FRAMEWORK AGREEMENT FOR THE SUPPLY OF PHARMACEUTICAL AND MEDICAL GOODS

SCI contract reference number: **FWA-MED-GLOBAL-2022-01**

**THIS AGREEMENT**

**PARTIES**

1. **Save the Children International**,a charitable company limited by guarantee registered in England and Wales (company number 03732267; charity number 1076822) whose registered office is at St Vincent House, 30 Orange Street, London, WC2H 7HH (the “**Customer**” or “**SCI**”);and
2. **Supplier** whose registered office is Address (the “**Supplier**”).

(each a “**Party**” and, together, the “**Parties**”).

**RECITALS**

1. The Customer has invited the Supplier to enter into this framework agreement to provide goods to the Customer and the Framework Purchasers from time to time on a call off basis.
2. This Framework Agreement sets out the general terms to govern each Contract made for the supply of goods by the Supplier to the Customer and the Framework Purchasers. The specific provisions applicable to each supply of goods will be set out in individual Purchase Order Forms (defined below), which may be issued by the Customer or any of the Framework Purchasers.

**GENERAL PROVISIONS**

# Definitions and interpretation

## In this Agreement unless the context requires otherwise:

### **Applicable Laws** means all applicable laws, rules, regulations or other requirements of regulatory authorities, as amended from time to time.

### **Applicable Privacy Laws**: means all privacy, security, data protection, direct marketing, consumer protection and workplace privacy laws, rules, regulatory requirements and regulations of any applicable jurisdiction, including: (i) the UK Data Protection Act 2018 (the “**DPA**”) and the UK General Data Protection Regulation as defined by the DPA, as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (together with the DPA, (the “**UK GDPR**”); (ii) the General Data Protection Regulation and any national laws, regulations and secondary legislation which implements, replaces, adds to, amends, extends, reconstitutes or consolidates such laws from time to time, in each case as, as amended, consolidated, re-enacted or updated from time to time.

### **Confidential Information**: means information provided directly or indirectly by one Party (the “**Disclosing Party**”), its employees, agents or subcontractors concerning the Disclosing Party’s business or its products or its services, to another Party (the “**Receiving Party**”) on or after the date of the Agreement including all technical or commercial know-how, specifications, inventions, processes or initiatives which have been marked as “confidential”, described as “confidential” or reasonably understood to be confidential. Such information may be provided in a number of ways, including without limitation, in oral or documentary or electronic form. Where the Disclosing Party is the Customer, Confidential Information will also include information concerning the business or operation of SCA, SCA members and associate members, that the Supplier receives during the term of the Agreement which, as between the Parties, shall be the Confidential Information of SCI.

### **Contract**: has the meaning given to it in Clause 3.3 of the Agreement.

### **Framework Agreement or Agreement**: means this agreement (including the Schedules attached to it but only Schedule 2 to the extent it is in template form).

### **Framework Purchasers:** means the entities listed in Schedule 4 which may be varied in accordance with Clause 26.6.

### **General Data Protection Regulation**: means Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

### “**Good Distribution Practices**”or “**GDP**” means all applicable current good distribution practices and standards, as applicable, promulgated or endorsed by the European Medicines Agency (EMA), EU or regulatory authorities, including the Medicines and Healthcare products Regulatory Agency (MHRA) as set out in European Commission Guidelines 2013/C 343/01 and the European Commission Guidelines of 19 March 2015 and 5 November 2013 on Good Distribution Practice of medicinal products for human use, each as may be amended and applicable from time to time.

### **Good Manufacturing Practice**: means all applicable standards, laws, regulations, codes and guidelines promulgated and administered by the regulatory authorities having jurisdiction, e.g. the current Good Manufacturing Practices as specified in the EU Good Manufacturing Guidelines (Eudralex – Volume 4 as based on Directive 2003/94/C) and any other applicable laws, guidelines, codes or regulations designed as a quality control measure outlining general rules for all aspects of pharmaceutical manufacturing including buildings and facilities, personnel, equipment, pharmaceutical components and containers, production, packaging and labelling, and record‑keeping to product mix‑ups, contamination, and mislabelling, in each case as the same may be updated, supplemented or amended from time to time.

### **Goods**: shall have the meaning given to it under Clause 3.1.

### **Incoterms**: means the international rules for the interpretation of trade terms of the International Chamber of Commerce, 2020 version. Unless the context otherwise requires, any term or expression which is defined in or given a particular meaning by the provisions of Incoterms shall have the same meaning in this Agreement, but if there is any conflict between the provisions of Incoterms and this Agreement, the latter shall prevail.

### **Member State**: means a member state of the European Union.

### **Order:** has the meaning given to it under Clause 3.2.

### **Personal Data**: has the meaning given to it under the General Data Protection Regulation.

### **Processor:** has the meaning given to it under the General Data Protection Regulation.

### **Purchase Order Form**: means each purchase order form based on the template purchase order form set out in Schedule 2 which has been agreed and signed by the Parties.

### **Recall**: means any action to recover title to or possession of the Goods (including market withdrawal) based upon regulatory authority action or the good faith belief that such action was necessary under the circumstances.

### **SCA**: means Save the Children Association, a Swiss Association formed pursuant to Articles 60-79 of the Swiss Civil Code.

### **Stringent Regulatory Authority**: means all regulatory authorities which are members or observers of The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), or those associated with an ICH member through a legally-binding mutual recognition agreement, as before October 23rd 2015.

### **Quality Technical Agreement**: means the Technical Agreement for Wholesale Dealers of Pharmaceutical & Medical Supplies set out in Schedule 6 to this Framework Agreement.

## If there is any conflict or ambiguity between the terms of the documents listed below, a term contained in a document higher in the following list shall have priority over one contained in a document lower in the list:

### the Quality Technical Agreement, solely with respect to matters set out therein;

### this Agreement (for the avoidance of doubt, excluding the Quality Technical Agreement);

### the Purchase Order Form;

### any tender documents including the invitation to tender and conditions of tendering. Where additional terms or particulars contained within those tender documents are not reflected in this Agreement and/or any Contract, such terms or particulars shall not be incorporated into the Agreement and/or Contract unless the Customer has relied on them and entered into the Agreement and/or Contract on that basis; and

### any invoice or quotation provided by the Supplier.

For the avoidance of doubt, both Parties agree and acknowledge that any terms and conditions attached to any invoice or quotation provided by the Supplier shall have no effect and shall not form part of the Agreement and/or any Contract.

## In this Agreement, unless the context requires otherwise, the following rules apply:

### A person includes a natural person, corporate or unincorporated body (whether or not having separate legal personality).

### A reference to a Party includes its personal representatives, successors or permitted assigns.

### A reference to a “Party” or the “Customer” shall be interpreted to include a Framework Purchaser in the context of a provision relating to a Contract entered into between the Supplier and a Framework Purchaser.

### A reference to a statute or statutory provision is a reference to such statute or provision as amended or re-enacted. A reference to a statute or statutory provision includes any subordinate legislation made under that statute or statutory provision, as amended or re-enacted.

### Any phrase introduced by the terms “including”, “include”, “in particular” or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

## The Supplier undertakes to comply with the provisions of the Quality Technical Agreement as set out in Schedule 6.

# Duration and Commencement

## The Agreement shall commence on July 1, 2022 (the “**Effective Date**”) and, subject to earlier termination in accordance with Clause 20 shall continue for a period of 2 years (the “**Term**”).

## No renewals of the Agreement will be allowed.

# Goods

## The Supplier is appointed to provide the goods in the following categories:

* + Pharmaceuticals;
  + Laboratory and diagnostic products;
  + Medical devices, equipment and consumables;
  + Emergency kits
  + Vaccines.

Items commonly bought by the Customer in each of the above categories are listed in Schedule 0. The lists in Schedule 10 are not exhaustive, and the Supplier may be requested to provide other goods in the above categories (any such goods ordered under a Contract entered into in accordance with this Agreement are referred to herein as the “**Goods**”).

## The Customer and/or any Framework Purchaser may, at its absolute discretion and from time to time during the Term of the Agreement, order specific Goods from the Supplier using the Purchase Order Form (“**Order**”).

## Each Purchase Order Form in respect of any individual Order of Goods will be deemed to incorporate all of the terms of this Agreement (including, for the avoidance of doubt, the Quality Technical Agreement). Each applicable Purchase Order Form (including the terms of this Agreement as incorporated therein) will form a separate “**Contract**” between the Supplier and the Customer and/or any Framework Purchaser.

## The Parties acknowledge and agree that:

### the supply of Goods under this Agreement is not an exclusive arrangement;

### the Customer may purchase from any third party, goods that are the same as, or comparable to, the Goods; and

### the Supplier may supply to any third party, goods that are the same as, or comparable to, the Goods.

## No undertaking nor any form of statement, representation or obligation shall be made or be deemed to have been made by the Customer in respect of the total quantities or purchase values of the Goods to be ordered by Customer pursuant to this Agreement, and the Supplier acknowledges and agrees that it has not entered into this Agreement on the basis of any such undertaking, statement or representation.

# Price for the Goods

## The total price for Goods will be set out in a Purchase Order Form and shall be calculated in accordance with the reference rates set out in Schedule 1.

## The prices for the Goods (specified in Schedule ‎1) shall be fixed until 6 months after the Effective Date. At this point, the Supplier reserves the right to provide updated prices against Customer’s product lists (as per Schedule 1) and, should the Customer confirm its agreement to these revised prices in writing, the prices will be considered to form part of this Agreement.

## The Supplier shall:

### provide a competitive price for the Goods at all times; and

### advise the Customer of potential savings for every Order placed by the Customer.

## Unless stated in Schedule 10 or the applicable Purchase Order Form, prices shall be deemed to include packing, labelling, carriage, insurance, storage, royalties and intellectual property licence fees (if applicable), quality assurance and quality control costs and all other charges, taxes, duties and impositions and shall not be subject to alteration for any reason whatsoever.

# Invoicing and payment

## Invoices for the Goods supplied under a Contract shall be sent on, or after, delivery of the Goods to the Customer’s satisfaction. Each invoice must quote the Order number, be in the currency stated in Schedule 3 and addressed to the contact specified in Schedule 4.

## Except where expressly stated in the Purchase Order Form, undisputed amounts of correctly rendered invoices will be paid either within 45 days from the date of invoice or within 45 days of delivery, whichever is the later.

## Supplier shall be entitled to charge interest if the Customer fails to pay undisputed amounts in accordance with Clause 5.2, such interest to be charged at the rate of 2% above the Bank of England base rate.

## Without prejudice to its rights in Clause 9.1, the Customer reserves the right to withhold payment or (where payment was already made) request and promptly receive a reimbursement in respect of Goods supplied which are defective, rejected or otherwise not in accordance with the requirements of the applicable Contract, and/or the applicable provisions of this Agreement (including the Quality Technical Agreement), provided that the Customer shall, on request, provide reasonable supporting documentation or other evidence that such defect was not caused by the Customer. For the avoidance of doubt, any Goods supplied to the Customer which are, in the reasonable opinion of the Customer, either falsified or counterfeit are deemed to be defective goods in accordance with Clause 8.18.

## The Customer may, without limiting any other rights or remedies it may have, set off any amount owed to it by the Supplier against any amounts payable by it to the Supplier under the Agreement and/or any Contract.

## All invoices provided under this Contract must be accurate and complete including a correct purchase order number. Where any invoice provided under this Contract is rejected by the Customer on the grounds that the invoice is inaccurate or incomplete, including if the purchase order number is inaccurate or missing, the Supplier shall re-submit a corrected invoice upon the Customer’s request and the date of invoice shall be amended accordingly.

# Change to Goods and Unavailability of Goods

## For each Order, the Customer may at any time, in writing, make reasonable changes to the Goods described in a Purchase Order Form. If any changes cause an increase or decrease in the cost of, or the time required for the supply or performance of, such Goods, an equitable adjustment shall be made in Supplier’s fee or delivery schedule, or both. Any Supplier claim for an adjustment must be asserted within 10 days following Supplier’s receipt of the change notification, and must be approved in writing by the Customer. If such adjustment cannot be agreed, the Customer may revert to the original specification or cancel the Order in which case it will reimburse the Supplier for any direct costs reasonably incurred and documented by the Supplier prior to cancellation, which costs the Supplier will take all reasonable steps to minimise.

## The Customer may at any time, in writing, make reasonable changes to the Goods in accordance with Clause 26.6.

## The Supplier shall promptly give notice to the Customer in the event that the Supplier considers there is a reasonable chance that it will be unable to supply, or there will be delays in the supply of the Goods as described in:

### a Purchase Order Form; or

### Schedule 1 to this Agreement.

## If the Supplier gives notice under Clause 6.3(a), the Customer will have the right to terminate the relevant Contract in accordance with Clause 20.1. If the Supplier gives notice under Clause 6.3(b), the Parties may amend the description of Goods in Schedule 1 or in the applicable Purchase Order Form in accordance with Clause 26.6.

# The Goods

## The Supplier represents and warrants that it has the right to and shall sell the Goods free of any charge, lien or other encumbrance.

## In providing the Goods, the Supplier shall ensure that the Goods:

### correspond with their description in the Purchase Order Form for that Order, the Quality Technical Agreement, the applicable specifications set out in this Framework Agreement and if applicable, any other specification or quality documentation agreed by the Parties;

### meet the international standards for quality relevant to the type of Good, where applicable and are supplied to the Customer in line with Good Manufacturing Practices and Model Quality Assurance System for Procurement Agencies (MQAS), and that are in line with the National Essential Drug List (NEDL) in the country in which they will be used;

### where applicable, are of satisfactory quality (within the meaning of the UK Sale of Goods Act 1979, as amended or any comparable Applicable Law) and fit for any purpose held out by the Supplier or made known to the Supplier by the Customer expressly or by implication, and in this respect the Customer relies on the Supplier’s skill and judgment;

### are new, and have not been rejected by any other entity prior to their supply to the Customer;

### unless the Parties agree otherwise in writing, have a shelf life (to the extent applicable) of the longer of: (i) the period set out in Schedule 1 to this Agreement; (ii) 2 (two) years from the date of delivery in accordance with Clause 8; or (iii) where the shelf life is less than 2 years at the time of manufacture, at least 75% of the shelf life remains as a minimum for the relevant Goods;

### are free from defects in workmanship, material and design;

### comply with all Applicable Laws in the country (or countries, if different) of manufacture, delivery and end use, including, without limitation, relating to the manufacture, labelling, packaging, storage, handling and distribution of the Goods;

### are stored and shipped under such storage conditions as are set out in the Quality Technical Agreement and otherwise as appropriate to ensure that the Goods are maintained in good condition at all times during the delivery process including, without limitation, as set out in Clause 8 below and the applicable provisions of the Quality Technical Agreement; and

### do not infringe the rights of any third party or cause the Customer to infringe any such rights.

## The Supplier shall not do or omit to do anything that may cause the Customer to lose any licence, authority, consent or permission on which it relies for the purposes of conducting its business, and the Supplier acknowledges that the Customer may rely or act on the Goods.

## The Supplier represents and warrants that it has obtained and shall make available to the Customer all licences, clearances, permissions, authorisations, consents and permits necessary to carry out its obligations under the Agreement.

## The Supplier shall not treat the Customer in any manner less favourable in supply of the Goods than the Supplier treats its other customers with respect to the Goods, including if there is a supply shortage that affects both Parties or that affects the Customer and the Supplier’s other customers.

## The Customer reserves the right at any time before or after delivery, to inspect and test the Goods, and inspect the premises where the Goods are being manufactured and/or stored. The Customer’s inspector may adopt any reasonable means to satisfy himself or herself that, inter alia, the correct materials, workmanship and/or care and skill are or have been used.

## If following such inspection or testing the Customer considers that the Goods do not conform or are unlikely to comply with any of the Supplier’s undertakings at Clause 7.2, the Customer shall inform the Supplier and at its discretion may exercise its rights under Clauses 8, 9 and 10.

## Notwithstanding the outcome of any such inspection or testing, the Supplier shall remain fully responsible for the Goods and the outcome of any such inspection or testing shall not reduce or otherwise affect the Supplier’s obligations under the Agreement, and the Customer shall have the right to conduct further inspections and tests after the Supplier has carried out its remedial actions.

## All Goods must be stored and shipped under such storage conditions as are appropriate to ensure that the Goods are maintained in good condition at all times during the delivery process, including, without limitation, as specified in the Quality Technical Agreement.

# Delivery

## The Supplier shall ensure that:

### the Goods are packed in a validated container using a validated method and secured in such manner as to maintain the quality and integrity of the product up until the arrival at the agreed destination, as further set out in the Purchase Order Form and/or Quality Technical Agreement;

### each delivery of the Goods is accompanied by (i) a delivery note which shows the date of the Order, the Order number (if any), the type and quantity of the Goods (including the code number of the Goods, where applicable), special storage instructions (if any) and, if the Goods are being delivered by instalments, the outstanding balance of Goods remaining to be delivered; and (ii) any other documentation required by the Quality Technical Agreement and this Agreement;

### it is available at the request of the Customer at all times, including outside normal business hours, in order to address the requirements of any emergency in a timely fashion.

## The Supplier shall deliver the Goods to the agreed destination as set out in the Purchase Order Form in accordance with the lead times specified in Schedule 7, ‘Service Level Agreements,’ or as otherwise instructed by the Customer or, where the Goods are being collected by the Customer (or an agent on its behalf) from the Supplier (or its agent’s) premises, shall ensure that the Goods are ready and available for collection by the Customer in accordance with the lead times specified in Schedule 7.

## Time shall be of the essence in respect of this Clause 8. If the Supplier fails to comply with the time requirement referred to in this Clause 8, the Customer, without prejudice to its other rights under the Contract, shall be under no obligation to make payment in respect of any Goods that are not accepted and shall have the right to cancel the relevant Order.

## Delivery shall be made and collection shall be available during the Customer’s usual business hours unless otherwise agreed.

## Ownership in the Goods will pass on the completion of the physical transfer of the Goods from the Supplier or its agents to the Customer or its agents at the agreed destination as set out in the Purchase Order Form. The Supplier shall be responsible for all quality matters set out in, and required by, the Quality Technical Agreement until the transfer of ownership of Goods to the Customer (or its agent). Following such transfer, the Customer (or its agent) shall be responsible for all such quality matters under the Quality Technical Agreement.

## Subject to Clause 8.8, risk of damage to or loss of the Goods (including, without limitation, the risk of deterioration in transit) shall pass to the Customer either:

### in accordance with the relevant provision of Incoterms identified in the Purchase Order Form; or

### where Incoterms are not specified for any reason or do not apply, the risk in the Goods shall pass to the Customer on completion of physical delivery or collection.

## Notwithstanding the provision of Clause 8.6(a), where the Supplier is delivering the Goods to the recipient country, the Supplier shall be responsible for obtaining at its own cost, such export licences and other consents in relation to the Goods as are required.

## The Supplier shall keep the Goods insured until risk passes to the Customer and shall retain the insurance and any proceeds thereof together with all its rights against any carrier of the Goods, on trust for the Customer until the Supplier has fulfilled all its obligations under the Contract and this Agreement (including, without limitation, the Quality Technical Agreement) to the Customer’s satisfaction.

## Where the Supplier is required to demonstrate to its local licencing authority that it has met its obligations for export, it shall collate all required documentation and permits (including, without limitation, any export licenses or authorizations) to ensure that the Goods are cleared for export and deliver the same to the Customer or its agent.

## Unless otherwise agreed in the Contract between the Supplier and the Customer with respect to importation of Goods into the country of delivery, the Supplier shall support and assist the Customer in any way required by local law, or as may reasonably be necessary or desirable, to provide documents required by the Customer to facilitate importation of Goods and prompt clearance through customs in the country of delivery.

## Notwithstanding Clause 8.10, upon receipt of a full set of shipping documents by the Customer or its agent, the Customer shall ultimately be responsible for ensuring that the Goods are authorised for importation by the government in the country of delivery, and cleared through customs.

## Upon dispatch, the Supplier will immediately dispatch to the Customer by email unless otherwise agreed and the consignee by courier the following documents listed and any other documents requested on the Order and/or the Quality Technical Agreement:

* + 1. Two certified commercial invoices showing the price of Goods
    2. Two Certificates of Origin.
    3. Two Certificates of Analysis, where applicable.
    4. Two Certificates of Conformity, where applicable.
    5. Two original copies of packing list, and
    6. SCI Certification of donation, if required, which will be supplied by the Customer.

## Where the Supplier is providing international transportation services, the Supplier should also provide, in addition to any documentation set out in the Quality Technical Agreement:

* + 1. one original and two copies of the negotiable, clean, on-board bill of marked “Freight prepaid” and two copies of non-negotiable bill of landing when Goods are sent through sea or Original Air way bill when Goods are sent through air;
    2. two copies of the Insurance Certificate, if required; and
    3. Two copies of the Supplier’s/manufacturer’s warranty, if required.

## The Customer may also request the following documents, which the Supplier must be able to provide if requested:

* + 1. Good Manufacturing Practices Certificate for the source manufacturer and manufacturing site of each product;
    2. International Organization for Standardization Certificate (ISO) as appropriate or equivalent certification from any Stringent Regulatory Authority;
    3. Certificate of Finished Pharmaceutical Products (COPP);
    4. Registration documents in manufacturing country and/or Stringent Regulatory Authority Country; and
    5. Any other document that may be specified in this Agreement (including any Schedule (including, without limitation, the Quality Technical Agreement)), or at the time of each procurement process and/or Purchase Order Form.

## If any Goods/services are not supplied on or by the agreed date then in accordance with the lead times specified in Schedule 7 (or any extended date agreed in writing between the Parties), the Customer shall, without prejudice to its other remedies, be entitled to deduct 1% of the overall price of the Goods ordered by way of that Purchase Order Form, for each week’s delay, up to a total of 10% of such overall price. The Parties agree that such deduction under this Clause 8.15.

### represents a price adjustment by way of refund for the value of the Supplier’s failure to meet the standard specified in the relevant Purchase Order Form;

### reflects the Customer’s legitimate interest in preventing the Supplier from failing to meet the standard specified in the relevant Purchase Order Form because of the adverse impact that such failure would have on the business of the Customer;

### has been negotiated by Parties of similar bargaining strength who have had the benefit of legal advice; and

### shall not preclude the Customer from recovering damages for the actual losses suffered by it (provided that such damages shall be reduced by an amount equal to the deductions levied by the Customer in respect of the same losses).

## The Customer shall not be deemed to have accepted any Goods until the Customer has had 30 days to inspect them following delivery or, if later, within 30 days after any latent defect in the Goods has become apparent. Signature of a delivery note shall not constitute or imply acceptance by the Customer. For the avoidance of doubt, payment will not be considered as being an acceptance of the Goods or acknowledgement of receipt by the Customer who, without prejudice to any other right or remedy, has the right to reject the Goods and request reimbursement in case of non-compliance with the requirements of the present Contract.

## The Customer shall not be obliged to return to the Supplier any packaging or packing materials for the Goods, whether or not any Goods are accepted by the Customer.

## The Customer shall be entitled to reject any Goods delivered which do not conform with the Contract (such Goods being “**Defective Goods**”) within a reasonable time of delivery. If any Goods are so rejected, at the Customer’s option, the Supplier shall forthwith re-supply replacement Goods which conform with the Contract. Alternatively, the Customer may cancel the Contract and claim costs and direct damages from the Supplier.

## If the Customer rejects any Goods, the property and risk shall immediately revert to the Supplier. Defective Goods shall be returned to the Supplier at its expense and the Supplier shall reimburse the Customer for the storage costs and any other expenses incurred by the Customer in respect of them.

# Customer Remedies

## Without prejudice to the provisions of the Quality Technical Agreement, if the Goods are not delivered in accordance with the applicable Contractorif following inspection or testing the Customer considers that the Goods do not conform or are unlikely to comply with the Supplier’s undertakings at Clause 7.2, whether or not it has accepted, acknowledged receipt or paid for the Goods, the Customer may exercise any one or more of the following remedies:

### to terminate the Agreement or the applicable Contract;

### to reject the Goods (in whole or in part);

### to require the Supplier to repair or replace the rejected Goods at its own cost and expense, or to provide a full refund of the price of the rejected Goods (if paid);

### to refuse to accept any subsequent delivery of the Goods which the Supplier attempts to make;

### to recover from the Supplier any costs incurred by the Customer in obtaining substitute goods from a third party; and

### to claim damages for any other costs, loss or expenses incurred by the Customer which are in any way attributable to the Supplier’s failure to carry out its obligations under the Contract including storage costs.

## If any Goods are so rejected, the property and risk shall immediately revert to the Supplier and the Supplier shall arrange for and bear the risk and expenses associated with the destruction or return of the rejected Goods.

# Recall

## If the Supplier intends to carry out a Recall of the Goods, or is the subject of a request, court order or other directive of a government or regulatory authority requiring or implementing a Recall which concerns any of the Goods, it will immediately (but within 24 hours at the latest) notify the Customer in writing (enclosing a copy of the relevant communication if requested by the Customer) (the “**Recall Notice**”).

## The Recall Notice will, inter alia, provide the following information:

### the name(s) and means of identifying the specific Good(s) impacted by the Recall (e.g. batch / lot numbers, Unique Device Identification (UDI), affected pack sizes etc.);

### the territorial scope of the Recall;

### any associated deadlines with which the Goods must be recalled by;

### the reason(s) for the Recall and any risks identified to patients, users or any other personnel, associated with the supply and use of the Good(s);

### specific instructions as to how the Customer is to facilitate the Recall; and

### information on how the Supplier intends to investigate the root cause of the Recall and plans to remedy any associated deficiencies.

## Without prejudice to Clause 15, the Supplier will promptly reimburse all reasonably incurred costs and expenses, including administrative and personnel costs, of the Customer or its agents relating to the Recall and any destruction costs reasonably incurred by the Customer.

## The Supplier will provide all reasonably necessary assistance and cooperation requested by the Customer in implementing any Recall.

## Without prejudice to any other remedies available to it, the Customer shall be entitled to request, at Customer’s option, either:

### a full refund from the Supplier with respect to the payment of any Good(s) which are subject to Recall, such refund to be paid within 28 days;

### credit against future orders to the value of the Good(s) which were subject to Recall; or

### replacement by the Supplier of the Good(s) which are subject to Recall, on a like-for-like basis, such replacement to be dispatched promptly by Supplier but within 14 days of Customer providing written notice of a request for replacement.

## For the avoidance of doubt, in the event that replacement Good(s) are requested in accordance with sub-Clause 10.5(c), Customer shall bear no liability for any price increases related to such replacement Good(s).

# Warranties

## The Supplier warrants to the Customer that:

### it has the power and authority to enter into and perform this Agreement and any Contract and such performance will not conflict with any contract or obligation entered into by it, its constitutional documents and any law or regulation applicable to it;

### it has all authorisations from all relevant third parties to enable it to supply the Goods without infringing any Applicable Law, code or practice or any third party’s rights and has all necessary internal authorisations to approve the execution and performance under the Agreement and/or any Contract and will produce evidence of that action to the Customer on its request;

### it will ensure that the Customer is made aware of all relevant requirements of any Applicable Law, or code of practice which applies or is relevant to the supply of the Goods to the Customer;

### information in written or electronic format supplied by, or on behalf of, the Supplier to the Customer at any stage during the tender process, the negotiation process, the due diligence process or the term of the Agreement was complete and accurate in all material respects at the time it was supplied, and any amendments or changes to the previously supplied information will be provided to the Customer without delay;

### the Supplier, and all of its directors, officers, employees, affiliates, agents, suppliers and subcontractors, are not themselves, and are not or owned or controlled by any party that is, targeted by any Sanctions and Export Control Laws;

### the Supplier is not aware of, and does not have any reason to suspect, any breach of Clause 13, and it is not aware and does not have any reason to suspect that performance of this Contract would put either Party at risk of breaching any Sanctions and Export Control Laws;

### it will not and will procure that none of its employees will accept any commission, gift, inducement or other financial benefit from any supplier or potential supplier of the Customer;

### none of its directors or officers or any of the employees of the Supplier has any interest in any other supplier or potential supplier of the Customer or is a party to, or are otherwise interested in, any other transaction or arrangement with the Customer;

### it shall comply with all applicable statutory and regulatory requirements applicable to the Goods in accordance with Clause 13.1;

### all Goods will have at least the minimum shelf life referred to at Clause 7.2(e); and

### it shall comply with the obligations set out in Clause 28.

## In case of any situation constituting or likely to lead to a breach of a warranty in Clause 11.1 during the Term of the Agreement, without prejudice to any other right or remedy available to the Customer, the Supplier shall:

### notify the Customer in writing and without delay of such breach; and

### take all necessary steps to rectify this situation including replacement of the relevant Goods where appropriate.

The Customer reserves the right to verify that the measures taken are appropriate and to request additional steps are taken within a specified time period. Failure to implement the requested measures may lead to the termination of the Agreement and/or any Contract. These rights are without prejudice to the Customer’s rights in Clause 20.

# Key contacts and service reviews

## The relevant contacts are as follows:

|  |  |  |
| --- | --- | --- |
|  | **Customer Contact** | **Supplier Contact** |
| *First contact* | **Name:**  **Address:**  **Email:**  **Tel:**  **Mobile:** | **Name:**  **Address:**  **Email:**  **Tel:**  **Mobile:** |
| *Second contract* | **Name:**  **Address:**  **Email:**  **Tel:**  **Mobile:** | **Name:**  **Address:**  **Email:**  **Tel:**  **Mobile:** |

## Purchase Order Forms may only be issued by a person named in this Framework Agreement as a Customer Contact in Schedule 4.

## The Customer reserves the right to conduct a formal review of the Agreement after 12 months of the Effective Date.

## The Parties shall carry out regular reviews of the Agreement every month or as otherwise agreed. The review meetings shall comprise the Contacts named in this Clause 12.

# Compliance

## The Supplier, its suppliers and sub-contractors shall observe the highest ethical standards and comply with all Applicable Laws, statutes, regulations and codes (including environmental regulations and the International Labour Organisation’s international labour standards on child labour and forced labour) from time to time in force in the country (or countries if different) of manufacture, delivery and end use of the Goods.

## The Supplier, its suppliers and sub-contractors shall not in any way:

### engage in transactions with, or provide resources or support to armed groups, individuals and entities which are sanctioned, or individuals and organisations associated with terrorism, or otherwise be involved directly or indirectly with terrorism,

### be involved directly or indirectly in the manufacture or sale of arms;

## have any business relations with governments for any war related purpose; or transport the Goods together with any military equipment. The Supplier shall (and shall also require that all of its directors, officers, employees, affiliates, agents, staff, suppliers and subcontractors shall):

### comply with all sanctions, export control, embargo, or similar laws, regulations, rules, measures, restrictions, restricted or designated party lists, licences, orders, or requirements, in force from time to time, including without limit those of the EU, the UK, the US and the UN (“**Sanctions and Export Control Laws**”), as applicable, and maintain policies and procedures designed to ensure continued compliance with such Sanctions and Export Control Laws;

### obtain any licences, authorisations or permissions required under the Sanctions and Export Control Laws or other Applicable Laws that are required to export, import, supply, sell, transport, or broker any hardware, software, technology, support or assistance or service that is provided by or on behalf of the Supplier under this Framework Agreement (including, but not limited to, obtaining any required export licences required for the export of goods by or on behalf of the Supplier to the Customer or its agents or any of the Framework Purchasers or their agents at the relevant delivery address), and shall further inform the Customer and the Framework Purchasers where any such hardware, software, technology, support or assistance or service provided is subject to controls or restrictions under the Sanctions and Export Control Laws and shall provide all relevant information that may be required by the Customer or any of the Framework Purchasers to apply for or obtain any further licences, authorisations or permissions.

### not make any funds or economic resources available, directly or indirectly, to or for the benefit of, any person or entity that is currently listed under or otherwise directly or indirectly targeted by any Sanctions and Export Control Laws (including any funds or economic resources paid by the Supplier on behalf of the Customer or any of the Framework Purchasers or received by the Supplier from the Customer or any of the Framework Purchasers in accordance with this Framework Agreement);

## The Supplier must ensure that it provides to the Customer the names and dates of birth of its key staff in order that the Customer can screen these names against sanctions lists, using the Customer’s third party screening provider. Before providing the names to the Customer, the Supplier must ensure that all its key staff have been informed that their names will be provided to the Customer for screening using a third party provider, and, if necessary, the Supplier has sought their consent.

### the Supplier must ensure that it regularly checks its staff, suppliers and sub-contractors against sanctions lists and must immediately inform the Customer of any apparent correlation.

### not do anything which would cause the Customer or any of the Framework Purchasers to be in breach of any Sanctions and Export Control Laws (including but not limited to supplying items from country of origin which would mean that any conceivable supply or use of these items would be restricted under the Sanctions and Export Control Laws).

## No provision of this Agreement shall give rise to an obligation on either Party that would constitute a breach of Council Regulation (EC) No 2271/96 (as amended) or other equivalent blocking or anti-boycott laws applicable from time to time.

## The Supplier shall commit to the Customer’s zero tolerance approach towards sexual exploitation and abuse, harassment, sexual harassment, intimidation and bullying. The Supplier, and its suppliers and sub-contractors shall not in any way engage in any actual, attempted or threatened:

### sexual exploitation or abuse of a child or children, including but not limited to physical or emotional abuse, exploitation, neglect or any other form of maltreatment;

### sexual exploitation or abuse of adults in vulnerable populations, including but not limited to the Customer’s adult beneficiaries, and the Customer’s staff and representatives; and

### sexual harassment, harassment, intimidation or bullying of the Customer’s staff, representatives or of anyone you come into contact with while delivering the terms of this Contract.

## The Supplier shall ensure that its employees, suppliers and sub-contractors are aware of, understand, and adhere to the Customer’s:

### Child Safeguarding policy;

### Fraud, Bribery and Corruption policy;

### Human Trafficking and Modern Slavery policy;

### Protection from Sexual Exploitation and Abuse (PSEA) policy; and

### Anti-Harassment, Intimidation and Bullying policy,

### (together, the “Mandatory Policies”) attached as Schedule 5.

## The Supplier shall take reasonable steps (including but not limited to having in place adequate policies and procedures) to ensure it conducts its business (including its relationship with any contractor, employee, or other agent of the Supplier) in such a way as to comply with the Mandatory Policies, and shall upon request provide the Customer with information confirming its compliance.

## The Supplier shall notify the Customer as soon as it becomes aware of any breach, or suspected or attempted breach, of the Mandatory Policies, and shall inform the Customer of full details of any action taken in relation to the reported breach.

## The Supplier shall cooperate with the Customer on any investigations into alleged breaches of the Mandatory Policies, including but not limited to inspection and access to documents and personnel related to the breach, suspected or attempted breach.

## The Customer may provide training or materials to the Supplier on protecting children and vulnerable populations from sexual exploitation and abuse, and on anti-harassment, intimidation and bullying. The Supplier shall, at the Customer’s request, share any training or materials with any contractor, employee or other agent of the Supplier who will come into direct contact with the Customer’s personnel, beneficiaries or members of the vulnerable population, through the performance of the terms of this Contract.

## The Supplier, its suppliers and sub-contractors shall be subject to, and shall in relation to the Agreement and any Contract act in accordance with, the IAPG Code of Conduct appearing in Schedule 0 (Part 4) and any local or international standards which are applicable to the Goods.

# Audit

The Supplier agrees to allow the Customer’s (and the “Framework Purchasers”) employees, agents, professional advisers or other duly authorised representatives to inspect and audit all the Supplier’s books, documents, papers and records and other information, including information in electronic format, and including information regarding the Supplier’s current and former personnel and other relevant Personal Data held by the Supplier, for the purpose of making audits, examinations, excerpts and transcriptions and for the purpose of verifying compliance with the requirements of Clause 13 (including for 10 (ten) years following the date of termination of the Agreement). The Supplier agrees the extension of such rights to duly authorised representatives of the European Commission, the European Court of Auditors and the European Anti-Fraud Office (“OLAF”), the United States Government, the Controller General of the United States and any other representatives instructed by a donor organisation of the Customer to carry an audit of the Supplier’s operations. The Supplier shall ensure that, it has informed each person whose Personal Data is being provided to/accessed by any person or entity pursuant to this clause, of the information shared and the purpose of sharing such data before providing/allowing access to the data and, where necessary, obtained such person’s consent.

# Indemnity

## The Supplier shall keep the Customer indemnified in full against all costs, expenses, damages and losses (whether direct or indirect), including any interest, penalties, and legal and other professional fees and expenses awarded against or incurred or paid by the Customer as a result of or in connection with:

### breach of any warranty given by the Supplier in Clause 11;

### personal injury, death or damage to property caused to the Customer or its employees, agents or subcontractors (excluding the Supplier) arising out of, or in connection with the acts or omissions of the Supplier, its employees, agents or subcontractors;

### any claim made against the Customer for actual or alleged infringement of a third party’s intellectual property rights arising out of, or in connection with, the supply or use of the Goods;

### any claim made against the Customer by a third party arising out of, or in connection with, the supply of the Goods, to the extent that such claim arises out of the breach, negligent performance or failure or delay in performance of the Agreement and/or any Contract by the Supplier, its employees, agents or subcontractors;

### any claim made against the Customer by a third party for death, personal injury or damage to property arising out of, or in connection with, defects in the Goods, to the extent that the defect in the Goods is attributable to the acts or omissions of the Supplier, its employees, agents or subcontractors;

### any claim in respect of death or personal injury howsoever caused to any of the employees of the Supplier whilst at the premises of the Customer save where caused by the direct negligence of the Customer or its respective employees or agents;

### where Defective Goods have been dispatched by or on behalf of the Customer, the cost of recalling any Defective Goods and their subsequent destruction or return to the Supplier; and

### all wasted administrative and personnel costs of the Customer or its agents relating to Defective Goods as well as all costs associated with advising, screening, testing, treating or otherwise providing healthcare in relation to Defective Goods.

# Customer property

The Supplier acknowledges that all materials, equipment and tools, drawings, specifications, and data supplied by the Customer to the Supplier (“**Customer Materials**”) and all rights in the Customer Materials are and shall remain the exclusive property of the Customer. The Supplier shall keep the Customer Materials in safe custody at its own risk, maintain them in good condition until returned to the Customer, and not dispose or use the same other than in accordance with the Customer’s written instructions or authorisation.

# Customer’s name, branding and logo

The Supplier shall not use the Customer’s name, branding or logo other than in accordance with the Customer’s written instructions and/or authorisation.

# Re-tendering

The Supplier undertakes to fully co-operate with the Customer in relation to any tender process which may, at the option of the Customer, be carried out at any time in relation to the supply of any of the Goods, including in the event that the Supplier is unsuccessful in any tender process.

# Insurance

## During the Term of the Agreement, the Supplier shall maintain in force, with a reputable insurance company, professional indemnity insurance, product liability insurance, public liability insurance and any other insurances it is required to maintain by Applicable Law to cover such heads of liability as may arise under or in connection with the Agreement and/or any Contract, and shall, on the Customer’s request, produce both the insurance certificate giving details of cover and the receipt for the current year’s premium in respect of each insurance.

## The Supplier shall keep the Goods insured until risk passes to the Customer and shall retain the insurance and proceeds thereof together with all its rights against any carrier of the Goods, on trust for the Customer until the Supplier has fulfilled all its obligations under the Contract to the Customer’s satisfaction.

# Termination

## The Customer may terminate the Agreement and/or any Contract in whole or in part at any time and for any reason whatsoever by giving the Supplier at least one (1) month’s written notice.

## The Customer may terminate the Agreement and/or any Contract with immediate effect by giving written notice to the Supplier and claim any losses (including all associated costs, liabilities and expenses including legal costs) back from the Supplier at any time if:

### the Supplier is in material breach of its obligations under the Agreement (including the Quality Technical Agreement and its other Schedules) and/or any Contract;

### the Supplier is in breach of its obligations under the Agreement (including the Quality Technical Agreement and any other Schedules) and/or any Contract and fails to remedy such breach (where the breach is capable of remedy) within 14 (fourteen) days of written request;

### the Supplier becomes insolvent or makes any voluntary arrangement with its creditors or (being an individual or corporate entity) becomes subject to an administration order or goes into liquidation or the Supplier ceases, or threatens to cease, to carry on business;

### the Customer reasonably believes that any of the events mentioned above in paragraphs (a) through (c) is about to occur in relation to the Supplier and notifies the Supplier accordingly;

### the Customer reasonably believes that (i) the Supplier, or any of its directors, officers, employees, affiliates, agents, suppliers and subcontractors has breached Clause 13, or (ii) the Supplier, or any of its directors, officers, employees, affiliates, agents, suppliers and subcontractors is listed under or otherwise directly or indirectly targeted by, any Sanctions and Export Control Laws, or (iii) continued performance of this Contract would otherwise be restricted by, or would put either Party at risk of breaching, any Sanctions and Export Control Laws;

### the Customer believes, in its sole and absolute discretion, that continuing contractual relations with the Supplier may damage the reputation and/or resources of the Customer;

### the Customer believes, in its sole and absolute discretion, that the Supplier has or is engaged in corrupt, fraudulent, collusive or coercive practices or may have failed to comply with any laws relating to prohibited parties, terrorism or money laundering or has or is likely to breach the requirements of Clause 13; or

### a donor ceases to provide the necessary funds for the Goods or requires the Customer in writing to terminate the Agreement and/or a Contract.

## Termination of Agreement and/or any Contract shall not affect:

### Clauses 1.2, 1.3, 21, 22, 23, 26.2, 26.7 and 27. which shall continue without limit in time;

### the Parties’ obligations existing under each Contract still in force at the time of termination, which shall survive and remain binding on each Party until the date on which the Supplier has discharged all its obligations under the relevant Contract. For the avoidance of doubt, any on-going Contract shall continue after the termination of this Agreement until that Contract terminates under its own terms or by agreement of the Parties (as the case may be); and

### any rights, liabilities or remedies arising under the Agreement and/or any Contract prior to such termination.

## Subject to Clause 20.5 below, upon termination or expiry of this Framework Agreement, each party shall promptly on request from the other Party:

### return to the other Party all equipment, materials and property belonging to the other Party that the other Party had supplied to it in connection with this Framework Agreement but excluding any Goods supplied under this Framework Agreement or any Contract;

### return to the other Party all documents and materials (and any copies) containing the other Party's Confidential Information;

### erase all the other Party’s Confidential Information from its computer systems (to the extent possible); and

### certify in writing to the other Party that it has complied with the requirements of this Clause 20.4.

## The Supplier agrees that the Customer may retain documents and other records that contain the Supplier’s Confidential Information to the extent necessary for the Customer to comply with:

### the Customer’s obligations under Applicable Laws; or

### contractual obligations owed by the Customer to third parties but only if such third party has assumed a legally binding obligation to Customer that it shall treat that information confidentially.

# Confidential Information

## Subject to Clause 21.2 below, a Receiving Party shall:

### keep in strict confidence all Confidential Information provided directly or indirectly by a Disclosing Party, its employees, agents or subcontractors;

### restrict disclosure of Confidential Information to such of its employees, agents or subcontractors as need to know it for the purpose of discharging the Receiving Party’s obligations under this Agreement and/or any Contract; and

### ensure that such employees, agents or subcontractors are subject to obligations of confidentiality corresponding to those which bind the Receiving Party.

## Clause 21.1 shall not apply to Confidential Information to the extent that:

### the Confidential Information is required to be disclosed by law or any Governmental Authority. If the Receiving Party believes that this Clause 21.2(a) applies, it shall, as far as it is practicable and lawful to do so:

#### first consult the Disclosing Party to give the Disclosing Party an opportunity to contest the disclosure; and

#### take into account the Disclosing Party’s reasonable requirements about the proposed form, timing, nature and extent of the disclosure;

### the Confidential Information is required to be disclosed for the purpose of any arbitral or judicial proceedings arising out of the Agreement and/or any Contract and/or pursuant to the dispute resolution procedure in Clause 25;

### the Confidential Information is required to be disclosed to meet the obligations set out in Clause 13; or

### the Confidential Information is required to be disclosed by the Customer for the purposes of satisfying Customer’s obligations referenced to in Clause 20.5(b) above, such information to be limited to what is strictly necessary in the circumstances.

# Data processing

## The Supplier and the Customer shall comply with Applicable Privacy Laws with respect to any Personal Data related to Customer or its personnel provided in connection with this Agreement.

# Notices

## Any notice under or in connection with the Agreement and/or any Contract shall be given in writing to the address specified in the Agreement or to such other address as shall be notified from time to time in accordance with this clause. Notice shall be sent by prepaid first-class post, recorded delivery, e-mail or by commercial courier. All notices sent internationally shall be sent by courier or e-mail.

## Any notice shall be deemed to have been duly received:

### if sent by prepaid first-class post or recorded delivery, on the 2nd (second) day after posting;

### if delivered by commercial courier, on the date that the courier’s delivery receipt is signed; or

### if sent by e-mail, at 9:00am [London time] on the next [London] business day after transmission.

## This Clause 23 shall not apply to the service of any proceedings or other documents in any legal action. For the purposes of this provision, “writing” shall include e-mails.

# Force majeure

## Neither Party shall be liable for any failure or delay in performing its obligations under the Agreement and/or any Contract to the extent that such failure or delay is caused by a Force Majeure Event provided that, in the case of a Force Majeure Event affecting the Supplier, the Supplier shall use best endeavours to cure such Force Majeure Event and resume performance under the Agreement and/or any Contract.

## A “**Force Majeure Event**” means any event beyond a Party’s reasonable control, which by its nature could not have been foreseen, or, if it could have been foreseen, was unavoidable, including strikes, lock-outs or other industrial disputes (whether involving its own workforce or a third party’s), acts of God, war, terrorism, riot, civil commotion, interference by civil or military authorities, armed conflict, malicious damage, nuclear, chemical or biological contamination, sonic boom, explosions, collapse of building structures, fires, floods, storms, earthquakes, loss at sea, epidemics or similar events, natural disasters, or extreme adverse weather conditions.

## If any events or circumstances prevent the Supplier from carrying out its obligations under the Agreement and/or any Contract for a continuous period of more than 14 (fourteen) days, the Customer may terminate the Agreement and/or any Contract immediately by giving written notice to the Supplier in accordance with Clause 23.

# Dispute Resolution

## If any performance dates or service level is not met, or if a Party otherwise fails to perform its obligations under the Agreement and/or any Contract, then without prejudice to the Parties’ rights under the Agreement and/or any Contract, the relevant Party shall escalate the issue to the Customer and Supplier Contacts and then to their respective senior management for resolution (including agreeing any necessary changes or improvements within a settled timeframe).

## If having used reasonable endeavours to settle a dispute informally either Party considers the dispute cannot be so settled, either Party may give notice that the dispute is being referred to settlement by the courts of England and Wales, in accordance with Clause 27.

## Nothing in the Agreement shall prevent any Party from taking such action as it deems appropriate (including any application to a relevant court) for injunctive relief or other emergency or interim relief.

# General

## Assignment and subcontracting

### The Customer may assign, transfer, charge, subcontract, novate or deal in any other manner with any or all of its rights or obligations under the Agreement and/or any Contract upon providing Supplier with 30 days prior notice.

### The Supplier may not assign, transfer, charge, subcontract, novate or deal in any other manner with any or all of its rights or obligations under the Agreement and/or any Contract without the Customer’s prior written consent. Any subcontract shall allow the Customer the same rights of inspection and testing as set out in Clause 7.6 above.

### The Supplier acknowledges and agrees that it shall remain liable for any acts or omissions under a subcontract.

## Severance

### If any court or competent authority finds that any provision of the Agreement and/or any Contract (or part of any provision) is invalid, illegal or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of the Agreement and/or any Contract shall not be affected.

### If any invalid, unenforceable or illegal provision of the Agreement and/or any Contract would be valid, enforceable and legal if some part of it were deleted, the provision shall apply with the minimum modification necessary to make it legal, valid and enforceable.

## Waiver and cumulative remedies

### No waiver of any right or remedy under the Agreement and/or any Contract shall be effective unless it is in writing and signed by both Parties. No failure or delay by a Party in exercising any right or remedy under the Agreement and/or any Contract or by law shall constitute a waiver of that or any other right or remedy, nor preclude or restrict its further exercise. No single or partial exercise of such right or remedy shall preclude or restrict the further exercise of that or any other right or remedy.

### Unless specifically provided otherwise, rights arising under the Agreement and/or any Contract are cumulative and do not exclude rights provided by law.

## No partnership

Nothing in the Agreement and/or any Contract is intended to, or shall be deemed to, constitute a partnership or joint venture of any kind between the Parties, nor constitute any Party the agent of another party for any purpose. No Party shall have authority to act as agent for, or to bind, the other Party in any way.

## Third party rights

A person who is not a party to the Agreement and/or any Contract shall not have any rights under or in connection with it.

## Variation

Any variation to the Agreement and/or any Contract, including the introduction of any additional terms and conditions, shall only be binding when agreed in writing and signed by the Parties.

## Entire agreement

The Framework Agreement (including, for the avoidance of doubt, any schedules thereto) and any applicable Purchase Order Form entered into between the Parties, as well as the Quality Technical Agreement, set out the whole agreement between the Parties in respect of the provision of the Goods and supersede any previous draft, agreement, arrangement or understanding, whether in writing or not, relating to the provision of the Goods. It is agreed that:

### no Party has relied on or shall have any claim or remedy arising under or in connection with any statement, representation, warranty or undertaking made by or on behalf of the other Party in relation to the provision of the Goodsthat is not expressly set out in the Agreement and any applicable Purchase Order Form under which the relevant Goods are being provided; and

### any terms or conditions implied by law in any jurisdiction in relation to the provision of the Goods are excluded to the fullest extent permitted by law or, if incapable of exclusion, any rights or remedies in relation to them are irrevocably waived.

Nothing in this Clause 26.7 shall limit any liability for (or remedy in respect of) fraud or fraudulent misrepresentation.

# Governing law and jurisdiction

The Agreement and any Contract shall be governed by and construed in accordance with English law. The Parties irrevocably submit to the exclusive jurisdiction of the courts of England and Wales to settle any dispute or claim arising out of or in connection with the Agreement and any Contract or their subject matter or formation (including non-contractual disputes or claims).

# Special terms and conditions

## Specific requirements for procurement agencies, wholesalers and distributors:

The Supplier must:

### be registered, licensed and authorised to procure, distribute and export pharmaceutical goods by their National Drug Regulatory Authority (NDRA);

### comply with Good Distribution Practice standards;

### comply with Model Quality Assurance Systems for Procurement Agencies (MQAS), particularly concerning manufacturer prequalification and product selection, as detailed by the WHO;

### be able to provide a copy of the ISO certificate for each medical device;

### be able to conduct a robust product Recall process; and

### be able to supply batch samples for QC testing of every pharmaceutical, sterile, or diagnostic item procured, and for at least 1 year after the product’s expiry date.

## Specific requirements for Finished Pharmaceutical Products

Finished pharmaceutical products (each, a “**Finished Pharmaceutical Product**”) must:

### be manufactured in accordance with Good Manufacturing Practices;

### be manufactured to conform with globally recognised pharmacopeia standards (e.g. WHO International Pharmacopeia, European Pharmacopoeia (EP), British Pharmacopoeia (BP), United States Pharmacopeia Convention (USP));

### be batch tested and certified for quality and conformity to their specifications;

### be authorised and registered by the National Drug Regulatory Authority of the country of manufacture or destination for orders placed;

### be labelled in compliance with Council Directive 2004/27/EC and subsequent amendments. The following information must be included:

* + - * International non-proprietary name of the active ingredient
      * Dosage form (tablet, ampoule, vial, etc)
      * Strength of active ingredients in the dosage form
      * Batch number
      * Expiry date
      * Specific storage conditions
      * Name and address of manufacturer
      * Number of units per packing;

### Include directions for use and precautions in leaflets (package inserts), which are not an alternative to labelling but provide supplementary information. As a minimum the leaflet should contain:

* + - * International non-proprietary name of the active ingredient and excipients
      * Dosage form (tablet, ampoule, vial, etc) and way of administration
      * Strength of active ingredients in the dosage form
      * Pharmacological therapeutic family
      * Therapeutic indication, instructions of use and standard posologies
      * Side effects, incompatibilities, contraindications and use of precautions
      * Pharmaceutical interactions
      * Specific storage conditions
      * Name and site of manufacturer

### be packaged as follows:

* + - * Tablets and capsules should be packed in sealed, waterproof containers
      * Liquids should be packed in unbreakable, leak-proof bottles and containers
      * Ampoules should be packed in plastic or in trays and all trays packed in outer cartons.
      * Ampoules should be one-ended and auto-breakable.
      * Light-sensitive products should be protected from ultraviolet light.
      * Outer cartons should:

be of strong, export-quality material able to withstand rough handling and climate conditions during transport and storage.

only contain products with the same expiry date and batch numbers, this should be printed on the carton as well as on the immediate containers.

### In addition, all products requiring reconstitution before use, e.g. powder for injection or vaccines, should have relevant instructions specifying:

* + - * The diluent that should be used
      * The volume and nature of the diluent to be added.

## Specific requirements for medical devices, equipment and diagnostics:

All medical devices, equipment and diagnostics must:

### comply with European Council Directive 93/42/EEC of 14 Jun 1993 or Regulation (EU) 2017/745 as applicable.

### for in vitro diagnostic medical devices, comply with Council Directive 98/79/EC of 27 Oct 1998 or Regulation (EU) 2017/746 as applicable.

### have a manufacturer with an ISO 13485:2016 certification. When ISO 13485 does not apply, the quality management system should be certified in accordance with ISO 9001:2015.

### comply with the general requirements of the International Medical Device Regulators Forum (IMDRF) and the Global Harmonization Task Force (GHTF SG1-N41:2005); and

### have Conformité Européene (CE) marking for EEA, UKCA marking for the UK (if applicable) or an equivalent and accepted mark of conformity.

Medical devices such as syringes and needles should respect Conformité Européene (CE), Association Française de Normalisation (AFNOR) International Standard Organisation (ISO), or equivalent colour codes.

## Specific requirements for vaccines

### All vaccines should meet the requirements listed for Finished Pharmaceutical Products.

### In addition to the packaging information for Finished Pharmaceutical Products listed above, the following applies for vaccines:

#### Instructions for use of the vaccine and information concerning contraindications and the reactions that may follow vaccination.

#### Information on the reduced stability of the vaccine if exposed to temperatures higher than that stated on the label.

#### Warnings that the vaccine should be protected from direct sunlight.

If reconstituted, a statement regarding the timeframe in which the vaccine should be used and how it should be stored during this period.

In the case of EHU Emergency Kits only:

## The Supplier confirms it will only dispatch the EHU Emergency Kits after the receiving Customer office in the country of destination has confirmed in writing that their importation process has been completed and they are ready to receive the Goods. A quote for freight will be accepted by SCI issuing a separate purchase order for freight services. The Supplier also confirms that it shall not consider its responsibility for the EHU Emergency Kits complete until such kits are handed over as per the agreed Incoterms specified in the relevant Purchase Order Form.

### the Supplier shall be obliged to maintain the minimum stock levels detailed in Schedule 1 throughout the term of this Agreement, no storage charges shall apply for this stock. Such Goods will be stored by the Supplier in such a way as to ensure they can be dispatched within the time frames set out in Schedule 7.

### the Supplier shall ensure the EHU Emergency Kits maintained in stock on behalf of the Customer have a minimum shelf life of one year. For the avoidance of doubt, this means that the Supplier will ensure that the stock is rotated to ensure that no item of stock is stored for longer than one year throughout the term of this Agreement.

### The Supplier shall hold stock for all prepaid EHU Emergency Kits exclusively on behalf of the Customer and must incorporate such stock into the Supplier’s current stock holdings, available for dispatch at the request of the Customer through an approved order release request;

### the Supplier shall replenish the number of EHU Emergency Kits maintained in storage upon receipt of an approved Customer purchase order; and

### on termination or expiry of the Agreement, the Supplier agrees to continue to store any EHU Emergency Kits it has in stock until the Customer requests their dispatch to a location to be determined. Any dispatch will be governed by the provisions in this Agreement concerning product specifications, delivery and storage conditions.

## All stock will be held at Supplier’s warehouses at the following addresses:

THIS AGREEMENT is entered into by the Parties on the date above stated.

|  |  |
| --- | --- |
| **Signed for and on behalf of the Supplier**: | **Signed for and on behalf of the Customer**: |
|  |  |
| ………………………………………………. Signature | ………………………………………………. Signature |
| ………………………………………………. Name | ………………………………………………. Name |
| ………………………………………………. Position | ………………………………………………. Position |
| Date: | Date: |
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1. SCHEDULE 1
2. AVAILABLE GOODS,SPECIFICATIONS,CHARGES
3. SCHEDULE 2
4. PURCHASE ORDER FORM TEMPLATE

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SAVE THE CHILDREN** | | | |  |  |  |  |  |  | **PURCHASE ORDER** |
|  |  |  |  |  |  |  |  |  |  | Version No. 1.0 / 061121 |
| **This Purchase Order is issued subject to the terms and conditions and the policies contained in the contract or framework agreement governing the Goods and/or Services (as applicable), between the Customer and the Supplier. In the absence of such contract or framework agreement, this Purchase Order is issued subject to the terms and conditions overleaf and the policies contained at https://www.savethechildren.net/sites/www.savethechildren.net/files/SC-PR-13%20Purchase%20Order%20Mandatory%20Policies.pdf** | | | | | | | | | | |
| **Date:** | |  | | | | **PO No:** | | PO-Country(3 letters)-Office(3 letters)-year-sequence | | |
| **Reference to framework agreement/contract:** (if relevant) | | | |  | |
|  |  |  |  |  |  |  |  |  |  |  |
| **SUPPLIER** | | | | | | **DELIVERY / COLLECTION ADDRESS** | | | | |
| **Company name:** | |  | | | | **Contact Name:** |  | | | |
| **Contact Name:** | |  | | | | **E-mail:** |  | | | |
| **E-mail:** | |  | | | | **Address:** |  | | | |
| **Phone:** | |  | | | |  |
| **Fax:** | |  | | | | **SAVE THE CHILDREN INVOICING ADDRESS** | | | | |
| **Mobile:** | |  | | | | **Contact Name:** |  | | | |
| **Address:** | |  | | | | **E-mail:** |  | | | |
| **Address:** |  | | | |
|  |  |  |  |  |  |  |  |  |  |  |
| **Delivery method / Incoterms:** (if applicable) | |  | | **Shipping requirements:** |  | **Required delivery date:** |  | | **Payment terms:** |  |
|  |  |  |  |  |  |  |  |  |  |  |
| **Project code** | **SOF code** | **PR no.** | **Line Item No.** | **Product Code** | **Description of Goods/Services** (add technical specification as attachment if very detailed) | **Unit/Form** | **Quantity required** | **Currency** | **Unit Price** | **Total Price** |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| *NB: Add more lines to the PO if required* | | |  |  |  |  |  | **Subtotal** |  |  |
|  |  |  |  |  |  |  |  | **Sales tax** (if applicable) |  |  |
|  |  |  |  |  |  |  |  | **Delivery charge** (if applicable) |  |  |
|  |  |  |  |  |  |  |  | **Other charges** (if applicable) |  |  |
|  |  |  |  |  |  |  |  | **TOTAL** |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  | **The Purchase Order number must be quoted on all correspondence and documents including delivery note and invoice** | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |
| **Prepared by: Procurement** | | | | | | **Authorised by Budget Holder (authorised under SoD):** | | | |  |
| *Confirms accuracy of contract/PO and procedural compliance to SCI policies* | | | | | | *Financial authorisation/ verification of budget (commitment to spend)* | | | | |
| **Name:** | |  | | | | **Name:** |  | | | |
| **Title:** | |  | | | | **Title:** |  | | | |
| **Signature:** | |  | | | | **Signature:** |  | | | |
| **Date:** | |  | | | | **Date:** |  | | | |
|  |  |  |  |  |  |  |  |  |  |  |
| **Supplier acceptance:** | | | | | | **Supplier Stamp ( it not available then signatures only)** | | | |  |
| **Name:** | |  | | | |  | | | | |
| **Title:** | |  | | | |
| **Signature:** | |  | | | |
|  | |  | | | |

2. SCHEDULE 3
3. PAYMENT TERMS

Invoices shall be in US Dollars.

1. SCHEDULE 4
2. FRAMEWORK PURCHASERS
3. SCHEDULE 5
4. SCI SupPLier Sustainability Policy

**SCHEDULE 6**

**Quality Technical Agreement**

|  |
| --- |
| **TECHNICAL AGREEMENT**  **For Wholesale Dealers**  **of Pharmaceuticals& Medical Supplies** |
| This agreement is between:  **Save the Children International**  (the CONTRACT GIVER) |
| and |
| **SUPPLIER**    (the CONTRACT ACCEPTOR) |

Approved by:

**Save the Children International:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Title** | **Name** | **Signed** | **Date** |
| Global Head of Warehousing & Distribution |  |  |  |
| Head of Medical & Nutrition Supply Chain |  |  |  |
| Global Head of Procurement |  |  |  |
| Quality Manager and Responsible Person |  |  |  |

Copy to within Save the Children International

|  |  |  |  |
| --- | --- | --- | --- |
| **Title** | **Name** | **Signed** | **Date** |
| Medical Director |  |  |  |
|  |  |  |  |

**THE CONTRACT ACCEPTOR:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Title** | **Name** | **Signed** | **Date** |
|  |  |  |  |
|  |  |  |  |

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# SCOPE

This technical agreement (TA) defines the quality responsibilities of Save the Children International (the Contract Giver) and the Contract Acceptor, (the party) for the wholesale dealing. These responsibilities will not be varied by either party without the written agreement of the other party.

The purpose of this TA is to ensure the quality and integrity of the products during all aspects of the wholesale dealing service are clearly defined.

To maintain the original quality of the products, every activity in the storage and distribution of products should be carried out according to Good Distribution Practice, as further defined below.

The commercial terms for the provision of the services are agreed in a separate commercial agreement.

To the extent that there is an inconsistency or discrepancy between this Quality Technical Agreement and the Framework Agreement to which it relates, the relevant provision of this Quality Technical Agreement shall govern and take precedence over the Framework Agreement with respect to any and all matters as described herein.

# DEFINITIONS

(which may be used in this technical agreement)

|  |  |
| --- | --- |
| **Adverse Event** | Any incident or deviation from the expected norm, this may include unauthorised access to shipping containers or vehicles, temperature excursions, customs seizures, none predicted delays at boarders. |
| **Audit** | an independent, objective assurance and consulting activity designed to add value and improve an organisation’s operations |
| **Ambient**  **Cool lines (Cold chain)** | a temperature between 8°c and 25 °c. as defined on packaging  a temperature between 15°c and 25 °c. as defined on packaging  a temperature between 15°c and 30 °c. as defined on packaging  a temperature between 8°c and 30 °c. as defined on packaging  a temperature between 2 °c and 8 °c. as defined on packaging |
| **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**  **Collection** | any act or process through which something becomes different which could impact the product quality, safety or efficacy.  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 or oral 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, for example, 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 Save the Children International including Save the Children International 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 TA and which may have an adverse impact on Service provided by contract acceptor to Save the Children International 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.” |
| **Distribution Conditions** | set of parameters having influence on Product properties, e.g. time, temperature, humidity, vibration, radiation, air exposure, etc. |
| **Frame work Agreement for the supply of freight services** | a [contract](http://en.wikipedia.org/wiki/Contract) between Save the Children International and contract acceptor which documents the terms and conditions of the services |
|  |  |
| **Good Distribution Practice** | means all applicable current good distribution practices and standards, as applicable, promulgated or endorsed by the European Medicines Agency (EMA), EU or regulatory authorities, including the Medicines and Healthcare products Regulatory Agency (MHRA), as applicable, as set out in European Commission Guidelines 2013/C 343/01 and the European Commission Guidelines of 19 March 2015 and 5 November 2013 on Good Distribution Practice of medicinal products for human use, each as may be amended and applicable from time to time.. |
|  |  |
| **Human Medicines Regulations 2012** | The Regulations, 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; and 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** | Pharmaceuticals and Medical Supplies distributed by Save the Children International and transported by contract acceptor |
| **Product Recall** | the removal of a Product from the Distribution chain. The recall will be initiated by Save the Children International |
| **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 for the supply of freight services. |
| **Shipping Unit** | The aggregation of several Containers in to 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 storing of cold chain 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. Save the Children International and the Contract Acceptor undertake to conform to GDP in relation to each party’s obligations regarding Transportation of Products.
  2. Any references to legislation or guidance contained herein shall be references to the legal instrument or guidance as it has been amended and as applicable from time to time.
  3. Except as required by law or regulation the Contract Acceptor undertakes not to vary any provisions of this TA other than by agreement with Save the Children International and will consider adopting any new standards, specifications and procedures at the written request of Save the Children International subject always to any requirement for the Frame Work Agreement or Order (via change control process) to be amended as a result of any such requirement.
  4. This TA is effective on the date of the last Approver and will be reviewed and updated by Save the Children International at least every 3 years after the Effective Date or on the termination or commencement of a new Framework Agreement if applicable . Any update will be treated by the parties as a variation of the TA in relation to 3.2 above. This TA shall terminate automatically upon termination of the Framework Agreement.
  5. GDP requires that a written contract exists between the Contract Giver and the Contract Acceptor relating to the provisions contained herein.
  6. The Contract Acceptor must provide Product and Product documentation that meets the requirements set out in the Framework Agreement document.
  7. This TA is an integral part of the Framework Agreement and any Order between the Parties in respect of the Services are intended as a guide providing a Wholesale dealing service in compliance with GDP.
  8. The validity, construction and performance of the TA shall be governed by English Law. Any dispute arising under or in connection with the TA shall be subject to the exclusive jurisdiction of the English courts to which the Parties irrevocably submit.
  9. The Contract Acceptor agrees not to **plan** to store products at any one of its premises, hubs, or vehicles for greater that 36 hours unless that site is registered to store medicines.
  10. The Contract Acceptor agrees that were products need to be stored for more than 36 hours such premises, hubs and vehicles will be registered as a licenced site for the storage of medicines with the appropriate National Regulatory Agency in the country were these products are stored.

# RESPONSIBILITIES

The responsibility matrix for Save the Children International and the Contract Acceptor is shown in Appendix B

# APPENDIX A – Designated Contacts

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Save the Children International | | | | |
| Name | Position | Email Address | Location Address | Contact number |
|  | Quality Manager and Responsible Person |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| THE CONTRACT ACCEPTOR | | | | | |
| Name | Position | Email Address | Location Address | Contact number |
|  |  |  |  |  |
|  |  |  |  |  |

Any TECHNICAL MATTERS, e.g. specification, logistics issues,

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Save the Children International | | | | |
| Name | Position | Email Address | Location Address | Contact number |
|  | Head of Medical Supply Chain |  |  |  |
|  | Global Head of Warehousing & Distribution |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| THE CONTRACT ACCEPTOR | | | | | |
| Name |  | Email Address | Location Address | Contact number |
|  |  |  |  |  |
|  |  |  |  |  |

# APPENDIX B – TA Responsibility Matrix

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| DOCUMENTS | | **Save the Children International** | | **The 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** | |
| Order for supply of Services | | **X** | |  | **A4** | |
| Acceptance of Order for supply of Services | |  | | **X** | **A5** | |
| ORGANISATION AND MANAGEMENT | | **Save the Children International** | | **The 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 the Products | |  | | **X** | **B1** | |
| Ensure that there is an adequate organisational structure and adequate resources to comply with defined duties of the contract and this quality technical agreement and that these can be performed | | **X** | | **X** | **B2** | |
| Ensure that adequate 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 9001:2008 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 Save the Children International on request | |  | | **X** | **B5** | |
| Save the Children International acknowledge and agree that the business continuity management plan provided/available to it by the Contract Acceptor is adequate | | **X** | |  | **B6** | |
| PERSONNEL | | **Save the Children International** | | **The Contract Acceptor** | **Reference Number** | |
| Individuals involved in delivery of Services to Save the Children International within the Contract Acceptor’s organisation will be trained in the Wholesale Dealing requirements set out GDP guidance and those individuals shall be deemed competent to meet these requirements | |  | | **X** | **C1** | |
| 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 Save the Children International, upon reasonable request for inspection. Verification of competency and understanding must be undertaken as part of the training process. | |  | | **X** | **C2** | |
| QUALITY MANAGEMENT | | **Save the Children International** | | **The Contract Acceptor** | **Reference Number** | |
| The Contract Acceptor operate and maintain a quality management system which shall demonstrate active participation of the management and individuals of the different Services involved and must cover all documentation generated during the transportation, transport conditions and engagement of sub-contractors. | |  | | **X** | **D1** | |
| A designated individual within the Contract Acceptor organisation 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 a change control process. All changes affecting agreed processes in this TA will be notified to Save the Children International prior to the change being carried out | |  | | **X** | **D3** | |
| There is a clear documentation trail of the supply chain in relation to Services and the documents are available to Save the Children International | |  | | **X** | **D4** | |
| If applicable, allow for an audit of warehouses by Save the Children International or its representative, subject to The Contract Acceptor operational restrictions at any time, i.e. access to secure areas, which are not allowed. A maximum of 3 Save the Children International 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 TA * Efficiency of the quality management system, including Customer Complaint handling * Bona Fides * Documentation * Monitoring of data * Training * Vehicles * Equipment * Facilities * Sub-contractor agreements * Procurement and verification of suppliers | |  | | **X** | **D5** | |
| The Responsible Person of Save the Children International 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 Save the Children International with a written response to the observations within 30 calendar days after receipt of the written report from Save the Children International. The Contract Acceptor will, as far as is reasonable, rectify any agreed deficiencies noted as observations during the inspection by Save the Children International and to the extent that any remedial action requires investment. | |  | | **X** | **D7** | |
| The Contract Acceptor shall notify Save the Children International 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 Service provided by The Contract Acceptor, The Contract Acceptor will inform Save the Children International within 5 working days and if reasonably requested will provide Save the Children International 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 TA will be notified by The Contract Acceptor to Save the Children International 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 Save the Children International on request. | |  | | **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 Save the Children International. A general supplier agreement is in place with each sub-contractor, a copy of which may be supplied to Save the Children International on request subject to any restrictions in relation to confidentiality. | |  | | **X** | **D14** | |
| STORAGE | | **Save the Children International** | | **The Contract Acceptor** | **Reference Number** | |
| General security measures are taken to prevent unauthorised persons from accessing Products | |  | | **X** | **E1** | |
| Temporary storage areas must offer sufficient capacity to allow for the orderly Temporary storage and easy retrieval of Products | |  | | **X** | **E2** | |
| All areas are clean and dry and maintained | |  | | **X** | **E3** | |
| Packages are processed in areas that reduce the risk of any Contamination from food stuffs, chemicals or pests for example | |  | | **X** | **E4** | |
| Receiving and dispatch bays, where possible, protect Products from the weather e.g. Sun, Rain extremes of heat and cold | |  | | **X** | **E5** | |
| Quarantine status must be ensured by storage in a separate area and these areas must be clearly marked and access allowed only to designated persons | |  | | **X** | **E6** | |
| Physical or other equivalent validated segregation should be provided for the storage of rejected, expired, recalled or returned Products | |  | | **X** | **E7** | |
| If notified by the Contract Acceptor of broken or damaged Products the Contract Acceptor shall inform Save the Children International immediately if there are any associated risks | |  | | **X** | **E8** | |
| Inform Save the Children International about any deviations related to Products owned by Save the Children International | |  | | **X** | **E9** | |
| Storage areas must be temperature mapping and monitored to ensure that storage is in line with product labelling requirements. | |  | | **X** | **E10** | |
| Products stored under Bond or Duty Suspension are not in free circulation so strict adherence to Bonding controls apply to ensure they don’t get released inadvertently | |  | | **X** | **E11** | |
| Pest control of facilities to prevent ingress of insects, rodents and other animals | |  | | **X** | **E12** | |
| Monitoring of the facilities humidity and temperature | |  | | **X** | **E13** | |
| DESPATCH | | **Save the Children International** | | **The Contract Acceptor** | **Reference Number** | |
| Despatch of Products from the Contract Acceptor is performed against the Contract Acceptor’s documented procedure | |  | | **X** | **F1** | |
| Where palletised product is despatched the double stacking of pallets should not cause damage to lower products | |  | | **X** | **F2** | |
| To assure all Products are labelled and packaged (in validated packaging where appropriate) in an appropriate manner and with GDP requirements. | | **X** | | **X** | **F3** | |
| Transport and Temporary Storage of Products in original packaging, and in appropriate level shipment packaging that is fit for purpose to the distribution conditions and modes. | |  | | **X** | **F4** | |
| Retain documentation relating to Products despatched for periods referred to in the Framework Agreement | |  | | **X** | **F5** | |
| Supply documentation relating to Products despatched as referred to in the Framework Agreement | |  | | **X** | **F6** | |
| Inform requirements for temperature monitoring devices to be included in ambient goods shipments | | **X** | |  | **F7** | |
| Ensure temperature data loggers are included in ALL ambient goods shipments to record temperature data for Product requiring storage and transportation below 25 or 30 Degrees Celsius in accordance with the manufacturers instructions)  Data must be readable by downloading via a USB interface to a windows operating system | |  | | **X** | **F8** | |
| Ensure temperature data loggers are included in ALL cold chain shipments required for products requiring storage and transportation between 2 °c and 8 °c. as defined on packaging  Data must be readable by downloading via a USB interface to a windows operating system | |  | | **X** | **F9** | |
| Despatch will be performed such as to minimise the risk of damage, loss or Contamination to the Products. Written procedures will be available from The Contract Acceptor upon reasonable request by Save the Children International. | |  | | **X** | **F10** | |
| Records of despatch contain enough information to enable traceability of the Save the Children International’s Products | |  | | **X** | **F11** | |
| Records for the despatch of products are prepared by The Contract Acceptor and include at least the following information:  - Date of despatch  - Name and address of the entity responsible for the distribution  - Name, address of the addressee  - a description of the Products  - quantity of Products  - assigned Batch Number and expiry date  - applicable transport and storage conditions  - a unique number to allow identification of the delivery order | |  | | **X** | **F12** | |
| To assure Products will be ready for collection at agreed times | |  | | **X** | **F13** | |
| If necessary, the Contract Giver will supply Contract Acceptor with additional shipping documentation. This needs to be done by email and before the agreed despatch date. | | **X** | |  | **F14** | |
| Additional shipping documentation (supplied by Contract Giver) will be included in the Cargo Shipping Documents before despatch | |  | | **X** | **F15** | |
| TRANSPORTATION AND DELIVERY (only applicable if Wholesale Dealer/Supplier also provides the international transportation services for a medical order as requested by the contract giver)**)** | **Save the Children International** | | **Contract Acceptor** | | | **Reference Number** |
| Services are provided in accordance with EC Directive (2013/C343/01) and in particular the Guidelines and Chapter 9 thereof (with the exception of any temperature control obligations) and any subsequent amendment. |  | | **X** | | | **G1** |
| Only temperature-controlled transport lanes will be used to transport the Save the Children International Products to the port of entry. Subject to any findings of route risk assessments.  Where local transport infrastructure provides a temperature transport lane this should be used. |  | | **X** | | | **G2** |
| The overall responsibility for carrying out route risk assessment will by Save the Children International, however it is expected that the Contract Acceptor will input into this process by making available their own route risk assessments to Save the Children International. | **X** | | **X** | | | **G3** |
| Define the requirements for the use of climate controlled shipment containers including, but not limited to, sea containers, aviation containers and containers or vehicles used for road or rail transportation. | **X** | |  | | | **G4** |
| Ensure that the use of climate controlled shipment containers is in accordance with SCI requirements. |  | | **X** | | | **G5** |
| All relevant Transportation and delivery documentation will be retained in a secure environment with limited access by authorised individuals only for minimum 5 years. This includes password controls for electronic copies and secure storage controls for paper copies. | **X** | | **X** | | | **G6** |
| Products are, in so far as is reasonably possible and if packaging guidelines are followed, and Containers are properly prepared, transported in such a way that:   * Containers packed and labelled are not lost or defaced * Products do not Contaminate and 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 * Appropriately assessed sub-contractors are used |  | | **X** | | | **G7** |
| To ensure the required conditions for temperatures of this TA for Products are maintained during transportation. Referring to Section G2 |  | | **X** | | | **G8** |
| To notify the quality contact of Save the Children International by email and by phone during normal UK office hours of temperature excursions identified during transportation. |  | | **X** | | | **G9** |
| To ensure a tracking system (to the extent that this is utilised by the Contract Acceptor) used allows Products to be tracked during Transportation to enable Save the children to know were product is during its journey (if required) |  | | **X** | | | **G10** |
| The appropriate documentation to allow Export and Import and other relevant documentation must accompany the shipment |  | | **X** | | | **G11** |
| To inform the quality contact in Save the Children International about any shipment unit or product that is visibly or knowingly damaged during distribution |  | | **X** | | | **G12** |
| To decide if container or product that is visibly or knowingly damaged during distribution shall be returned or delivered. | **X** | |  | | | **G13** |
| 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** | | | **G14** |
| To assure **vehicles** are not left unlocked during the transportation. Shipping container seal mechanisms must also to remain locked unless requested by customs to be opened. |  | | **X** | | | **G15** |
| Delivery is attempted of all Products to the destination address within the timescale state and that the delivery is never left at an address which is not detailed on the Freight Movement Purchase Order |  | | **X** | | | **G16** |
| To reassure each delivery is received by the consignee appointed by Save the Children International. |  | | **X** | | | **G17** |
| In case the delivery address is different to the address provided by Save the Children International. This is confirmed with Save the Children International before the delivery is released. E.G. The address is 45 x road, but the premises are located at 54 x road |  | | **X** | | | **G18** |
| There is a clear documentation trail in relation to Services and the documents must be available to Save the Children International by way of Proof of Delivery (POD) Documentation. This documentation must be provided to Save the Children International |  | | **X** | | | **G19** |
| 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** | | | **G21** |
| Temperature controlled vehicles and shipping containers with 30 minutes or less interval for the temperature measurement will be used to transport Save the Children International Products, if available with reference to F2 |  | | **X** | | | **G22** |
| To ensure temperature monitoring equipment is calibrated against national standards at least on an annual basis. |  | | **X** | | | **G23** |
| QUALIFICATION AND VALIDATION | | **Save the Children International** | | **The Contract Acceptor** | **Reference Number** | |
| Periodic review of the Service to ensure compliance with this TA | | **X** | | **X** | **H1** | |
| TECHNICAL COMPLAINTS | | **Save the Children International** | | **The Contract Acceptor** | **Reference Number** | |
| Save the Children International must inform the Contract Acceptor of a relevant Customer Service Complaint within 48 hours of receiving the Customer Complaint | | **X** | |  | **I1** | |
| The Contract Acceptor inform Save the Children International about any Customer Complaint, Adverse Event related to the Save the Children International Products within 24 hours on receipt of such notification. | |  | | **X** | **I2** | |
| 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** | **I3** | |
| Any Customer Complaint is documented, investigated and recorded as per the documented procedure | |  | | **X** | **I4** | |
| Any investigation should be completed within 5 days: if further time is required to properly complete the investigation Save the Children International are informed | |  | | **X** | **I5** | |
| To assist the Contract Acceptor with any returns upon Save the Children International request. | |  | | **X** | **I6** | |
| REJECTED, RETURNED OR RECALLED PRODUCTS | | **Save the Children International** | | **The Contract Acceptor** | **Reference Number** | |
| Maintain a product recall procedure for use when it is necessary to recall a defective product from market, and test the procedure at least annually. | | **X** | | **X** | **J1** | |
| Inform Contract Giver within 24 hours after notification about defective product and recall or potential recall. | |  | | **X** | **J2** | |
| To ensure rejected or recalled Products which are returned from Save the Children International are appropriately segregated and identified. | |  | | **X** | **J3** | |
| The tracking reference assigned to a returned, rejected or recalled Container/Product will be available to view by Save the Children International using the Contract Acceptor despatch tracking link. | |  | | **X** | **J4** | |
| To inform the Contract Acceptor about the return by sharing the relevant shipping documentation. If destruction of the product(s) is required, SCI will provide a Certificate of Destruction. | | **X** | |  | **J5** | |
| Provision will be made for the proper and safe Transportation of returned, rejected or recalled Containers/Product | |  | | **X** | **J6** | |
| RETAINED RECORDS | | **Save the Children International** | | **The Contract Acceptor** | **Reference Number** | |
| Records will be retained minimum 5 years. | |  | | **X** | **K1** | |
| To ensure only authorised personnel can maintain and access Save the Children International Records. | |  | | **X** | **K2** | |
| To ensure records are available to Save the Children International upon request within 24 hours. This including documents or evidence which may be held on the Contract Acceptor computer systems or web portals | |  | | **X** | **K3** | |

**SCHEDULE 7**

**SERVICE LEVEL AGREEMENTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | **PROGRAMME REQUIREMENT** | | **HUMANITARIAN REQUIREMENT** | |
| **Stocked Item** | **Non-Stocked Item** | **Stocked Item** | **Non-Stocked Item** |
| **1** | **Response to Quotation (FCA)** |  |  |  |  |
|  | *Time between SCI requesting pricing from Supplier and Supplier providing back a quotation to SCI* | within xx hours | within xx hours | within xx hours | within xx hours |
| **2** | **Response to Quotation (inc Freight)** |  |  |  |  |
|  | *Time between SCI requesting pricing from Supplier and Supplier providing back a quotation to SCI* | within xx hours | within xx hours | within xx hours | within xx hours |
| **3** | **SCI confirmation or rejection of a quotation** | 10 working days | 10 working days |  |  |
|  |  |  |  |  |  |
| **4** | **Acceptance of Purchase Order** |  |  |  |  |
|  | *Time between SCI issuing a complete Purchase order and Supplier confirming receipt of PO and accepting the order* | within xx hours | within xx hours | within xx hours | within xx hours |
| **5** | **Item Ready for Dispatch** |  |  |  |  |
|  | *Time between PO acceptance and when Supplier have all items packed and ready to be dispatched* | within xx working days | as per quotation | within xx hours | as per quotation |
| **6** | **SCI confirmation of dispatch (greenlight)** |  |  |  |  |
|  | *Number of days between receipt of shipping documents and greenlight to ship* | within 10 working days, with the exception of programmes where the shipping documents are required to apply for an import license: Iraq & Afghanistan | within 10 working days, with the exception of programmes where the shipping documents are required to apply for an import license: Iraq & Afghanistan |  |  |
| **7a** | **Delivery Lead Time (to port of destination)** | Monitor/Report | Monitor/Report | Monitor/Report | Monitor/Report |
| **7b** | **Delivery Lead Time (including clearing customs)** | Monitor/Report | Monitor/Report | Monitor/Report | Monitor/Report |
|  | *Time from Goods being despatched to fulfilment of the Purchase Order Incoterms* |  |  |  |  |
| **8** | **Provide Tracking Details on Items in Transit** |  |  |  |  |
|  | *Issuing the shipping agent tracking number* |  |  |  |  |
|  |  | **Target** | **Reporting Frequency** |  |  |
| **9** | **Orders Delivered On Time** |  |  |  |  |
|  | *Based on lead time stated in order confirmation* | 80% | Monthly |  |  |
| **10** | **Orders Delivered in Full** |  |  |  |  |
|  | *Number of orders with short shipments* | 95% | Monthly |  |  |
| **11** | **Order completeness** |  |  |  |  |
|  | *Number of orders shipped as one shipment and not split* |  |  |  |  |
| **12** | **Product Availability** |  |  |  |  |
|  | *% of products supplied from virtual stock* |  |  |  |  |
| **13** | **Product Availability** |  |  |  |  |

**SCHEDULE 8**

**Special Terms and Conditions for SCI Myanmar**

The provisions of this Schedule 8 shall apply to all purchases made by or on behalf of SCl's country office in Myanmar. For the avoidance of doubt, this Schedule 8 shall not apply to any other purchases by SCI.

To the extent that there is an inconsistency or discrepancy between this Schedule 8 and the Framework Agreement (including the other schedules to it) to which it relates, the relevant provision of this Schedule 8 shall govern and take precedence over the Framework Agreement (including the other schedules to it) with respect to any and all matters as described in this Schedule 8.

Medical standards

Clause 7.2(b) of the Framework Agreement shall be deleted as replaced with:

"meet the international standards for quality, are being supplied to the Customer in line with Good Manufacturing Practices and Model Quality Assurance System for Procurement Agencies (MQAS), and that either (i) are in line with the National Essential Drug List (NEDL) in the country in which they will be used or otherwise (ii) meet all the criteria for importing by the relevant authorities in Myanmar;"

Clause 28.2(d) of the Framework Agreement shall be deleted as replaced with:

"unless SCI otherwise agrees in writing on the grounds that such goods are not capable of being registered, **be authorised and registered by the National Drug Regulatory Authority of the country of destination for orders placed**;"

4 Price for the Goods

Clause 4.1 of the Framework Agreement shall not apply. Instead, prices will be agreed between the Parties based on specific volumes provided by SCI to the Supplier and in accordance with the below.

Clause 4.2 of the Framework Agreement shall not apply.

For the avoidance of doubt, Clause 4.3 of the Framework Agreement shall apply.

In order to agree pricing for the Myanmar Country Office, the Parties shall comply with the following process:

SCI shall submit to the Supplier the list of products to supply with their specifications, the quantities of each and the estimated delivery schedule.

The Supplier shall provide a quotation with the following information:

- Detailed description/brochure of the product;

- Country of origin;

- Lead time;

- Manufacturing shelf-life;

- Price;

- Packaging used for transportation; and

- Confirmation that the Supplier shall provide all the documents mentioned in Clause 8.12 of the Framework Agreement prior to shipment.

After clarification and evaluation of the quotation, SCI will provide the final list of ordered products in contract annex to the framework agreement. SCI will order the products through several Purchase Orders against this contract annex A variance of up to an increase of 20% or decrease of 20% in quantities ordered by SCI per product is permitted between the Contract Appendix and the Purchase Orders based on SCI updated requirement.

7 The Goods

The following provisions related to the Goods shall apply in addition to the terms and conditions set out in the Framework Agreement (including the Quality Technical Agreement).

Cold Chain equipment

In providing the Goods, the Supplier shall ensure that the Goods requiring cold chain logistic are within a cold case that will keep the Goods to the temperature required by SCI for at least 72h00 under any weather conditions.

Change of specification after order

In case of a change of specification or quantities after SCl's order, the Supplier must inform and obtain SCl's prior written approval.

Quality assurance

The Supplier must carry out every activity in the storage and distribution of Goods according to the following documents:

* Global Fund Policies on Procurement and Supply Management dated October 2018 and subsequent revisions.
* Global Fund Quality Assurance Policy for Pharmaceutical Products dated January 2011 and subsequent revisions.

Weather conditions

Unless specified during the tender process the Supplier must provide Goods as per WHO standard, that are stable under Myanmar standard weather conditions: 30 °C and 75% Relative Humidity.

The Supplier must provide, upon request, the "in-house" quality control testing method for goods which are not registered in one of the following pharmacopeia:

* WHO International Pharmacopeia standards European Pharmacopoeia standards (EP)
* British Pharmacopoeia standards (BP)
* The United States Pharmacopeia Convention (USP)

Shelf life

The Supplier, if after having agreed a shipment within shelf-life clauses stated in the framework agreement and quoting a freight price, is unable to meet the shelf-life clause and therefore has to split the shipment into multiple shipments (of the same transport modality) agrees to bear the incremental cost of splitting into several shipments.

Documentation required by the Supplier

For the avoidance of doubt, the Supplier shall not require SCI to complete any documentation (related to sanctions) unless otherwise set out in the Framework Agreement or required by applicable law. If any such documentation is required in accordance with this clause, the Supplier shall inform SCI (in advance of shipment of the relevant Goods) of the documents required and in reasonable detail the content of that documentation in accordance with Clause 11.1(c) of the Framework Agreement.