SCI/ESA/MEDICAL/018/001

**PHARMACEUTICAL TENDER RESPONSE**

**Please provide information against each requirement**

Additional rows can be inserted for all questions as necessary

**ESSENTIAL CRITERIA**

In order to qualify as a bidder, you must be able to answer ‘Yes’ against all of the Essential Criteria. After passing the essential criteria, your bid will be scored against the Capability criteria.

1. Do you have a legitimate business/official address AND are you registered for trading or tax purposes with the authorities : Yes/ No
2. Do you agree to comply with our standard policies and procedures as stated in RFQ or Invitation to Tender (ITT) document: Yes/No
3. Do you confirm that you are not, as far as you are aware, on any prohibited parties lists or on Government blacklists: Yes/ No

# Bidder’s general business details

1. General information

|  |  |  |  |
| --- | --- | --- | --- |
| Organisation Name: | | | |
| Registered name of company (if different): | | | |
| Any other trading names of company: | | | |
| Contact Name: | | Job title : | |
| Phone: | | Fax: | |
| Email: | | Website: | |
| Principle Address: | Registered Address: | | Payment Address: |
| Registration number: | | Country of registration: | |
| Date of registration: | | VAT/Tax registration number: | |
| Legal status of company (i.e. sole trader, partnership, private limited company, other): | | | |
| Audited accounts | | Please provide your 2016 audited accounts | |
| Duration of audited accounts: | | If this is more than 12 months, please explain why: | |
| Annual Turnover: | | Total net assets: | |
| Profit: | | Total current assets: | |
| Expenditure: | | Total current liabilities: | |
| Names of Directors: | | | |
| Names of shareholders having more than 10% stake: | | | |
| Names of any major subsidiary companies: | | | |
| Location of bank account for depositing payments relating to this contract: | | | |

1. Information relating to parent or holding company (if applicable)

|  |  |
| --- | --- |
| Registered name of parent or holding company: | |
| Registration number: | Date of registration: |
| Country of registration: | |
| Legal Status (i.e. sole trader, partnership, private limited company, other): | |

Please note that all further details provided after this question 2 should relate to the company that will be the contractual partner if this tender application is successful.

1. Please provide address details for any other international sites: branches, warehouses, offices.

|  |  |  |
| --- | --- | --- |
| **Facility** | **Function i.e. warehouse, QA testing site, sales office etc.** | **Location** |
|  |  |  |
|  |  |  |
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1. What kind of organisation is your company?

* Procurement agency / distributor / wholesaler (circle) Yes / No

If yes, please submit Annex 1 in addition to Sections A - F of this questionnaire.

* Manufacturer of pharmaceuticals (circle) Yes / No

If yes, please submit Annex 2 in addition to Sections A - F of this questionnaire.

* Manufacturer of materials, devices, laboratory or diagnostic equipment? (circle) Yes / No

If yes, please submit Annex 3 in addition to Sections A - F of this questionnaire.

**CAPABILITY CRITERIA**

**A: Bidder capacity**

1. Please indicate for each of the below categories, whether you are bidding to supply this product category and your company’s total annual value of sales for that category in 2016

|  |  |  |  |
| --- | --- | --- | --- |
| **Product group** | **Bidding to supply** Yes / No | **Further instruction** | **Value of sales** (& currency) |
| Drugs |  | If yes, please also complete Annex 4 |  |
| Medical materials |  | If yes, please also complete Annex 5 |  |
| Medical equipment |  | If yes, please also complete Annex 6 |  |
| Laboratory and diagnostic items |  | If yes, please also complete Annex 7 |  |
| Emergency health kits |  | If yes, please also complete Annex 8 |  |
| Vaccines |  | If yes, please also complete Annex 9 |  |
| Other products | N/A | N/A |  |

1. Please list the employees who would be involved with Save the Children (include out of hours contact details for those persons nominated as key contacts out of hours)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Job title** | **Role for Save the Children account** | **Direct telephone number** (one person should have 24hr availability by mobile) | **E-mail Address** |
|  |  |  |  |  |
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1. Please outline any major changes (e.g. mergers, partnerships) planned in your organisation over the next two years:

…………………………………………………….

1. Please confirm that you have sufficient insurance cover to provide for all your potential liabilities under the agreement for supply of goods and that you will maintain an adequate level of insurance cover throughout the term of the agreement

Circle: *Yes / No*

1. Please give details of the levels and kinds of insurance held by your organisation and describe to which areas of the service / organisation that insurance applies:

……………………………………………………

1. Please provide details of your 3 largest customers, and the turnover relating to each in the latest audited accounts and annual report:

|  |  |
| --- | --- |
| **Client Organisation** | **Turnover relating to customer** (please also indicate currency) |
| 1. |  |
| 2. |  |
| 3. |  |
|  |  |

1. Please provide details of at least 3 client references which Save the Children may contact:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Client Organisation** | **Contact** | **Phone no.** | **E-mail address** | **Annual contract value & type of goods supplied** |
|  |  |  |  |  |
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# B. Product range and stock information

1. Please refer to file: ‘Pharmaceutical Tender Annexes 4-9: Product Lists’. Each tab of this worksheet contains a separate Annex. Please complete the relevant tab for each lot you are bidding to supply (Annex 4 – Drugs; Annex 5 – Medical materials; Annex 6 – Medical equipment; Annex 7 – Laboratory and diagnostic items; Annex 8 - Emergency health kits, Annex 9 - Vaccines), indicating on each tab:
   1. Which products you are able to supply. Please take care to note the form and strength required and indicate packing unit. If you do not stock this product, then please indicate what you are able to offer as an alternative
   2. Which products you hold as stock and which are manufactured to order
   3. Please indicate the lead-time from order until readiness to despatch, for items that are manufactured/supplied to order and for those that are held in stock (lead times should include any kitting, packing and document preparation required)
   4. Please indicate if there are any minimum order quantities for any products on the list.
2. What is your primary stock holding location?

|  |
| --- |
|  |

1. Do you have stocks held in any other locations around the world? If yes, please indicate where.

|  |
| --- |
|  |

1. What is your stock-holding policy and how would you ensure stock availability for Save the Children if you were awarded a contract?

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| --- |
|  |

1. Would your organisation be prepared to hold either virtual or actual supplies for Save the Children for emergency use without advance payment or commitment to use? (this is of particular interest for emergency health kits, see Annex 8)

(circle) Yes / No

If yes, please give details of quantities that you will hold for Save the Children and locations where you will hold them:

|  |  |  |
| --- | --- | --- |
| **Location** | **Item / kit** | **SC stock level** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. How quickly would you be able to mobilise these stocks in a Humanitarian emergency situation where it includes sudden onset natural disasters and conflict, protracted conflict or natural disasters (slow-onset) and contexts of persistent vulnerability and instability requiring immediate action, and are categorised (1 – 4) based on the SCI grading system.

……………………………………………………

## C – Service and Delivery

1. What are your standard working hours?

……………………………………………………

1. What after-hours services do you provide in the event of a sudden onset natural disasters and conflict or protracted conflict.

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| --- |
|  |

1. Does your organisation close over holiday periods e.g. religious festivals such as Christmas and Eid or summer/winter breaks

Circle *Yes / No*

If yes, please outline the dates and duration

|  |  |  |
| --- | --- | --- |
| **Holiday** | **Date** | **Duration** |
|  |  |  |
|  |  |  |
|  |  |  |

1. Would your organisation be able to meet the lead-times outlined in the table below? If not, please indicate what lead-times you are able to offer.

|  |  |  |  |
| --- | --- | --- | --- |
| **Activity** | **Number of days** | **Yes/No** | **If No, what times do you offer?** |
| Providing quotes on EXW and FCA basis | 1 working day |  |  |
| Providing quotes including freight | 2 working days |  |  |
| Confirming an order & providing delivery schedule | 1 working day |  |  |
| Provide information on orders in transit | Same day |  |  |

1. Do you have in place any of the below listed performance indicators for customer service?

Circle *Yes / No*

If yes, can you confirm what is the target value for each, and how often you will be able to report on them? If you use other performance measures please indicate them.

|  |  |  |
| --- | --- | --- |
| **Performance indicator** | **Target** | **Frequency in which they are monitored** |
| Lead-time for response to quotes |  |  |
| Lead-time for order confirmation |  |  |
| Lead-time from order placed to despatch of goods |  |  |
| Number of delivered orders ‘on time & in full’ (based on time stated in order confirmation) |  |  |
| Order completeness (number of orders shipped as 1 shipment and not split) |  |  |
| Stock availability (% of line items supplied from stock) |  |  |
| Other? |  |  |

1. If no, would you be willing to put these measures in place if you were awarded a contract?

Circle *Yes / No*

1. How many customer complaints did you have last year?

……………………………………………………

1. List your 3 most frequent customer complaints, defining the kind of complaints and your rectification measures.

|  |  |  |
| --- | --- | --- |
| **Complaint** | **Number of times occurred in last year** | **Rectification measures** |
|  |  |  |
|  |  |  |
|  |  |  |

1. What is your process for assessing your subcontractors/suppliers in terms of competitiveness and capacity to supply?

|  |
| --- |
|  |

1. **Can you export and transport for Save the Children within East and Central Africa (Save the Children currently requires shipment to the following locations, however this is subject to change) Nairobi, Kampala, Juba, Addis Ababa, Khartoum, Goma, Dar el Salaam, Kigali, Maputo, Mogadishu, Hargeisa, Berbera, Garowe, Bosaso, Baidoa, Kismayo; Lilongwe, Lusaka, Harare?**

(Circle *Yes / No*

**Provide as much as possible details for each country (**Including lead times**) Kenya, Uganda, South Soudan, Ethiopia, Soudan, Tanzania, Mozambique, Rwanda, Somalia, Zambia, Zimbabwe, Malawi, DRC:**

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1. Which countries do you have experience of supplying?

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| --- |
|  |

1. Are there any countries you are not able to supply to?

(circle) Yes / No

If yes, please indicate which countries and why

|  |  |
| --- | --- |
| **Country** | **Reason** |
|  |  |
|  |  |
|  |  |

1. Can you provide a validated mechanism for temperature monitoring in shipments?

Circle Y*es / No / Not applicable*

If yes, please provide details below and if possible provide a copy of the specifications

|  |  |  |
| --- | --- | --- |
| **Product** | **Make** | **Cost** |
|  |  |  |
|  |  |  |

1. What does your organisation provide for the transportation of cold-chain items? Please provide details of packing materials and monitoring devices used to ensure the cold chain is not broken.

|  |
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**COMMERCIAL CRITERIA**

## D. Pricing

1. Prices for all products bid for should be completed on the ‘Pharmaceutical Tender Annexes 4-9: Product Lists’ worksheet (see separate tabs).
2. How long can you fix the prices indicated in Annexes 4 to 9 for?

……………………………………………………

1. By what average percentage (please indicate + or -) did the prices of your products fluctuate over the last 12 months?

……………………………………………………

1. Do you benchmark your pricing against the International Drug Price Indicator Guide published by Management Sciences for Health?

Circle *Yes / No*

If yes, does this apply to all drugs you supply?

1. Circle *Yes / No* When providing quotes please confirm the validity period you are willing to offer with reference to:

* Prices: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Stock availability: \_\_\_\_\_\_\_

1. When providing quotes, would you provide weights of the items? Circle *Yes / No*

E. **Ethical standards**

1. Do you conform to any relevant health and safety standards for your industry?

Circle Yes / No

If yes, detail any relevant standards

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| --- |
|  |

1. Please provide details of any safety related incidents that have occurred at any of your facilities during the last 3 years

|  |
| --- |
|  |

1. Please provide a statement explaining your policy, procedures and practices (including any accreditation) relating to the environment

|  |
| --- |
|  |

1. Please provide a statement explaining your policy, procedures and practices relating to labour standards, in particular child and forced labour

|  |
| --- |
|  |

1. What is your process for assessing your subcontractors/suppliers in terms of ethical standards?

|  |
| --- |
|  |

1. How do you ensure ethical manufacturing practices? (question only applies to manufacturers)

|  |
| --- |
|  |

## F. Confirmation of Bidder’s compliance

We, the Bidder, hereby certify that our tender is a bona fida offer and intended to be competitive.

We confirm compliance with:

* The required specifications for the products, including Save the Children’s specific quality assurance requirements for procurement agencies, distributors and wholesalers; for manufacturers of drugs; for finished pharmaceutical products; for medical devices; and for vaccines
* The Conditions of Tendering, including exclusion criteria
* Save the Children’s General Terms and Conditions for Supply of Goods
* Save the Children’s Child Safeguarding Policy
* Save the Children’s Anti-Bribery and Corruption Policy
* The IAPG code of conduct

The following documents are included in our bid (all bidders):

* Company registration certificate
* Copy of latest audited accounts and annual report for last 3 years

Additionally, the following documents are included in our bid (where relevant):

* Details of temperature devices for transport
* Copy of certificate of registration with National Drug Regulatory Authority
* Copy of license to distribute drugs
* Copy of organisational chart
* Copy of job profile for QA Manager
* Proof of ISO 13485 certification or quality management system certification to ISO 9001 for medical device manufacturers
* WHO prequalification certification for diagnostics and syringes.
* Standard product dossiers
* List of sources (manufacturers and suppliers) if wholesaler or distributor

We agree that Save the Children may verify the information provided in this form itself or through a third party as it may deem necessary, including through a pharmaceutical quality assurance audit.

We confirm that Save the Children may in its consideration of our offer, and subsequently, rely on the statements made herein.

Signed …………………………….

Print Name………………………….

Job title: …………………….

Company: ………………….

Date: ………………………….

## Annex 1: Quality assurance for procurement agencies, distributors and wholesalers

1. Is the company licensed as a drug distributor? (Circle *Yes / No*

If yes, please provide copy of valid licence.

1. Does your company conduct activities other than drug distribution? Circle *Yes / No*

If yes, please provide details:

|  |
| --- |
|  |

1. Is the company registered with the National Drug Regulatory Authority of your country?

Circle *Yes / No* If yes, please provide copy of certificate of registration.

1. Has your company’s compliance with WHO GDP and MQAS standards been verified by an independent external auditor within the last 2 years?

Circle *Yes / No*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Inspected by** | **Date** | **GDP (Yes/No)** | **MQAS (Yes/No)** | **Result** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. What is the total number of employees within your organisation?

……………………………………………………

1. Do you have an organisational chart showing your Quality Management function?

Circle *Yes / No*

If yes, please attach a copy

1. Does your Quality Assurance (QA) Manager have a Job Profile?

Circle *Yes / No* If yes, please attach a copy

1. How many years of experience in pharmaceuticals does your QA Manager have?

……………………………………………………

1. How many licensed pharmacists are employed in your organisation?

……………………………………………………

1. Do QA, Sales and Purchasing staff have to complete a conflict of interest declaration regarding dealing with suppliers?
2. Circle *Yes / No* Does your organisation have policies and/or SOPs for the following activities in place? Please indicate validity date and name of document.

|  |  |  |  |
| --- | --- | --- | --- |
| **Policy/SOP** | **Yes/No** | **Valid from** | **Name of document** |
| Product validation |  |  |  |
| Manufacturers audit |  |  |  |
| Batch recall |  |  |  |
| Quality control |  |  |  |
| Storing conditions |  |  |  |
| Control at reception for all products |  |  |  |

Please note: if you are shortlisted during this tender process these documents will need to be made available for inspection as part of an audit prior to any award of contract.

1. Is the laboratory for quality control of samples WHO pre-qualified?

(Circle *Yes / No*

1. Is an internal audit process in place?

Circle *Yes / No* If yes, please provide details

|  |
| --- |
|  |

1. Does your organisation have a standard product dossier that you use to validate all products?

Circle *Yes / No* If yes, please provide copies

If no, please provide the list of your sources (manufacturers and suppliers)

1. Do you have an [Interagency Pharmaceutical Product Questionnaire](http://www.who.int/medicines/areas/quality_safety/quality_assurance/MQAS-Inter-AgencyFPP-questionnaire-QAS13-556_06082013.pdf) completed for all your products?
2. Circle *Yes / No* What product acceptability standards do you follow? Please provide details.

|  |
| --- |
|  |

1. Does your organisation systematically audit manufacturers for Good Manufacturing Practices (GMP) compliance?

Circle *Yes / No* If no, please explain why not

|  |
| --- |
|  |

1. Would your organisation be able to provide certificates of analysis on request for each batch all pharmaceutical products you supply?

Circle *Yes / No* If no, please provide details of what you will be able to provide

|  |
| --- |
|  |

1. Will your organisation commit to supplying pharmacueticals in any future contract to Save the Children that have a shelf life of at least 2 years, or, for products with shelf life of less than 2 years at time of manufacture, at least 75% of shelf life remaining?

Circle *Yes / No* If no, please provide details of what your organisation is able offer

|  |
| --- |
|  |

1. Can you package and label all Finished Pharmaceutical Products as per the Specification in the Invitation to Tender?

Circle *Yes / No* If no, please identify any variations

|  |
| --- |
|  |

1. Can you adapt labelling of pharmaceutical products to any of the following languages:?

* English Circle *Yes / No*
* French Circle *Yes / No*
* Portuguese Circle *Yes / No*
* Arabic Circle *Yes / No*

1. Please confirm medical devices are sourced from manufacturers with ISO 13485 certification or quality management system certification to ISO 9001.

(Circle *Yes / No*

1. Can you provide WHO prequalification certification for all diagnostics and syringes you supply??

Circle *Yes / No* If yes, please provide copy of certificate.

If not, please confirm what alternative quality management systems are in place and provide certificate(s).

|  |
| --- |
|  |

## Annex 2 – Quality assurance for manufacturers of pharmaceuticals

1. Is the company licensed as a drug manufacturer? Circle *Yes / No*

If yes, please provide copy of valid licence.

1. Is the company registered with the National Drug Regulatory Authority of your country?

Circle *Yes / No* If yes, please provide copy of certificate of registration.

1. Have your manufacturing facilities’ compliance with WHO GMP standards been verified by an independent external auditor within the last two years?

Circle *Yes / No*

|  |  |  |  |
| --- | --- | --- | --- |
| **Manufacturing site** | **Inspected by** | **Date** | **Result** |
|  |  |  |  |
|  |  |  |  |
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|  |  |  |  |

1. What is the total number of employees within your organisation?

……………………………………………………

1. Do you have an organisational chart showing your Quality Management function?

Circle *Yes / No*

If yes, please attach a copy

1. Does your Quality Assurance (QA) Manager have a Job Profile?

Circle *Yes / No* If yes, please attach a copy

1. How many years of experience in pharmaceuticals does your QA Manager have?

……………………………………………………

1. How many licensed pharmacists are employed in your organisation?

……………………………………………………

1. Does your organisation have policies and/or SOPs for the following activities in place? Please indicate validity date and name of document

|  |  |  |  |
| --- | --- | --- | --- |
| **Policy/SOP** | **Yes/No** | **Valid from** | **Name of document** |
| Control of API at reception |  |  |  |
| Batch recall |  |  |  |
| Batch release |  |  |  |
| Quality control on Finished Pharmaceutical Products |  |  |  |
| Storing conditions |  |  |  |

Please note: if you are shortlisted during this tender process these documents will need to be made available for inspection as part of an audit prior to any award of contract.

1. Is an internal audit process in place?

Circle *Yes / No* If yes, please provide details

|  |
| --- |
|  |

1. Do you have an [Interagency Pharmaceutical Product Questionnaire](http://www.who.int/medicines/areas/quality_safety/quality_assurance/MQAS-Inter-AgencyFPP-questionnaire-QAS13-556_06082013.pdf) completed for all your products?
2. Circle *Yes / No* Do all the products you manufacture conform to WHO, European Pharmacopoeia standards (EP), British Pharmacopoeia standards (BP) or the United States Pharmacopeia Convention (USP)?

Circle *Yes / No* If no, explain why and detail what norms and standards you follow

|  |
| --- |
|  |

1. Would your organisation be able to provide certificates of analysis on request for each batch for all pharmaceutical products you supply?

Circle *Yes / No* If no, please provide details of what you will be able to provide

|  |
| --- |
|  |

1. Will your organisation commit to supplying pharmaceuticals in any future contract to Save the Children that have a shelf life of at least 2 years, or, for products with shelf life of less than 2 years at time of manufacture, at least 75% of shelf life remaining?

Circle *Yes / No* If no, please provide details of what your organisation is able offer

|  |
| --- |
|  |

1. Can you package and label all Finished Pharmaceutical Products as per the Specification in the Invitation to Tender?

Circle *Yes / No* If no, please identify any variations

|  |
| --- |
|  |

1. Can you adapt labelling of pharmaceutical products to any of the following languages:

* English Circle *Yes / No*
* French Circle *Yes / No*
* Portuguese Circle) Yes / No
* Arabic Circle *Yes / No*

## Annex 3 – Quality assurance for manufacturers of materials, devices, equipment, laboratory or diagnostic equipment

1. Is the company registered with the National Drug Regulatory Authority of your country?

Circle *Yes / No* If yes, please provide copy of certificate of registration.

1. Do you have an organisational chart showing your Quality Management function?

Circle *Yes / No*

If yes, please attach a copy

1. Does your Quality Assurance (QA) Manager have a Job Profile?

Circle *Yes / No* If yes, please attach a copy

1. How many years of experience in pharmaceuticals does your QA Manager have?

……………………………………………………

1. Please confirm you have ISO 13485 certification or CE mark?

Circle *Yes / No* If yes, please provide copy of certificate.

If not, please confirm what alternative quality management systems are in place and provide certificate(s).

|  |
| --- |
|  |

1. Can you provide WHO prequalification certification for all diagnostics and syringes you supply?

Circle *Yes / No* If yes, please provide copy of certificate.

If not, please confirm what alternative quality management systems are in place and provide certificate(s).

|  |
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|  |