République Togolaise

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Caisse Nationale de Sécurité Sociale - CNSS

REFERENCE HOSPITAL PROJECT: SAINT PEREGRIN

Tender Specifications

ACQUISITION, INSTALLATION AND MAINTENANCE OF POCT BIOCHEMISTRY EQUIPMENT

TECHNICAL SPECIFICATIONS

SUMMARY

1. Context

1.1. Description of the project

This scope statement takes place during the creation of the new Saint Pérégrin hospital in Lomé, Togo. It will bring healthcare solutions of great quality at an affordable price for the local population. The ambition of this hospital is to become a reference in Togo with occidental standards of quality thanks to the best training of the medical team and the accreditation of the staff and equipment.

In that regard, a strategy of implementing "Point of Care testing" (POCT) devices has been chosen for all the biology in order to replace the classic laboratory. A POCT is defined as a medical diagnostic tool used near or at the point of care.

In accordance with that strategy, it is necessary to equip the hospital with devices which will allow to run all the routine biochemical tests near the patient. The objective of this scope statement is to find a cheaper and more efficient solution than classic laboratory. All by respecting quality standards in a future process of accreditation of the hospital.

As the opening of the hospital is planned to be during the first trimester of 2020, every supplier who will receive this document will have to emit an offer in the six (6) weeks following the receipt of these specifications.

1.2. Planned activity

The healthcare offer of this new hospital of reference will be deployed on the whole Lomé agglomeration (1,500,000 inhabitants). In the following table are detailed the planned amount of ***consultations per day and per specialties***:

Specialty	CONSULTATIONS
Cardiology	3
General surgery	1
Dermatology	6
Endocrinology, metabolic disorder	1
Gynaecology and obstetrics	3
Hepato-gastro-enterology, nutrition	3
Infectiology and parasitology	46
Family medicine	6
Neurology	1
Ophthalmology	4
ORL	11
Orthopaedic traumatology	9
Paediatrics	9
Pneumology	3
Stomatology	1
Urology	1
Total	**116**

And in the following table is detailed the estimated hospitalisations per week and per specialty:

Specialties	Hospitalisations /week
Cardiology	3
Endocrinology	1
Gynaecology	1
Haematology	2
Hepato-gastro-enterology	1
Infectious disease	12
Family medicine	2
Nephrology	1
Neurology	3
Paediatrics	3
Pneumology	1
Rheumatology	1
Digestive surgery	2
Ophthalmology	<1
ORL / Stomatology	1
Orthopaedic Traumatology	4
Urology	1
TOTAL	**39**

The estimated activity is set to 35,000 consultations for medical specialties and 11,000 hospitalisations. To which we need to add 50,000 consultations for general medicine.

2. General framework of the services delivered

2.1. Presentation of the Purchaser

The "Caisse Nationale de Sécurité Sociale" (CNSS) of Togo. As it has a special status, the CNSS is exempted of taxes and customs clearances. It is important to know that the Purchaser will be helped by the French company Altao to analyse the technical parts of the offers.

2.2. Consultation procedure

During the consultation phase, this specifications document is addressed by the Purchaser to the economic operators (suppliers) of its choice, selected during a prior research phase. In return, the receivers of this scope statement can submit to the Purchaser propositions of products and services accordingly to the prior discussions. The Purchaser will proceed to the selection of the suppliers with an analysis of the different propositions received according to their adequacy with the needs, their price and respect of the general aspects seen in this document.

2.3. Call for tender planning

Hereafter is the planning for this procedure as well as the various deadlines:

- May 2019: the preselected suppliers will receive this document and the official call for tender will start;
- June 30th, 2019: deadline to answer and emit an offer, meaning each supplier has about 6 weeks to answer;
- July 30th, 2019: deadline to analyse, discuss and negotiate the different offers received and selection of the selected candidate(s);
- Third trimester 2019: order of the products,
- First trimester 2020: delivery and installation of the products on-site;
- March 1st, 2020: opening of the Saint Pérégrin hospital.

3. Lots

The service provider will be able to answer for all or a part of the following needs. Its offer must involve the devices and disposables which will fit the needs and their quantification.

3.1. Needs listed and quantified

The equipment(s) must be able to run as many of the tests bellow and each test is followed by an estimation of the annual needs:

- Haematology:
  - Complete Blood Count: 7,000/year
  - White Blood Cell Count + Haematocrits: 7,000/year
  - Blood group typing (ABO/Rh):4,500/year
- Urinary Test (Ketonuria, Glycosuria, Proteinuria, …): 4,000/year
- Biochemistry:
  - C-reactive Protein (CRP): 50,000/year
  - Electrolytes measures (Na, K, Cl, Ca, …): 35,500/year
  - Uric acid: 11,000/year
  - Creatinine level: 8,500/year
  - Procalcitonin: 7,500/year
  - Blood glucose: 5,500/year
  - Lipids analysis (CHOL, LDL, HDL, Triglycerides) + Blood Urea Nitrogen (BUN): 2,500/year
  - Brain natriuretic peptide (BNP): 2,500/year
  - Ferritin: 2,500/year
  - Serum iron and transferrin saturation coefficient: 2,500/year
  - Vitamin D: 2,000/year
  - Blood gas: 1,000/year
  - Glycated haemoglobin:1,000/year
  - Partial thromboplastin time: 1,000/year
- Malaria: 20,500/year
  - P. Falciparum
  - P. Vivax
  - P. Malariae
  - P. Ovale
- Virology
  - HIV (1&2): 1,300/year
  - Human Influenza virus (all kind): 1,300/year
- Bacteriology
  - E. Coli: 2,500/year
  - Salmonella: 750/year
  - Shigella: 500/year
- Mycology
  - Candida albicans: 300/year

3.2. Specifications

Every POCT test offered by a supplier must be a solution without any need of maintenance, calibration and manipulation of liquid reagents. Every test working on a blood sample must be doable with capillary blood, with **no exceptions**.

For the haematology and complete blood count, as there is no real POCT solutions on the market, the appropriate solutions will be those close enough to what is needed in a POCT one. The selected analyser will need as few maintenance, calibration and manipulations as possible. Every analyse will have to be doable on capillary blood.

There is a similar problem for the analyse of blood gas and electrolytes, but similar solutions exist. Therefore, these solutions will have to meet the same requirements seen previously.

This document also includes the need of a lector which will be able to read and upload all the rapid diagnostic tests not affiliated with any reader. This device will be able to send those results directly on the hospital's information system.

4. Expected characteristics of the devices

4.1. Accreditations: CE, FDA, other

In order to ensure the quality of the devices and to ease the future accreditation process of the hospital, priority will be given to the devices which have recognized accreditations such as CE marking or the FDA approval for example. The suppliers will precise, for each device and each disposable every marking, norms, agreements and certifications it has, and he will provide these documents in its offer.

4.2. Available interfaces and communication processes

4.2.1. User interface

In order to ensure an optimal use of the equipment, the following criteria must be considered:

- ergonomic interface,
- interface in French or in English,
- help menu for the user,
- user manual in French or in English.

4.2.2. Electronic interface

It is agreed that all electronic interfaces and various ports should be listed:

- WIFI, Ethernet, Bluetooth, RS232, USB, etc.;
- barcode reader for patient identification,
- alimentation type or battery charger.
- possibility to export results on a Cloud based information system.

4.2.3. Data transfer protocols

The supplier will precisely define the available data transfer protocols of the device. These protocols will be open source, available, and they will follow security standards toward the exported information.
It will be defined if there is any way to export directly the results on a dedicated cloud through internet and without any local server. Indeed, the information system of the hospital will likely be a cloud based serverless solution. That is why it is important that each device can be connected to the internet, with a wired connexion, in order to export the results directly on the information system. The export protocols will be secured and detailed in the offer. Those protocols will be divided in two levels: how the device can be linked (Ethernet, RS232, USB, … protocols) and how the information is sent (data format and exchange protocols). The availability or possibility to include in the device a standard Biology exchange protocol will strengthen the offer.

5. Expected answer

For every solution given by a supplier, it will be needed to provide:

- details about the supplier and the constructor (if different),
- the range of the services (number of tests, assistance, formation, …),
- proofs of the tests' precisions compared to gold standards,
- description of the software (if any),
- technical data, for example: technology used, size and weight of the devices, energy needs, battery lifetime, test speed, hygiene rules, …;
- the communication and data export protocols, the format and composition of these data;
- the frequency of the quality controls if needed,
- delivery time of the consumables,
- conditioning of the consumables (shape and size),
- maintenance program,
- spare parts delivery time,
- the supplier's knowledge on this kind of project,
- general conditions,
- repairs or replacing time in case of failure,
- delivery schedule.

Each supplier should know that they are free to make an offer and some variants of it which will also fit the detailed needs. Every variant will be independently analysed.

6. Implementation and maintenance

6.1. Dates and place of delivery

The delivery modality will have to be specified. Only the products delivered in Lomé, Togo, will be considered. A DDP quotation with an on-site delivery in Lomé, Togo, will be preferred. It is important to remind that the Purchaser (CNSS of Togo) is exonerated of taxes and customs clearance thanks to its status.

6.2. Commissioning phase and assistance

During the commissioning of the device(s), the supplier will have to:

- ensure the product will be delivered,
- install or provide help for the installation of the device(s),
- ensure that the product is fully operational upon delivery,
- formation of the users.

6.3. Documentation

In order to study every proposition, a complete documentation of the product(s) will be needed:

- explanation of the technology used,
- size and weight of the device(s),
- energy consumption,
- lifetime of the battery (if any),
- testing speed,
- user manual,
- hygiene rules,
- details about the conservation of the disposable items,
- etc.

The technical and functional documentation must be given in French or in English. Every change in the documentation must be updated systematically and given as soon as possible.

6.4. Formation

Every offer shall specify formations prices and conditions (prerequisite, amount of trainee, amount of time needed, …):

- users in order to ensure a good use of the devices,
- engineers and technicians in charge of the maintenance, level 1 for simple devices and level 2 for the more complex ones.

6.5. Assistance and maintenance

In each offer will be specified the possibilities and modalities of:

- user support,
- maintenance assistance hotline,
- after sales services,
- the hot line's working hours,
- the procedures and phone numbers to call,
- the closest repair centres,
- intervention/reparation time,
- penalties if these delays are not respected.

Even if the expected products should not require a lot of maintenance, it is still necessary that the supplier specifies its modalities. Furthermore, for each device needing to be checked throughout the year in order to prevent some problems, it will be important to precise at which frequency and to schedule these interventions in advance.

6.6. Warranties

In order to ensure the quality and continuity of the healthcare services once the device(s) will be in use, a reliable warranty must be defined according to the following aspects:

- expiry date of the warranty,
- back-up device(s) if needed,
- how will the warranty be applied (on-site reparation, factory repairs? …),
- warranties about delivery and stocks availability,
- rapidity to fix the problems.

So, it is needed that the supplier specifies the warranty period of their products and the modalities of this warranty. Each supplier will also have to specify how each of their device will be supported when the warranty period will be over.

For the single use strips, cassette, rapid diagnostic test and so on, a warranty will be needed which will ensure that all the lots of a single product are the same. Therefore, an on-site quality control procedure and conformity verification will be presented.

6.7. Transport and delivery

Any disposable associated with a device needing to be stocked, therefore transported, in special conditions of temperature, pressure and humidity will be identified. The supplier will provide warranties for an optimal transport of the products respecting these conditions, mostly for the products which need to be refrigerated. It will be necessary to follow the international standards of quality in that domain and to provide the necessary tools to evaluate the delivery's quality. Any supplier who is not able to ensure the quality of the transport of its products will not be selected in this tender.

7. Price, terms of payment:

7.1. Payment method

The prices in the offer will be either in Euro or in American Dollar and in Francs CFA (XOF). The payment will be in Francs CFA by bank transfer, within 60 days after receiving the facture.

In each offer will be detailed the total cost of the solution over 8 years including the equipment, the transport, the installation, the maintenance and the disposables.

7.2. Negotiations

The Purchaser keep the option to negotiate with the candidates. This negotiation can concern all the elements of the offer, including the price.

8. Evaluation criteria

Every supplier submitting a solution for this scope statement will be evaluated by the following criteria:

- cost of the device(s) and the disposables,
- ease of use,
- number of tests doable by each device,
- possibility to deliver the Togo on a long-term basis,
- quality of the product and certifications,
- connectivity with the hospital's information system,
- respect of the planning: it is important to know that, in order to ensure that Saint Pérégrin is operational as soon as possible, a short delivery time is essential.

Every supplier who have emitted an offer will receive an answer, even if it has not been accepted. The suppliers whose offer has been accepted will be invited in Altao's office, in Lille, France, to present more in details their offer.

9. Obligations of the supplier

9.1. Obligations

In addition to what have been said previously, the supplier will be held by the following obligations.

9.1.1. Confidentiality

The staff of the supplier participating in the execution of the services are held to professional secrecy, mostly toward the data and documents accessed during the realisation of the services. Every support of confidential data given to the supplier must be given back at the end of the contract. The supplier cannot give any document to potential contract worker without prior notice. If the supplier gives, with an authorisation, confidential documents to contract workers, they are held by the same obligations. Furthermore, the supplier and the Purchaser agreed to not give away any confidential information they could get from each other during the contract.

9.1.2. Responsibilities

It is expressly agreed that the service provider is held by an obligation of results in the execution of the contract and that he will not be able to dismiss his responsibilities toward the Purchaser until he proved that potential damage results only from a fault of the Purchaser or from a force majeure.

9.1.3. Delays

Contractual delays of delivery and maintenance are committing the supplier so that he will endorse all the responsibility if any prejudice happened to the Purchaser which could result in direct or indirect immaterial damage if those delays where not respected.

9.1.4. Insurances

The different products will have to be insured by the supplier during the shipping and delivery on-site process.

He will also have a liability insurance covering any damage that could be caused on the goods or people during the installation of the devices or during its normal use.

9.1.5. Obligations of collaboration

Both the Purchaser and the service provider will agree to collaborate closely during their contractual relation, to optimise the whole implementation of the different parts of the contract.

The service provider is committed to communicate the difficulties he may find, all along the project, in order to consider them rapidly enabling the success of the whole project.

Everyone mutually commit to communicate all information, events and/or documents which could be useful to the success of the contract.

9.1.6. Obligations of counselling

The service provider is held to an obligation of reinforced counselling. For this reason, it must give spontaneously to the Purchaser all the necessary advises, warnings, recommendations and alerts. Mostly in terms of formation, technical and functional recommendations, technological choice, state of the art and evolutions.

For this reason, the service provider will signal to the Purchaser all the elements which could, by their nature, compromise the good execution of the contract.

All the advises given by the service provider for the good execution of the contract must be written in a report given to the Purchaser.

9.1.7. Obligation of information

The service provider commits to declare within 30 days to the Purchaser every changes or modifications of the juridical or financial structure of the service provider's company.

9.2. Applicable laws – Litigation

9.2.1. Applicable laws

The Purchaser and the supplier are submitting the sale and everything around it to the United Nations Convention on contracts for the International sale of goods (Vienna, 1980).
However, the contract signed will prevail on the convention every time it is planned in it.
If any case were not treated in the contract or the Vienna convention, it will be judged by the OHADA right.

9.2.2. Litigation

In any case of litigation resulting from the contract, the Purchaser and the supplier agree to solve the litigation by applicating the Mediation Rules of the International Chamber of Commerce (ICC). If the litigation could not be solved with those rules within 45 days following the mediation demand, the Purchaser and the supplier agree to solve the litigation by application of the Arbitrary Rules of the ICC. One or more judges will be named, in conformity with those rules.