**ANNEX 7**

**QUALITY TECHNICAL AGREEMENT**

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| **TECHNICAL AGREEMENT**  **For the transport and delivery**  **of Pharmaceuticals & Medical Supplies** |
| This agreement is between:  **Save the Children International**  St Vincent House,  30 Orange Street,  London, WC2H 7HH,  United Kingdom  (the ***CONTRACT GIVER*** or ***SCI***) |
| and |
| [●]  (the ***CONTRACT ACCEPTOR***) |

Approved by:

**Save the Children International:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Title** | **Name** | **Signed** | **Date** |
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**Contract Acceptor:**

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| **Title** | **Name** | **Signed** | **Date** |
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Copy to within CONTRACT ACCEPTOR:

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| **Title** | **Name** | **Signed** | **Date** |
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Copy to within Save the Children International

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| **Title** | **Name** | **Signed** | **Date** |
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# SCOPE

This Quality Technical Agreement (“QTA”) defines the quality responsibilities of Save the Children International (“SCI”) and the Contract Acceptor (each a “Party” and together, the “Parties”) for the distribution of medicinal products, as defined in the Human Medicines Regulation 2012 (as amended) and subsequent amendments, to the designated address in a Purchase Order. These responsibilities will not be varied by either party without the written agreement of the other party.

In the context of a Call-Off Contract and/or specific Purchase Order, references to “SCI” in this QTA shall be deemed to include the Framework Purchaser.

The distribution of medicinal product is covered by numerous activities that may occur during the collection of products from SCI’s suppliers through the distribution activity to the delivery address on the Purchase Order. The purpose of this QTA is to ensure the quality and integrity of the Products is maintained during all aspects of the distribution and to comply to EU Guidelines on Good Distribution Practice.

To maintain the original quality of the Products, every activity in the distribution of Products should be carried out according to the European Commission Directive 2013/C343/01 and subsequent amendments, EU Guidelines on Good Distribution Practice (“GDP”) published 5 November 2013 and subsequent revisions thereof based upon the EC Directive, in addition to any subsequent Regulation or Statutory Instrument primarily concerned with quality assurance of products and that this is maintained through adequate controls during the numerous activities which occur during the performance of the Distribution Services.

The commercial terms for the provision of the Distribution Services are agreed in the Framework Agreement.

Throughout the term of this Quality Technical Agreement [●] will be the control tower for all SCI movements. [●] will manage communication and administration in-line with GDP standards to [●] locations overseas.

# DEFINITIONS

|  |  |
| --- | --- |
| **Adverse Event** | Any incident or deviation from the expected norm, this may include unauthorised access to shipping containers or vehicles, temperature excursions, customs seizures or unpredicted delays at borders. |
| **Audit** | An independent, objective assurance and consulting activity designed to add value and improve an organisation’s operations. |
| **Ambient** | A positive room temperature as defined on outer packaging typically ranging between:   * 8°C and 25°C; or * 15°C and 25°C; or * 15°C and 30°C; or * 8°C and 30°C. |
| **Cool lines (Cold chain)** | A positive temperature for refrigerated items as defined on packaging ranging between 2°C and 8°C |
| **Batch Number** | A distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch record and corresponding certificates of analysis applied by Manufacture to the Product. |
| **Change** | Any act or process through which something becomes different which could impact the product quality, safety or efficacy. |
| **Collection** | The act of collecting the product from the agreed collection point for onward shipment to the address identified on the packaging and delivery documentation. |
| **Complaint** | A written note objecting to the quality, packaging or documentation of a product or the service. |
| **Container** | Any material employed by the Contract Acceptor in the packaging for transport of medicinal products including validated packaging which may contain one or more batch numbers, E.g., a box, a carton, a pallet, a pallet box or a shipping container. |
| **Contamination** | The undesired introduction of foreign matter from the contents of one container with the container containing medical Products. |
| **Customer** | Recipients of medical Products from SCI including SCI’s own operations. |
| **Dangerous Goods** | Any article, substance or material classified as “Dangerous Goods” and which are packed, marked and labelled in accordance with the Limited Quantity section of the applicable model regulations ADR (International Agreement for the Carriage of Dangerous Goods by Road 2015), IATA (International Air Transport Association – Dangerous Goods Regulations 56th Edition), IMDG (International Maritime Dangerous Goods Code) and which are deemed low risk for transportation and which are ordinarily small amounts over packed in an outer container and labelled as “LQ”. |
| **Deviation** | An event where a process, supporting system or a combination of both are outside the approved operating parameters set out in this QTA and which may have an adverse impact on Service provided by Contract Acceptor to SCI or an impact to product quality. |
| **Distribution** | The movement of Products from the Collection location to the consignee address inclusive of all modes and nodes, for both procured and gift in kind distribution. |
| **Distribution Conditions** | Set of parameters having influence on Product properties, e.g. time, temperature, humidity, vibration, radiation, air exposure, etc. |
| **Framework Agreement** | Commercial [contract](http://en.wikipedia.org/wiki/Contract) between Save The Children International and Contract Acceptor which documents the terms and conditions of the services. |
| **Framework Purchaser** | The entity or branch that enters into a Call-Off Contract (as defined in the Framework Agreement) with the Supplier in accordance with the Framework Agreement. |
| **Good Distribution Practice** | European Commission Directive 2013/C343/01 and subsequent amendments, EU Guidelines on Good Distribution Practice (GDP) of 5 November 2013 and subsequent revisions thereof based upon the EC Directive, in addition to any subsequent Regulation or Statutory Instrument primarily concerned with quality assurance of Products and that this is maintained through adequate controls during the numerous activities which occur during the Product distribution process. |
| **Human Medicines Regulations 2012** | The UK medicines legislation which set out a comprehensive regime:   * for the authorisation of medicinal Products for human use * for the manufacture, import, distribution, sale and supply of those Products; * for their labelling and advertising; * for pharmacovigilance. |
| **Labelling** | The process of identifying a container. |
| **Limited Quantity** | Products or Dangerous Goods which are packed in small enough sizes to reduce the risks relating to Distribution and potential Contamination providing an acceptable level of safety. |
| **Product** | Medicinal products distributed by SCI and transported by Contract Acceptor. |
| **Product Recall** | The removal of a Product from the Distribution chain. The recall will be initiated by SCI. |
| **Purchase Order** | Means the individual freight movement purchase order issued by the Framework Purchaser in accordance with the Framework Agreement. |
| **Quality Assurance** | A wide-ranging concept covering all matters that individually or collectively influence the quality of a Product. It is the totality of the arrangements made with the object of ensuring that Products are of the quality required for their intended use. |
| **Quarantine** | The status of finished Products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing. |
| **Services** | All Distribution services provided by Contract Acceptor in accordance with the Framework Agreement and the Call-Off Contract (as defined in the Framework Agreement) for the supply of distribution services. |
| **Shipping Unit** | The aggregation of several Containers into a single item for onward transportation. |
| **Storage** | The planned storing of Ambient Products during distribution, for a period of greater than 36 hours. Or the planned storing of cold chain products during distribution. |
| **Sub-Contractor** | An individual or company hired by the Contract Acceptor. |
| **Temporary Storage** | Where Products are held within an approved contract acceptor site or their subcontractor’s depot for less than 36 hours for Ambient Product. |

**GENERAL TERMS AND CONDITIONS**

* 1. SCI and the Contract Acceptor undertake to conform to GDP in relation to each Party’s obligations regarding Distribution of Products.
  2. Except as required by law or regulation the Contract Acceptor undertakes not to vary any provisions of this QTA other than by agreement with SCI and will consider adopting any new standards, specifications and procedures at the written request of SCI subject always to any requirement for the Framework Agreement (via change control process) to be amended because of any such requirement.
  3. This QTA will be effective from the date of the last approver, once signed by both parties and shall be reviewed and updated by SCI at least every 3 years after that effective date of signing or on the commencement of a new Framework Agreement. Any update will be treated by the Parties as a variation of the QTA in relation to 3.2 above. This QTA shall terminate automatically upon termination of the Framework Agreement or the date of completion of the Services under the final Purchase Order (whichever is later).
  4. GDP requires that a written contract exists between the Contract Giver and the Contract Acceptor relating to the provisions contained herein.
  5. The Contract Acceptor must provide documentation that meets the requirements set out in the Framework Agreement document.
  6. This QTA is an integral part of the Framework Agreement and any Call-Off Contract between the Parties in respect of the Services and is intended as a guide to handling packages in compliance with GDP.
  7. The validity, construction and performance of the QTA shall be governed by English Law. Any dispute arising under or in connection with the QTA shall be subject to the exclusive jurisdiction of the English courts to which the Parties irrevocably submit.
  8. The Contract Acceptor agrees not to store products at any premises, hubs, or vehicles for greater than 36 hours unless that site is authorised to store medicinal products for that duration or those set by the respective National Competent Authority.
  9. The Contract Acceptor agrees that where products need to be stored for more than 36 hours in the UK such premises shall be MHRA approved for the storage of medicinal products or where the National Regulatory Agency in the country does not require this then written confirmation from the National Regulatory Agency will be provided to confirm requirements. In either case Contract Acceptor will ensure that the quality and integrity of medicinal products will be maintained.
  10. This QTA may be executed in any number of counterparts, each of which is an original but all of which together constitute one and the same instrument.

# RESPONSIBILITIES

The responsibility matrix for SCI and Contract Acceptor is shown in Appendix B

# APPENDIX A – Designated Contacts

Any QUALITY ASSURANCE MATTERS, e.g. customer complaints, emergency contact – out of hours

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| --- | --- | --- | --- | --- |
| Save the Children International | | | | |
| Name | Position | Email Address | Location Address | Contact number |
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| THE CONTRACT ACCEPTOR | | | | |
| Name | Position | Email Address | Location Address | Contact number |
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Any TECHNICAL MATTERS, e.g. specification, logistics issues,

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| --- | --- | --- | --- | --- |
| Save the Children International | | | | |
| Name | Position | Email Address | Location Address | Contact number |
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| THE CONTRACT ACCEPTOR | | | | |
| Name | Position | Email Address | Location Address | Contact number |
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# APPENDIX B – TECHNICAL AGREEMENT RESPONSIBILITY MATRIX

| **A. DOCUMENTS** | **SCI** | **Contract Acceptor** | **Reference Number** |
| --- | --- | --- | --- |
| Preparation of Technical Agreement. | **X** |  | **A1** |
| Approval of Technical Agreement. | **X** | **X** | **A2** |
| Agree and Sign Framework Agreement. | **X** | **X** | **A3** |
| Freight Purchase Order for supply of Services. | **X** |  | **A4** |
| Acceptance of Freight Purchase Order for supply of Services. |  | **X** | **A5** |

| **B. ORGANISATION AND MANAGEMENT** | **SCI** | **Contract Acceptor** | **Reference Number** |
| --- | --- | --- | --- |
| Ensure that the Contract Acceptor or the organisation, to which the Contract Acceptor belongs, is an entity that is appropriately authorised to perform the intended functions in terms of the applicable legislation in relation to maintaining the quality and integrity of distributed products. | **X** |  | **B1** |
| Ensure that there is an adequate organisational structure and adequate resources to fulfil defined duties within this quality technical agreement and that these those duties can be suitably performed. | **X** | **X** | **B2** |
| Ensure that adequate contingency measures are in place and staff can implement those measures which shall include a contact being available 24 hours each day. | **X** | **X** | **B3** |
| Ensure that in accordance with ISO 9001:2015 there is a suitable business continuity management plan and disaster recovery plan are in place to minimise the risk of Service disruption. |  | **X** | **B4** |
| A summary of the business continuity management plan is available to SCI on request. |  | **X** | **B5** |
| SCI acknowledge and agree that the business continuity management plan provided/available to it by the Contract Acceptor is adequate. | **X** |  | **B6** |
| Ensure there is in place managerial and technical teams with authority to identify and correct deviations from the established quality system for distribution of medicinal products. | **X** | **X** | **B7** |

| **C. PERSONNEL** | **SCI** | **Contract Acceptor** | **Reference Number** |
| --- | --- | --- | --- |
| Ensure personnel involved in management of this agreement and distribution of medicinal products have the relevant training, ability and experience. | **X** | **X** | **C1** |
| Individuals involved in delivery of Services to SCI within the Contract Acceptor will be trained in the appropriate applicable procedures and GDP requirements set in the current EU GDP guidelines . Those individuals will have been deemed competent to meet these requirements. |  | **X** | **C2** |
| Any training provided by the Contract Acceptor must be documented in a training record for the individual concerned. The training records are monitored by the Contract Acceptor and are available to SCI, upon reasonable request for inspection. Verification of competency and understanding must be undertaken as part of the training process. |  | **X** | **C3** |
| Ensure training of personnel include training on product security, integrity and identification | **X** | **X** | **C4** |

| **D. QUALITY MANAGEMENT** | **SCI** | **Contract Acceptor** | **Reference Number** |
| --- | --- | --- | --- |
| The Contract Acceptor shall operate and maintain a quality management system which shall demonstrate the active participation of the management and individuals in the different Services involved and must cover all documentation generated for storage and distribution of and engagement of sub-contractors.  The Contract Acceptor will ensure procedures are in place for managing the GDP activities relating to this agreement. |  | **X** | **D1** |
| A designated individual within the Contract Acceptor is identified and responsible for and oversees compliance arrangements in respect of quality management. |  | **X** | **D2** |
| All changes that have GDP impact will be handled by reference to a change control process. All changes affecting agreed processes in this QTA will be notified to SCI prior to the change being carried out. |  | **X** | **D3** |
| There is a clear documentation trail in relation to Services and the documents must be available to SCI by way of Proof of Delivery (POD) Documentation. This documentation must be provided to SCI. |  | **X** | **D4** |
| If applicable, allow for an audit of the offices used by Contract Acceptor which control the Services supplied to SCI by SCI or its representative, subject to the Contract Acceptor’s operational restrictions at any time, i.e. access to secure areas which are not allowed. A maximum of 3 SCI representatives will be given access for up to 2 days to inspect the facilities and quality management systems. The inspection will cover topics including, but not limited to:   * Correct implementation of the QTA; * Efficiency of the quality management system, including customer complaint handling; * Bona Fides; * Documentation; * Monitoring of data; * Training; * Vehicles; * Equipment; * Facilities; * Sub-contractor agreements. |  | **X** | **D5** |
| The Responsible Person and/or Quality Manager of SCI will provide a written report within 30 calendar days of an inspection, to the Contract Acceptor detailing observations. | **X** |  | **D6** |
| The Contract Acceptor will provide SCI with a written response to the observations within 30 calendar days after receipt of the written report from SCI. The Contract Acceptor will, as far as is reasonable, rectify any agreed deficiencies noted as observations during the inspection by SCI and to the extent that any remedial action requires investment. |  | **X** | **D7** |
| The Contract Acceptor shall notify SCI if it is informed of any audits to be performed by regulatory bodies or competent authorities which relate to the Service and shall provide a copy of the outcome of the inspection. |  | **X** | **D8** |
| If the Contract Acceptor are audited by a regulatory body or competent authority and any issues arise relating to the Services provided by the Contract Acceptor, the Contract Acceptor will inform SCI within 5 working days and if requested will provide SCI with a copy of that inspection report and any review undertaken by it. |  | **X** | **D9** |
| Take reasonable steps to ensure compliance with any audit findings subject always to the change control procedure. |  | **X** | **D10** |
| Deviations from the QTA will be notified by the Contract Acceptor to SCI no later than the following working day. |  | **X** | **D11** |
| The Contract Acceptor will trend Deviations on a 12-month rolling basis to monitor the performance and the quality of the Service. Resulting actions or recommendations will be reported to SCI. |  | **X** | **D12** |
| The Contract Acceptor has an annual internal audit schedule which is based on their own risk assessments as agreed by their senior management. |  | **X** | **D13** |
| The Contract Acceptor are responsible for ensuring that any sub-contractors are comprehensively assessed for their suitability for purpose and meet requirements of SCI. A general supplier agreement is in place with each sub-contractor, a copy of which may be supplied to SCI on request subject to any restrictions in relation to confidentiality. |  | **X** | **D14** |

| **E. COLLECTION** | **SCI** | **Contract Acceptor** | **Reference Number** |
| --- | --- | --- | --- |
| Provide the Contract Acceptor with the Purchase Order or relevant documentation required to collect the products from the SCI supplier | **X** |  | **E1** |
| Collection of Products from SCI collection address is performed against a documented procedure. |  | **X** | **E2** |
| All Products collected by the Contract Acceptor are checked for correctness (shipping unit) in accordance with the Purchase Order provided by SCI. |  | **X** | **E3** |
| Retain documentation relating to the Purchase Order for a minimum period of 5 years. |  | **X** | **E4** |
| Supply documentation relating to Products collected (i.e. Signed acceptance of collection) from the collection address stated on the Purchase Order. |  | **X** | **E5** |
| Records of collection contain enough information to enable traceability of the SCI’s Products. |  | **X** | **E6** |
| To assure Products will be ready for collection at agreed times. | **X** |  | **E7** |

| **F. TRANSPORTATION AND DELIVERY** | **SCI** | **Contract Acceptor** | **Reference Number** |
| --- | --- | --- | --- |
| Services are provided in accordance with EC Directive (2013/C343/01) and in particular the EU GDP Guidelines and Chapter 9 thereof (with the exception of any temperature control obligations) and any subsequent amendment. |  | **X** | **F1** |
| Only temperature-controlled transport lanes will be used to transport the SCI Products to the port of entry. Subject to any findings of route risk assessments.  Where local transport infrastructure provides a temperature-controlled transport lane this should be used. |  | **X** | **F2** |
| The overall responsibility for carrying out route risk assessments will by SCI, however it is expected that the Contract Acceptor will input into this process by making available their own route risk assessments to SCI. | **X** |  | **F3** |
| Define the requirements for the use of temperature-controlled shipment containers including, but not limited to, sea containers, aviation containers and containers or vehicles used for road or rail transportation. | **X** |  | **F4** |
| Ensure that the use of temperature-controlled shipment containers is in accordance with SCI requirements and that selection is based on ability to maintain the storage conditions for the products transported. |  | **X** | **F5** |
| All relevant transportation and delivery documentation will be retained in a secure environment with limited access by authorised individuals for minimum 5 years. This includes password controls for electronic copies and secure storage controls for paper copies. | **X** | **X** | **F6** |
| Products are transported in properly prepared containers in such a way to ensure that:   * Containers packed and labelled are not lost or defaced; * Products are secured properly and there are leakages. * Products are not contaminated by other Products; * Adequate precautions are taken against, spillage, breakage, misappropriation and theft; * Containers are secure and are not subjected to unacceptable, light, moisture or other adverse influence, or may be attacked by micro-organisms or pests; |  | **X** | **F7** |
| To ensure the required conditions for temperatures of this QTA for Products are maintained during transportation. Referring to Section F2. |  | **X** | **F8** |
| Immediately notify the quality contact of SCI by email and by phone of temperature excursions (outside the limits specified on the Purchase Order) identified during transportation. |  | **X** | **F9** |
| To ensure a tracking system (to the extent that this is utilised by the Contract Acceptor) used allows Products to be tracked during distribution to enable SCI to know were product is during its journey (if required). |  | **X** | **F10** |
| The appropriate documentation to allow for the processing of Export and Import and other relevant documentation must accompany the shipment. |  | **X** | **F11** |
| To inform the quality contact in SCI about any shipment unit or product that is visibly or knowingly damaged during distribution. |  | **X** | **F12** |
| To decide if container or product that is visibly or knowingly damaged during distribution shall be returned or delivered. | **X** |  | **F13** |
| Loading and unloading of a vehicle will be carried out in minimum time with no Products left in vehicles for prolonged periods of time (more than 36 hours) at collection points or delivery destinations. |  | **X** | **F14** |
| To assure vehiclesare not left unlocked during the transportation. Shipping container seal mechanisms must also to remain locked unless requested by Customs (or other Authority who are authorised) to be opened. |  | **X** | **F15** |
| Delivery is attempted of all Products to the destination address within the timescale stated and that the delivery is never left at an address which is not detailed on the Purchase Order. |  | **X** | **F16** |
| To ensure each delivery is received by the consignee appointed by SCI as per shipping request. |  | **X** | **F17** |
| In case the delivery address is different to the address provided by SCI. This is confirmed with SCI  before the delivery is released. E.G. The address is 45 x road, but the premises are located at 54 x road. |  | **X** | **F18** |
| There is a clear documentation trail in relation to Services and the documents must be available to SCI by way of Proof of Delivery (POD) Documentation. This documentation must be provided to SCI. |  | **X** | **F19** |
| Where temperature-controlled vehicles and freight containers are used they shall be subject to qualification and temperature mapping and routine maintenance and calibration at least annually. |  | **X** | **F21** |
| Temperature controlled vehicles and shipping containers with 30 minutes or less interval for the temperature measurement will be used to transport SCI Products, if available with reference to F2. |  | **X** | **F22** |
| To ensure temperature monitoring equipment is calibrated against national standards at least on an annual basis. |  | **X** | **F23** |
| Ensure appropriately assessed sub-contractors are used with prior approval from SCI |  | **X** | **F24** |
| Ensure a procedure is in place for investigating, handling and managing all temperature excursions during transportation |  | **X** | **F25** |

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| **G. QUALIFICATION AND VALIDATION OF EQUIPMENT** | **SCI** | **Contract Acceptor** | **Reference Number** |
| Periodic review of the Service to ensure compliance with this QTA. | **X** |  | **G1** |

| **H. TECHNICAL COMPLAINTS** | **SCI** | **Contract Acceptor** | **Reference Number** |
| --- | --- | --- | --- |
| SCI must inform the Contract Acceptor of a relevant Customer Service Complaint within 48 hours of receiving the Customer Complaint. | **X** |  | **H1** |
| The Contract Acceptor must inform SCI about any Customer Complaint, Adverse Event related to the SCI Products within 24 hours. |  | **X** | **H2** |
| A written procedure is in place for the handling of Customer Complaints, including the identification and completion of corrective and preventative actions with a formal report being produced which details:   * Brief description of event; * Determination of the cause; * Quality impact; * Possible corrective and / or preventive actions. |  | **X** | **H3** |
| Any Customer Complaint is documented, investigated and recorded as per the documented procedure. |  | **X** | **H4** |
| Any investigation should be completed within 5 days: if further time is required to properly complete the investigation SCI are informed. |  | **X** | **H5** |

| **I. REJECTED, RETURNED,RECALLED AND SUSPECTED FALSIFIED PRODUCTS** | **SCI** | **Contract Acceptor** | **Reference Number** |
| --- | --- | --- | --- |
| SCI will initiate or confirm a requirement for a return of Product and ensure returns are only applicable to product that has not left the UK for example delayed flights | **X** |  | **I1** |
| To ensure rejected or recalled Products which are returned from SCI are appropriately segregated and identified. |  | **X** | **I2** |
| The tracking reference assigned to a returned, rejected or recalled shipping unit must be able to be tracked (if required) during its return transport leg. |  | **X** | **I3** |
| Provision will be made for the proper and safe Transportation of returned, rejected or recalled Containers/Product. | **X** |  | **I4** |
| The necessary assessment will be carried out by authorised personnel and the decision regarding the disposition of the Products will be performed by the Responsible Person upon SCI approval. |  | **X** | **I5** |
| Ensure addresses notified to the Contract Acceptor for collection and delivery are legitimate in accordance with the applicable country laws/national competent authorities | **X** |  | **I6** |
| Ensure adequate security during transportation of medicinal products |  | **X** | **I7** |
| Ensure any products suspected to be falsified or defective are immediately reported to the relevant national competent authority and/or Marketing Authorisation Holder where applicable | **X** | **X** | **I8** |

| **J. RETAINED RECORDS** | **SCI** | **Contract Acceptor** | **Reference Number** |
| --- | --- | --- | --- |
| Records relating to this agreement and GDP will be retained for a minimum 5 years. | **X** | **X** | **J1** |
| To ensure only authorised personnel of the Contract Acceptor can maintain and access SCI Records. |  | **X** | **J2** |
| To ensure records are available to SCI upon request within 24hours. |  | **X** | **J3** |