP) certificate pertaining to their most recent GDP inspection by the MHRA, with a summary of any actions resulting from the inspection. If this is unavailable, please state why.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C9** Notification of proposed changes must be made in writing via Atamis, ideally three months prior to the proposed change date. However, it is understood that this level of notification is not always possible in which case notice must be made as far in advance as is reasonably possible.

All changes must be approved by the Authority and its Participating Authorities before implementation.

**MANDATED Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**C10** Provide your Site Master File and Quality Policy.

These should include organogram(s), and descriptions of:

* + - premises, critical equipment, and automated processes
    - current pest control arrangements and results of these arrangements over the past 12 months
    - medicines storage and handling arrangements
    - documentary evidence demonstrating that suitable housekeeping/cleaning of premises/warehouse/facilities is undertaken e.g. copies of relevant Standard Operating Procedures (SOPs) and descriptive statement(s)
    - description of suitable medicines storage and handling arrangements
    - critical equipment
    - quality review meetings
    - arrangements for quality management within the organisation e.g., ISO quality certification
    - copies of formal Quality Management Certificates (if held)

Provide documentary evidence as an attachment(s) for this site following the naming protocol.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C11** Provide a brief description of how quality incidents are investigated and managed. This should include:

* + deviations (non-conformances) and errors
  + complaints
  + recalls
  + investigations
  + root cause analysis.
  + risk assessment.
  + CAPA
  + trending of deviations and complaints

Please submit the SOPs and policies that provide evidence for all the above relevant to this site following the naming protocol.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C12** Provide your policies and procedures for change management.

This must include reference to:

* + changes that may impact on product including, but not limited to, MA holder, manufacturer, supplier, SPC or PIL (including translations), packaging, licensing status including country of origin, over-label changes (where applicable)
  + internal changes
  + changes which may impact on customers and other stakeholders.
  + risk assessment of the impact of proposed changes
  + how the change is managed
  + review of the change once implemented.
  + evidence of effective document control

If the policies and procedures do not describe all the above, please provide other relevant documents or a supporting statement explaining how changes are managed.

Please submit the SOPs and policies that provide evidence for all the above relevant to this site following the naming protocol or a summary.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C13** Where over-labelling and translation services are offered, the Supplier (Offeror) will provide a statement signed and dated by their Head of Quality (or equivalent) describing validated provision for these services including:

* + - stock segregation/management arrangements.
    - label positioning.
    - measures taken to retain FMD where applicable.
    - label approval and product release procedure.
    - confirmation that overlabelling meets the requirements of Specialist Pharmacy Services: Packaging and labelling for safety: Unlicensed imported medicines - Guidance for the overlabelling and provision of translated information - Edition 2 December 2018

[Unlicensed-imported-medicines-Guidance-for-the-ovelabelling-and-provision-of-translated-information-Dec-2018.pdf (sps.nhs.uk)](https://www.sps.nhs.uk/wp-content/uploads/2024/04/YCD-unlicensed-imports-overlabelling-and-translation.pdf) *(document has been produced on behalf of the NHS Pharmaceutical Quality Assurance Committee)*

The supplier (Offeror) will provide a copy of the ISO 17100 (or equivalent) accreditation and/or membership of a recognised translated association and a statement describing translation services, how validation of translated documents is completed and how version control is managed.

The supplier (Offeror) will provide a copy(s) of indemnity insurance for described translation services (If insurance is part of another indemnity as provided via the SSQ please provide detail)

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1** **and Tab 2 for additional sites if applicable.**

**C14** The Supplier (Offeror) shall provide details of quality checks completed on their supplier(s) and imported products from the country of origin. This should cover:

* + - A statement describing all measures undertaken to guarantee the bona fide status of suppliers and prevent falsified or counterfeit medicines entering the supply chain. This must include details on what checks are made of products forwarded and received back from Sub-Contractors, where applicable e.g., overlabelling service.
    - Copies of Supplier Approval SOP(s) and other relevant SOP(s) evidencing bona fide status of suppliers and checks for falsified and counterfeit medicines. These must include SOP(s) on what checks are made of products forwarded and received back from Sub-Contractors, where applicable e.g., overlabelling service.
    - A statement describing the risk evaluation, quality assessment and approval process used to procure imported medicines.
    - Copies of relevant SOP(s) evidencing that risk and product quality assessment/approval processes are delivered.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points C4 to C19 must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1** **and Tab 2 for additional sites if applicable.**

**C15** Please confirm you have training and competence policies for all levels of staff who contribute to the Supplier’s (Offeror’s) organisation for supply chain function.

Please provide a statement describing training and competence. Where SOPs are provided, please highlight the reference point in your statement.

This statement should cover:

* the arrangements for ensuring that all activities are undertaken by staff members who are appropriately competent.
* accreditation, where appropriate
* validation and re-validation of competence in all tasks deemed appropriate to the service.
* confirmation that training, competence, and assessments are fully documented, signed by trainee and assessor, and retained for an appropriate duration in accordance with Specialist Pharmacy Services (SPS) guidance ([Retaining and storing pharmacy records in England – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](https://www.sps.nhs.uk/articles/retaining-and-storing-pharmacy-records-in-england/)).

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C16** Confirmation that your Validation Master Plan (or equivalent) and associated policies and procedures include all the following:

* + facility maintenance & validation
  + equipment maintenance & validation including all cold and ambient storage areas
  + computer systems
  + validation of people
  + validation of automated devices

Please provide a statement from your Head of Quality (or equivalent) confirming that you comply with all the above and that the associated documents are within the review dates.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C17** Provide policies, procedures, and reports for temperature-controlled storage (ambient & refrigerated) at all site(s) holding and handling medicines.

These must include:

* + validation and temperature mapping of storage areas
  + operating procedures for temperature monitoring
  + out of specification temperature mapping and monitoring results procedure

Please submit the SOPs and policies, including any cold-chain certification that provide evidence for all of the above relevant to this site following the naming protocol.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C18** Provide policies, procedures, and reports for temperature-controlled distribution (ambient & refrigerated) that provide validated assurance that the products are maintained within the temperature range specified by the manufacturer/MA holder throughout the supply chain to the Participating Authority's premises.

These must include:

* + validation and temperature mapping of delivery vehicles
  + validation and temperature mapping of insulated shippers (cool boxes) where used.
  + operating procedures for temperature monitoring during transport (if applicable)
  + out of specification results procedure

Provide documentary evidence as an attachment for this site following the naming protocol.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C19** Provide your internal audit policies and procedures.

These must include:

* current internal audit programme including dates of planned audits
* completed audits that demonstrate adherence to the audit policies and procedures

The Supplier will carry out self-inspections of their quality system at regular intervals and record the results and raise corrective and preventative actions for any non-conformances found.

Provide documentary evidence as an attachment for this site following the naming protocol.

If there are additional site(s) or sub-contractor(s) to be used under this agreement, specification points **C4 to C19** must be completed for each site / sub-contractor Tab 2 - Response Per Site.

**ADJUDICATED Point (Evaluated & Scored) please Document 8 Specification Tender Response (Component 2) Tab 1 and Tab 2 for additional sites if applicable.**

**C20** Goods delivered must have a reasonable proportion of the shelf life left remaining. The term “reasonable” may be interpreted to mean that at least 50% of licensed shelf life is still valid. Where the expiry date is limited, i.e., less than 6 months, and an agreement that this is acceptable with the Participating Authority (PA) has been reached, this should be clearly indicated on any delivery note relating to the purchase.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**D: Delivery**

**D1** Suppliers (Offerors) are required to offer ordering and delivery arrangements which ensure continuity of supply and ensuring cover for all public holidays and match the core opening hours of Participating Authorities at such times.

Normal working hours are classified as Monday to Friday, 09.00hrs to 17:00hrs.

The Supplier (Offerors) normal working hours (hours of service provision) must match or exceed Monday to Friday 09:00hrs - 17.00hrs excluding bank holidays.

Suppliers (Offerors) are required to provide at least one month's notice of planned closures around bank holidays and these closures should not last for more than two normal working days.

Suppliers (Offerors) must advise in advance of any increase in product lead times as a result of these closures (the increase in lead time should not be greater than two days). Closure includes any of the following activities:

* receipt and processing of orders
* delivery of prepared orders
* restriction on activity (i.e. suspension of license)

Suppliers (Offerors) will be required to specify their operating lead time for normal deliveries in days. Details to be provided in Document 9 Commercial Schedule, Terms of Business.

Participating Authorities require a consistent delivery lead time, and this consistency may be measured using the Key Performance Indicators detailed in Document 9a Contract Management Information.

Suppliers (Offerors) are required to provide an emergency service if, in exceptional circumstances, an urgent delivery within normal hours within less than the agreed lead time or outside normal working hours is deemed essential by a Participating Authority. Suppliers (Offerors) are required to provide emergency service contact details in Document 9.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**D2** Suppliers (Offerors) and Participating Authorities are required to work together to meet variations in demand, recognising that significant changes in service levels require time on both sides to be implemented.

**For Information only (Not Evaluated & Not Scored)**

**D3** Suppliers (Offerors) must provide a statement to evidence that products shall be transported and delivered in packaging that provides robust protection from damage (i.e., a rigid or semi-rigid container), throughout the supply chain.

Participating Authorities (PA) reserve the right to return/reject goods, which, upon inspection after delivery, are found to be in an unusable/unacceptable condition and will be replaced or refunded in an agreed timeframe at no cost to the PA

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1.**

**D4** Under sections 3 and 6 of the Health and Safety at Work Act 1974 there is a duty to protect people not in a company's employment who may be affected by handling loads they have supplied.

Therefore, it is good practice for manufacturers and suppliers to mark weights (and, if relevant, information about the heaviest side) on loads if this can be done easily.

Please see: <http://www.hse.gov.uk/msd/labellingloads.htm>

The Supplier (Offeror) must comply with all relevant packaging and labelling regulations and outer packaging must be sealed.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**E: Product Shortages**

**E1** In the event of a supply problem beyond the control of the Supplier (Offeror), the Supplier (Offeror) will notify the Participating Authority as soon as reasonably practical and both parties will work in partnership to minimise additional costs to the Participating Authority whilst maintaining patient safety. Where this is a national problem The Authority (NEYPPC) should be notified.

Suppliers (Offerors) will provide a regular fortnightly update on product supply status utilising Document 9a Contract Management Information, Tab 8 Product Supply Updates.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**F: Communications**

**F1** Key individuals will be designated the point of contact for the Unlicensed Imported Medicines Service within each Participating Authority.

Participating Authorities will confirm contact names and details as and when they join the agreement with the supplier. Details will be provided using the Schedule 7 call off contract and the "Order Form" within Document 5 NHS-Framework-Agreement-for-the-Supply-of-Goods-and-the-Provision-of-Services

**For Information only (Not Evaluated & Not Scored)**

**F2** Suppliers (Offerors) are required to provide named individuals and contact details for the categories indicated below. It will be the responsibility of the Suppliers to keep this information up to date and inform all parties.

The person responsible for each category listed below should be sufficiently senior within the organisation to be able to take action as necessary

The Supplier (Offerors) will submit information in Document 9 Commercial Schedule, Terms of Business.

Categories: -

* Contact details of person completing the tender
* Company Details
* Ordering Details
* Emergency Out of Hours
* Technical Queries
* Contract Queries
* Finance / Invoice Queries
* Delivery Terms
* Evaluation Contact Availability
* Data Provider
* Framework Agreement sign off contacts.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**G: Ordering & Invoicing**

**G1** Suppliers (Offerors) shall indicate if they are able to perform electronic transmission of ordering and invoicing information.

Please also indicate if you can trade electronically in Document 9 Commercial Schedule, Terms of Business. If currently unable to do so, Suppliers (Offerors) shall agree to work towards meeting this specification point.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**G2** Orders will be placed separately by the individual Participating Authority and payment for goods will be made direct by them.

On receipt of an order, Suppliers (Offerors) will notify the Participating Authority as soon as is reasonably possible if the agreed lead times or the complete order delivery may be compromised.

Suppliers (Offerors) should only submit one invoice per delivery.

Part deliveries are acceptable in exceptional circumstances only. Where part deliveries are anticipated, they should be notified to Participating Authorities in advance.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**H: Contract Management**

**H1** The Authority reserves the right to audit suppliers throughout the life of the framework agreement. Following a reasonable period of notice by the Authority, Suppliers (Offerors) shall accommodate the audit process as requested.

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**H2** Contract monitoring meetings will be held with each of the successful Suppliers (Offerors) by the Participating Authorities and / or The Authority, twice yearly or at more frequent intervals if required. Please refer to Document 9a Contract Management Information Tab 2 for template agenda.

**For Information only (Not Evaluated & Not Scored)**

**H3** Suppliers (Offerors) will ensure that Management Information (MI), Complaints and KPI data is supplied to the Authority and where applicable the Participating Authority monthly, within 10 working days from the end of the previous month.

Participating Authorities will also keep their own record so that issues, complaints, and concerns can be logged, compared, and raised with relevant suppliers.

Supplier (Offerors) will ensure that the Supply status data is provided to the Authority week 1 and week 3 of the month. This should include a status update of awarded lines that a supplier is unable to provide to a Participating Authority.

Examples of the individual templates to be used for data collection are included in Document 9a - Contract Management Information.

Final versions of the templates will be provided following the contract award. Suppliers (Offerors) must ensure that all lines are completed correctly. Where there have been **NIL** sales for this framework relevant documents as stated must still be returned.

Suppliers (Offerors) will comply with all requests for ad hoc data to be provided in respect of the products supplied and service charges under this agreement. This information is to be provided within 10 working days for ad hoc requests.

* **Document 9a Contract Management includes: -**
* Tab 3 Product Supply Status
* Tab 4 Management Information (Sales Data)
* Tab 5 Complaints A (Authority)
* Tab 5.1 Complaints PA (Participating Authority)
* Tab 6 KPI Definitions
* Tab 7 KPI Data Sheet
* Tab 8 KPI Report (Information Only)

**COMPLIANCE Point (Evaluated & Scored) please provide a response in Document 8 Specification Tender Response (Component 2) Tab 1**

**I: Innovation:**

**I1** The expectation is that the Supplier (Offeror) will through innovation deliver continuous improvements to the Participating Authorities for procurement and distribution solutions.  Please provide examples of how you consider your company to be innovative.

**For Information only (Not Evaluated & Not Scored)**

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| --- |
| **Please provide a response below** |
|  |

**4. Specification (Social Value Model)**

**J: Environmental & Social Value**

**J1** Under the Public Services (Social Value Act), the Supplier will consider where added value and benefit, in relation to economic, social, and environmental aspects (Social Values) can be achieved as part of this procurement exercise.

* High level info/context: <https://www.gov.uk/government/publications/social-value-act-information-and-resources/social-value-act-information-and-resources>
* Procurement Policy Notice: <https://www.gov.uk/government/publications/procurement-policy-note-0620-taking-account-of-social-value-in-the-award-of-central-government-contracts>
* Direct link to the quick reference table: <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940828/Social-Value-Model-Quick-Reference-Table-Edn-1.1-3-Dec-20.pdf>

**J1 is for Information only (Not Evaluated & Not Scored) Please see J2 and J3 for scored criteria.**

**J2** Social Value -

The Theme is **Fighting Climate Change**

The Policy Outcome is **Effective stewardship of the environment.**

Supplier (Offeror) is asked to describe how they have embedded effective measures to deliver additional environmental benefits in the performance of the framework including working towards net zero greenhouse gas emissions.

Detail how, through the delivery of the framework agreement you plan to reduce carbon emissions in the supply chain associated with the delivery of products to trusts and the importing of medicines to the UK.

Using a maximum of 1,000 words describe the commitment your organisation will make to ensure that opportunities under the framework deliver the outcome and Award Criteria. Please include:

● your ‘Method Statement’, stating how you will achieve this and how your commitment meets the Award Criteria, and

● a timed project plan and process, including how you will implement your commitment and by when. Also, how you will monitor, measure and report on your commitments/the impact of your proposals. You should include but not be limited to:

○ timed action plan

○ use of metrics

○ tools/processes used to gather data

○ reporting

○ feedback and improvement

○ transparency

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1 and upload supporting evidence to section 6 Social Value requirement envelope in the Atamis e-tendering portal**

**J3** Social Value -

The Theme is **Tackling Economic Inequality (Workforce)**

The Policy Outcome is **Create new businesses, new jobs, and new skills.**

The Supplier (Offeror) is asked to describe how they plan to create new jobs and new skills in your workforce which benefits in the performance of the framework including:

* Create employment and training opportunities, particularly for people in industries with known skills shortages or in high growth sectors.
* Support educational attainment relevant to the contract, including training schemes that address skills gaps and result in recognised qualifications.

Detail how, through the delivery of the framework you will ensure that there is a skills policy that focuses on increasing the average level of skills of the workforce and reduce inequalities in the way skills are distributed among the population, keeping the supply of skills aligned and responsive to market needs.

Using a maximum of 1,000 words describe the commitment your organisation will make to ensure that opportunities under the framework deliver the outcome and Award Criteria. Please include:

● your ‘Method Statement’, stating how you will achieve this and how your commitment meets the Award Criteria, and

● a timed project plan and process, including how you will implement your commitment and by when. Also, how you will monitor, measure and report on your commitments/the impact of your proposals. You should include but not be limited to:

○ timed action plan

○ use of metrics

○ tools/processes used to gather data

○ reporting

○ feedback and improvement

○ transparency

**ADJUDICATED Point (Evaluated & Scored) please provide response in Document 8 Specification Tender Response (Component 2) Tab 1 and upload supporting evidence to section 6 Social Value requirement envelope in the Atamis e-tendering portal**

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| **Abbreviations** | |
| BCP | Business Continuity Plan / Contingency Plan |
| BP | British Pharmacopoeia |
| CC | Change Control |
| cGDP | Current Good Distribution Practice guidelines issued by MHRA |
| cGMP | Current Good Manufacturing Practice guidelines issued by MHRA |
| GPhC | General Pharmaceutical Council |
| DHSC | Department of Health and Social Care |
| EEA | European Economic Area |
| EMA | European Medicines Agency |
| ICH | The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| ISO | International Organization for Standardisation |
| KPI | Key Performance Indicators |
| MA | Marketing Authorisation |
| MIA | Manufacture/Importation Authority |
| MPSC | Medicines Procurement Supply Chain |
| MHRA | Medicines and Healthcare Products Regulatory Agency |
| MRA | Mutual Recognition Agreement |
| MS | Manufacture Specials (Human) |
| NHS | National Health Service |
| PA | Participating Authority |
| PIL | Patient Information Leaflet |
| PLGB | Great Britain Product License |
| PMSG | Pharmaceutical Market Support Group |
| QM | Quality Manual |
| SLA | Service Level Agreement |
| SMF | Site Master File |
| SPC (SmPC) | Summary of Product Characteristics |
| SSQ | Standard Selection Questionnaire |
| TA | Technical Agreement |
| TSE | Transmissible Spongiform Encephalopathies |
| WDA(H) | Wholesale Distribution Authorisation (Human) |
| YCD | Yellow Cover Document |
| NEYPPC | North East & Yorkshire NHS Pharmaceuticals Purchasing Consortium |

| **Definitions** | |
| --- | --- |
| Authority | For the purpose of this Framework the Authority is the North East & Yorkshire NHS Pharmaceutical Purchasing Consortium (NEYPPC). |
| Business Continuity Plan / Contingency Plan | Contingency arrangements for managing an unexpected interruption to one or more of their facilities or logistics partner. ISO 22301 is the business standard for a robust Business Continuity Plan. |
| British Pharmacopoeia | The national pharmacopoeia of the United Kingdom. It is an annually published collection of quality standards for medicinal substances in the UK, which is used by individuals and organisations involved in pharmaceutical research, development, manufacture, and testing. |
| Call-off Contract | Means any contract entered into under this Framework Agreement by any Participating Authority with a Framework Supplier as further defined in the Call-off Terms and Conditions for the Supply of Goods & Services. |
| Change Control | A systematic approach to proposing evaluating, approving, implementing, and reviewing changes. (MHRA Orange Guide - ICH Q10 International conference on harmonisation of technical requirements of registration of pharmaceuticals for human use Section 3.2.3).  [ICH guideline Q10 on pharmaceutical quality system - Step 5 (europa.eu)](https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-guideline-q10-pharmaceutical-quality-system-step-5_en.pdf) |
| Consortia / Consortium | The North East and Yorkshire Pharmaceutical Purchasing Consortium supports the contracting and procurement of medicines and medicines services, including full quality assurance support for all the fourteen acute Trusts in North East & Yorkshire Humber.  The consortium provides member Trusts (Participating Authorities [PA]) and commissioners with strategic purchasing support, procurement expertise and commercial skills. |
| Current Good Manufacturing Practice (cGMP) | The minimum standard that a medicines manufacturer must meet in their production processes. Products must be of consistent high quality be appropriate to their intended use. |
| Eligible Participating Organisations | Includes and for the benefit of publicly funded (both wholly and partially funded) entities in the United Kingdom, including Northern Ireland, Scotland, Wales and England. This will include but is not limited to: Acute; (including their third-party providers); Ambulance; Mental Health; Clinical Commissioning Groups; Health and Care Trusts; Area Teams; Local Authorities and Special Health Authorities; HSC in Northern Ireland; NHS Scotland and NHS Wales, including any successor or emerging organisations, which will include but is not limited to the emerging landscape of combined health and social care commissioners and providers. (Ref Doc 7 - NEYPPC Members & Eligible Participating Authorities). |
| Framework Agreement | The Framework Agreement for Imported Unlicensed Medicines, the overarching agreement that Suppliers are awarded to from which Call-Off Contracts with Participating Authorities can be made. |
| Key Performance Indicators (KPIs) | Key Performance Indicators are quantifiable measurements, agreed to beforehand, that reflect the critical success factors of an organisation. |
| Manufacture Specials (Human) | To make, assemble or import human medicines, a company will need a manufacturers' licence, issued by the Medicines and Healthcare Products Regulatory Agency (MHRA). To qualify for a manufacturer licence the company will must show the MHRA that they comply with EU good manufacturing practice (GMP) and pass regular GMP inspections of their site. |
| Marketing Authorisation | Medicines which meet the standards of safety, quality and efficacy are granted a marketing authorisation (previously a product licence), which is normally necessary before they can be prescribed or sold. This authorisation covers all the main activities associated with the marketing of a medicinal product. |
| Out of hours | Any time not specified as normal working hours (Monday to Friday 9am to 5pm) for the relevant activity. |
| Offeror | The supplier submitting the tender offer. |
| Order Form | The receipt by the Participating Authority of an Order Form countersigned by the Supplier shall form a binding call-off agreement between the Supplier and the Participating Authority for the Provision of the Products specified in the relevant Order. |
| Procedure | For the purposes of this specification 'procedure' is used to describe, but is not limited to, any of the following determined on how your company manages documents;  • Work Instruction • Standard Operating Procedures • Procedures • Policies • Guidance Notes/Documents |
| Participating Authority | The Trust / Authority entitled to place Orders under this Framework Agreement as set out in the Key Provisions (Doc 7 - NEPPC Members & Eligible Participating Authorities). |
| Product Range | A group of products of a similar nature. |
| Sub-Contractor | A company that undertakes work on behalf of the Supplier. This could include subcontract manufacturing or distribution services. |
| Supplier | The "Offeror" submitting the tender offer and the Aseptic Compounding Manufacturer awarded to supply unlicensed medicines to the Participating Authority (PA). |
| Supplier Quality Assessment | Assessment of the supplier against the award methodology and evaluation criteria by QA Specialists (North East & Yorkshire NHS Pharmaceutical Purchasing Consortium (NEYPPC). |
| Unlicensed Medicine | A medicine that does not have a UK Marketing Authorisation (PLGB) OR a licensed medicine that is being used for an un-licensed indication OR a manufactured special (MS) or extemp or borderline substances OR re-packaged licensed products. |
| Wholesale Dealers Licence | Any company or individual wishing to wholesale deal medicinal products (defined as selling, supplying, or procuring to anyone other than the end-user) within the EU must hold a WDA(H) – Wholesale Distribution Authorisation (Human). |
| Yellow Cover Document | Guidance documents prepared and issued by the NHS Pharmaceutical Quality Assurance Committee. |