



African Association of Essential Drugs Purchasing Centres
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SERVICE CONTRACT
FOR PROCUREMENT MANAGEMENT
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APPENDIX II

TERMS OF REFERENCE

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1. GENERAL INFORMATION

1.1. Beneficiary countries

Beneficiary countries include the 16 West African countries:

National Purchasing Centres of these countries expressed their wish to get specialized training sessions on pharmaceutical products supply. This is the purpose of these terms of reference.

These training sessions are part of the African Association of Essential Drug Purchasing Centres programme (ACAME) relating to the capacity building of Purchasing Centres.

1.2. Tendering power

ACAME, which Head office is located in Ouagadougou (Burkina Faso) is the Tendering Power.

1.3. Useful information relating to beneficiary countries

Purchasing Centres of the above-mentioned beneficiary countries are gathered in a network under ACAME.

They sometimes show some heterogeneousness in their structures, their countries characteristics and their running procedures. However, they share the same fundamental principles and they globally have similar needs, namely regarding training.

1.4. Current situation of the relevant sector

Each one of the beneficiary countries has an Essential Drugs Purchasing Centre, which mission, identical from one country to the other, is essential for the health policy of these countries

These are non-profit Purchasing Centres being under the technical supervision of the Ministry of Health and under the financial supervision of the Ministry of Finance.

They must conciliate public health requirements with goals peculiar to a self-managed trading company, which play a part on the international market and must ensure its self-development.

To achieve these goals, the Centres intends to strengthen:

- ✚ The implementation of adapted procedures for the management of all the supply process,
- ✚ Their purchases and stocks planning method,
- ✚ The inventory planning of physical and financial flows
- ✚ Their technical skills for the setting up of a system to secure quality

The achievement of this project should enable to increase the performance of Centres and to optimize their use regarding the supply for priority diseases control programmes

financed by Donors (Antiretroviral drugs for HIV/AIDS, ACT for anti-malarial, anti tuberculosis drugs).

1.5. Related Programmes and other activities of donors

This programme is financed by the European Commission through the 9th European Development Fund (West Africa Regional Health Project, managed from the European Commission Delegation up to one West African capital city at the choice of the tenderer).

Other partners support ACAME programme (French Cooperation) or can together support Purchasing Centres individually, through complementary action.

2. GOALS AND EXPECTED OUTCOMES

2.1. Global objectives

- ✚ Global objective 1: Build the managerial and technical capacities of Purchasing Centres within the supply process.
- ✚ Global objective 2: Strengthen the setting up of a quality insurance system within Purchasing Centres.

2.2. Specific goals

- ✚ Specific goal 1: Promote the setting up of supply procedures that meet the standards of the donors and particularly for ARV supply to their countries
- ✚ Specific goal 2: Encourage Purchasing Centres to comply with fundamental principles of good practices regarding distribution.

2.3. Outcomes to be achieved by the service provider

- ✚ Outcome 1: Purchasing Centres are able to develop a supply system meeting donors' requirements, namely regarding antiretroviral drugs in their country.
- ✚ Outcome 2: Purchasing Centres can analyse various technical documents, which guarantee the quality of the products. They can also apply fundamental principles of Good Practices regarding Distribution.

3. HYPOTHESES & RISKS

3.1. Underlying Hypotheses behind the project

ACAME assessed the needs with the active participation of Purchasing Centres.

Beneficiaries support is thus guaranteed since trainings are concrete and illustrated with realistic examples.

3.2. Risks

With the presence of non Francophone countries, ACAME will make necessary arrangements to provide simultaneous interpretation for participants who need it and see that training reports are also translated into English.

4. SPHERE OF INTERVENTION

4.1. Generalities

4.1.1. Project presentation

ACAME aims at improving the physical and financial access of African poor populations to essential generic drugs.

For this purpose, it launched a huge support programme for Purchasing Centres, which will enable Centres to share their experiences and work. This programme will also help to develop multidisciplinary trainings and assist Centres with the implementation of a strategic development plan.

The Permanent Secretariat of ACAME, located in Ouagadougou (Burkina Faso) is in charge of coordinating this programme.

General Managers of ACAME however not concerned with the exclusion of most of the Purchasing Centres from the supply of priority diseases programmes: antiretroviral drugs (ARV), new combined artemisine-based anti-malarial drugs (ACT) and anti-tuberculosis drugs.

Faced with this situation, Purchasing Centres must therefore build their capacities and show efficiency. This mainly depends on supplies and stocks management control and the development of a quality insurance system.

This specialized training project should enable Purchasing Centres to improve their technical and management skills, and be thus approved by partners and donors regarding their programmes supply.

This approach aims at ensuring local capacity building, national supply and distribution systems streamlining and the sustainability of national bodies.

The purpose of this is to implement two training modules:

- The first training focuses on "Procurement cycle management and ARV supply".
- The second training focuses on "Development of a quality insurance system within Purchasing Centres".
- The third training focuses on "Purchase planning and stock/cash strategic management".

4.1.2. Geographical covered area

Beneficiary countries are listed at item 1.1. These countries are located in West Africa and most of them are French speaking countries (9). However, some of them are English speaking countries (5) or Portuguese-speaking countries (2).

The two trainings therein presented will be conducted in French, in Ouidah (Benin), (with simultaneous interpretation in English).

4.1.3. Target group

Target group is made up of 16 Purchasing Centres, involved in the project, and two representatives of the Permanent Secretariat of ACAME.

More specifically, trainings focused on "Development of a quality insurance system for pharmaceutical products" and "supply management" are priority targets of pharmacists in charge of the Purchasing Centres' supply.

However, ACAME entrusts each Purchasing Centre with the task of designating the candidate who will attend each one of these training sessions.

4.2. Specific activities

4.2.1. 1st training session: "Management of procurement cycle and ARV supply"

This training session aims at building the capacity of Purchasing Centres regarding supply cycle management and presenting an adequate process for ARV supply by Purchasing Centres.

The service provider should organize for this purpose a specialized training session, including two components: comprehensive analysis of an adequate procurement system and ARV supply.

This training session shall last 5 days and shall be held in Ouidah (Benin)

Analysis of procurement cycle

The first part of this training session shall focus on the whole procurement process of an essential drug Purchasing Centre.

The service provider in charge of this training session shall review various points usually analyzed by experts during the assessment of a Centre to approve its possible use by donors.

For each one of the components of the procurement system, the service provider shall explain the required principles, mention pitfalls to be avoided and clearly state adequate methods and means. It shall use concrete examples.

It shall use modern, dynamic and interactive teaching techniques favouring the participation of beneficiaries. It shall organize workshops that will put participants in a real life situation according to given themes.

It shall present the methodology required for the development of a procurement plan, and illustrate its remarks with examples to follow.

The trainer shall consider the following issues, while striving to present solutions to current problems:

Legal framework

- Does the Purchasing Centre work in compliance with national laws and regulation? Does the Purchasing Centre have a procedure manual stating methods relating to procurement, etc?
- Is there a transparent basis (are invitations to tender and results published? are envelopes publicly opened? Are usage conditions of various procurement methods clearly stated? Are there fair and adapted conditions to be met by tenderers?)

Procurement cycle management

- Is the Purchasing Centres procurement management adequately organized? Are various procurement and supply functions differentiated? Are there sufficient human resources? Is the staff being provided with clear instructions? Are the functioning, the composition, and the autonomy of market committees satisfactory?
- Is there a plan for procurement? Is there a good method to take into account technical and financial constraints? Are the needs assessment techniques rational? Are the execution calendars of various phases met and acceptable?
- Do invitations to tender include specific administrative, technical and financial clauses guaranteeing fair conditions? Are risks covered in requests for presentation of tender and good execution guarantees?
- Is the system of shortlisting clear, and does it guarantee a transparent process?
- Are receipt and opening of envelopes carried out as required? Do evaluators have satisfactory technical skills? Do reports objectively describe the assessment of the committee in detail?
- Are the criteria on which contracts are awarded in line with the requirements of the invitation to tender package? Does the handling of registers allow a clear restitution of decisions regarding award and rejection? What is the validation mechanism for the decisions made by the contract committee? Are there external pressures and possibilities of amending decisions? Etc.

Market management

- How are organized contract monitoring system (description, chronology and timing of different stages), delivery, price, and deadline control)

- Are suppliers paid in due time, and following what reception or control procedure basis?
- How are disputes addressed?

Control systems

- How is market control organized? Are there audits?

At the end of this training session, beneficiaries should be able to suggest adjustments for the procedures in force in their Purchasing Centres or organizational changes.

✚ Management of ARV specific supply

The second part of the training shall concern the whole ARV supply process, to be put in place by a Purchasing Centre to comply with recognized standards in this area.

The service provider shall lay emphasis on the specific aspects of ARV supply and the critical stages of these products distribution line:

- **Impact of trade related aspects of intellectual property rights on ARV supply**

The service provider shall suggest a well-sustained methodology on reference examples to allow each country to possibly adapt its national laws in order to work in accordance with international laws and WTO rules.

- **Inventory and management of purchase and stocks**

The trainer shall namely address the following aspects, by suggesting specific recommendations:

- Difficulties in quantifying ARV needs (new process for treatment centres, limited access to a number of PLHA due to financing, difficulty in planning new inclusions in the active file, emergence of resistances that require in change treatment, method of calculation and updating the number of first and second line treatments, difficulties related to the decentralization of distributions, etc.)
- Selection of molecules and galenical forms (according to protocols, simple forms and combined forms (FDC), generics and specialties).
- Different types of suppliers (innovative manufacturers, generics manufacturers, international recognized wholesalers).
- WHO shortlisting system and the use of the updated validation file.

- Availability of ARV stocks with suppliers (how supply managers should behave according to risks of disruption in terms of security stocks determination).
- Specificity of supply process (financial and logistical constraints: expensive products, with a short use-by-date, few paediatric forms, some products require a cold chain, air delivery, security instructions to be applied, etc.).
- ARV quality Control

- **Adaptation of procurement documents**

The service provider shall present required adjustments to be done regarding above-mentioned key procurement documents (invitation to tender files, qualification packages), particularly for ARV.

For instance, references to WHO shortlisting, award of contract packages to many suppliers to prevent depleting in supply source, setting up of global multi-order contracts could be addressed.

- **Presentation of an adapted quantification software**

The service provider shall present in detail quantification software for the needs and the management of supplies. It shall train beneficiaries to use the software.

4.2.2. Setting up quality insurance system within Purchasing Centres:

This second training session shall last 5 days. It will also be held in a West African capital city designated by the tenderer following the first training.

The training session will be split into two themes of equal importance as regard the length of treatment: shortlisting of manufacturer/product, tools, and methods in accordance with good practices of distribution (GPD).

 **Shortlisting of manufacturer/product**

Purchasing Centres member of ACAME want to move toward a progressive system of product selection, which will enable to analyse technical documents in detail.

Indeed, international invitations to tender offer few possibilities for the development of this fundamental work, as deadline is very short. Moreover, they seem so much recurrent and make the capitalization of outcome difficult from one operation to the other.

Therefore, Purchasing Centres must turn toward a selection of the manufacturer/product through a shortlisting system opened to supplier, allowing to examine in detail required technical documents, according to the following successive validation stages:

- Approval of the international wholesaler (if need be)
- Approval of the manufacturer for each product manufacturing site
- Technical approval of the pharmaceutical product (drugs and surgical consumables)

To carry this approval process, pharmacists in charge of assuring the quality of supplies shall control essential technical documents, which shall be presented by the supplier who tender, and be able to interpret provided solutions.

For this reason, ACAME want them to get a specialized training to help them master shortlisting process methodology and also in depth technical analysis of the technical documents.

At each stage, the service provider in charge of training shall clearly show the required documents to the supplier by underlying the essential items that enable their approval.

The training session shall include theoretical courses and practical works on real life situations that require the provision of documents to be analyzed by the service provider.

At the end of the training session, each beneficiary shall be able to:

- Have a good command of international systems of reference and standards: characteristics of various pharmacopoeias (BP, EP, USP, IP, in House), compliance with international standards (ISO, etc), WHO guidelines regarding the approval of pharmaceutical products sold on the international market (BPF, Pharmaceutical Products Certificates)
- Make a list of various technical documents or certificates to be required from service providers for each level of the approval line.
- Interpret these documents so as to assess their compliance with international rules (principles governing master files sites, components of a drug master file, correspondence of a stability study, correspondence of bio-equivalence study, requirements of an analysis certificate, physicochemical, pharmaceutical and technical, microbiological control); assess the quality of the raw material in the absence of a certificate of compliance EP, knowledge of reference standards relating to manufacturing of consumables, and analysis of certificates showing the correspondence of CE marking, etc.)
- Avoid risks related to some practices in force on the international market (products having only export certificates, international wholesaler deregulating batches and claiming to be manufacturer, subcontracting and traceability, difficulties regarding the identification of manufacturing site with the same manufacturer, counterfeiting).

Presentation of tools and methods for the implementation of good practices of pharmaceutical distribution (GPD)

Trainer providing the service shall address the following issues:

- Tools and methods to be used for the implementation of good practices of distribution.
- Physical management of premises and stocks: organize stores and control flow management
- Logistics applied to the drug chain: setting up of a LMIS (Logistic Management Information System)?
- Development of activities and quality indicators.

4.3. Project management

4.3.1. Body in charge of the project management

The Permanent Secretariat of ACAME, located in Ouagadougou is in charge of the project management.

4.3.2. Management structure

The Permanent Secretariat of ACAME shall, through its accountant, see to the strict compliance with procedures governing contracts financed through the 9th EDF.

5. LOGISTIC AND SCHEDULE

5.1. Project site

The two training sessions shall be held at the IRSP of Ouidah (Benin)

5.2. Starting date and period of execution

The service provider shall conduct the two training sessions during from January 28th until February 08th (each training session shall last one week).