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File Ref: PO 7079
Date: 29 January 2016
Contract Amendment No: 3

CONTRACT FOR:

Procurement of Health Case Management Equipment, Anti-Malaria tablets and Malaria Rapid Diagnostics Test kits to the Government of Ghana

With reference to the contractual letters dated 19 and 23 March 2015 and 05 October 2015 whereby your firm was engaged to undertake to scope of work as directed at Annex A of the Contractual letter, I confirm that the UK Government wishes to make the following amendment to the letters of 19 and 23 March 2015 and 05 October 2015:

Section 1

Paragraph 1.1

DELETE 31st March 2016 and INSERT 30th April 2016

Section 1

Paragraph 3.1, Line 1

DELETE “£2,564,341.49” and INSERT £3,518,341.49

Annex A3

INSERT the Annex A3 attached.

Annex B3

INSERT the Annex B3 attached.

Annex C

DELETE Annex C and INSERT the Annex C attached.

Annex D

DELETE Annex D and INSERT the Annex D attached.

This amendment relates to an additional procurement of Sulfadoxine/Pyrimethamine and Amodiaquine Hydrochloride Tablets, with a £954,000 increase to the overall financial limit of the contract.

Please confirm in writing by signing and returning one copy of this letter that you accept the amendments set out herein.

Please note the provision in the contractual letter that the financial limit of the UK Government's liability to the Consultants under this engagement shall not exceed the sum specified unless the amount of any such excess has been agreed by the Department for International Development in writing before the Consultants take any action which might result in the financial limit being exceeded.

For and on behalf of the
Secretary of State
for International Development

Name:

Position: Procurement Manager

Signature:

Date: 29th January 2016

For and on behalf of
Crown Agents Ltd
St Nicholas House
St Nicholas Road
Sutton
SM1 1EL

Name:

Position:

Signature:

Date:

:

**Annex A3
Terms of Reference
For
Procurement of Anti-Malaria tablets**

Introduction

Under the Ghana Malaria Prevention, Diagnosis and Data Programme Business Case the UK will provide up to £18.8 million to deliver immediate malaria and diagnosis activities. This includes a provision to administer anti-malaria drugs to children under 5 years during the rainy season as a means of protecting them against malaria. This component has been plagued by bad luck – last year the Seasonal Malaria Chemoprevention (SMC) drugs couldn't be distributed on time for the season and then went up in smoke in January's Central Medical Stores fire. Crown Agents were later contracted under PO 7079 to procure SMCs from KinaPharma Ltd (sole manufacturers of the drugs in Ghana – with an approved waiver - WAIV14_062 on the basis of extreme urgency).

The Food and Drug Authority and an independent laboratory based in Singapore conducted a quality tests on the drugs and the outcome was successful; and subsequently the drugs were delivered to the MoH in line with the terms of the contract.

The programme is being implemented in the Upper West Region and the drugs will be transported there amongst other logistics for the second phase of the programme. The SMC drugs are to be manufactured and delivered to the region before the start of the rainy season in May/June 2016.

DFID through Crown Agents will procure the following:

Malaria: Sulfadoxine/Pyrimethamine and Amodiaquine Hydrochloride Tablets:

This is DFID's core funding procurement under the malaria programme with the National Malaria Control Programme to dose children under 5 years. The overall cost of procuring these drugs is under £1,000,000 including that of Crown Agents fees.

Objective

1. Provide comprehensive quality assurance for both components, in particular the latter (Sulfadoxine/Pyrimethamine + Amodiaquine Hydrochloride Tablets) as the source of supply is not a WHO pre-qualified manufacturer.

Recipient

2. The primary recipients are the Ministry of Health, Ghana Health Service, and National Malaria Control Programme.

Scope of work

3. The Procurement Agent's role will include having an oversight of the procurement planning, drafting of technical specifications, sourcing, tendering, technical and commercial evaluation, contract placement, expediting, quality assurance and inspection, progress and financial reporting, reviewing payment and advising on payments.
4. **The Procurement Agent will procure**, as per annex B3:
Sulfadoxine/Pyrimethamine and Amodiaquine Hydrochloride Tablets.
5. Present a **comprehensive Quality Assurance (QA) plan**. The plan will include the following:
 - 5.1. Due diligence of the end supplier, include documentation:-
 - 5.1.1. Evidence of current valid registration for the formulations to be supplied with the Ghana Food and Drug Authority (FDA) to be provided prior to delivery.
 - 5.1.2. Confirmation of the sources of the Active Pharmaceutical Ingredients for the products to be supplied, including copies of the Certificates of Analysis for these.
 - 5.1.3. Evidence that the manufacturing plant complies with the principles of Good Manufacturing Practice, and has appropriate quality assurance policies in place

- 5.2. Batch testing at a WHO pre-qualified laboratory
- 5.3. Physical pre-shipment review of the product, copies of the certificates of analysis for the actual batches to be supplied. (Review for compliance with the product requirements).

Cost proposal will reflect these elements in details, and how the QA will be managed throughout the life of the project. (At this stage only estimated costs for the quality assurance element of sampling and batch testing are included in this call-down as they will be dependent upon the number of batches produced and the size of those batches. As an indication the cost for testing is USD 1,450.00 per batch, plus courier charges for sending the samples to the laboratory and also time costs for the sampling itself. These costs are indicated at the moment, and will be confirmed by CA in their summary of costs).

6. The Procurement Agent will liaise directly with Ministry of Health, Ghana Health Service, National Malaria Control Programme, and DFID.

Outputs / Deliverables

7. The Procurement Agent will:
 - 7.1. Undertake all **sourcing** as per the terms and conditions of their framework agreement with DFID, and as detailed in Waiver **WAIV15_062**.
 - 7.2. Provide advice on **QA** – and in particular detail QA recommendations for Sulfadoxine/Pyrimethamine and Amodiaquine Hydrochloride Tablets from the end supplier. DFID to provide acceptance of recommendations before implementation
 - 7.3. Ensure that **procurement** of the commodities is done in line with the project timelines and aims of the project
 - 7.4. Help manage the **supply base** in relation to quality, cost and delivery time and assist with all supply contracts.
 - 7.5. Provide a **procurement plan** with key milestones and progress reports upon achievement of these milestones. These reports shall be submitted to DFID Ghana's Senior Programme Officer.
 - 7.6. Ensure the **supplies are delivered** to a warehouse appointed by DFID.

Coordination

8. Clear communication channels and / or approval processes will be established within Procurement Agent and between Crown Agent, DFID and the Government of Ghana represented by the Ministry of Health.

DFID Ghana Programme Manager, will have overall responsibility for the SP Amodiaquine Programme including Financial Management and Administration.

9. DFID Ghana Programme Manager will be responsible for all technical and policy aspects of the project.

Reporting

10. A narrative report at the end of May 2016 will be submitted. This will include a breakdown of costs for material, logistics, insurance (if any) and procurement fee to DFID.

Financial Management

Payments will be linked to outputs. Outputs shall be explained in details in the project plan, along with associated budget and timeframe. Schedule of price is included in annex B3.

Media and communication

11. Crown Agents will be responsible for answering any media questions related to the management of the process. They will consult with DFID and other relevant parties as appropriate.
12. Whenever appropriate Crown Agents will acknowledge that DFID is providing the funding for this programme and will work with DFID and other key stakeholders when necessary to publicise the programme.

Timeframe

11. Deliveries should be finalised by 30th April 2016.

**Annex B3
SPECIFICATIONS**

Schedule of Requirement: Procurement of Sulfadoxine/Pyrimethamine + Amodiaquine Hydrochloride Tablet, 500MG/25MG + 200MG

The following shall be written on each blister strip:

Batch Number:

Manufacturing Date:

Expiry Date:

Product must possess a valid Ghana Food and Drug Authority registration certificate by the time of delivery to the warehouse

SPECIFICATIONS

DESCRIPTION	SPECIFICATION
FOR 12-59 MONTHS OLD CHILDREN	<p>Tablet Description.</p> <ul style="list-style-type: none"> a. White, round with a score line on one side dispersible tablet containing 500 mg sulphadoxine and 25 mg pyrimethamine. b. Yellow round scored dispersible tablet containing 150 mg amodiaquine <p>Packaging: The finished tablets should be packed on a colourless transparent PVC-Aluminium card containing 1 tablet SP and 3 tablets amodiaquine. The secondary packs should be a pack of 50 blister cards.</p> <p>Labelling should clearly state the age band (12-59 months) "For Seasonal Malaria Chemoprevention use ONLY" and the dates of manufacture and expiry.</p>
FOR 3-11 MONTHS OLD INFANTS	<p>Tablet Description.</p> <ul style="list-style-type: none"> c. White, round dispersible tablet containing 250 mg sulphadoxine and 12.5 mg pyrimethamine. d. Yellow round dispersible tablet containing 75 mg amodiaquine <p>Packaging: The finished tablets should be packed on a colourless transparent PVC-Aluminium card containing 1 tablet SP and 3 tablets amodiaquine. The secondary packs should be a pack of 25 blister cards.</p> <p>Labelling should clearly state the age band (3-11 months) "For Seasonal Malaria Chemoprevention use ONLY" and the dates of manufacture and expiry.</p>

The following shall be written on each blister strip:

Batch Number:

Manufacturing Date:

Expiry Date:

Product must possess a valid Ghana Food and Drug Authority registration certificate by the time of delivery to the warehouse.