**TERMS OF REFERENCE FOR A CONSULTING FIRM FOR CONDUCTING AN ASSEESSMENT OF CAPACITY AND COMPETENCE FOR TESTING AND CERTIFICATION OF PHARMACEUTICAL PRODUCTS IN THE COMESA REGION**

1. **Background and context**

The Common Market for Eastern and Southern Africa (COMESA**)** has received a grant from the African Development Fund to finance the COMESA Support Towards Regional Pharmaceutical Sector Development (CSTRPSD) to support development of the pharmaceutical sector in the region.

The pharmaceutical sector is an integral part of industry at regional, continental, and global levels and within the sector, pharmaceutical quality assurance (QA) is high on the agenda as evidenced by the creation of the African Medicines Agency (AMA) which seeks to promote regulatory harmonization of medical products across the continent and ensure access to medical products that are safe, efficacious, and of assured quality to the African population.

Substandard and Falsified Medicines Products (SFMP) pose a major threat to global health, and they cause more than one million deaths per year and reduce the effectiveness of authentic medical treatment. Global pandemics like COVID-19 can disrupt the supply of quality-assured medicines and lead to increased proliferation of substandard and falsified medicines[[1]](#footnote-1). Between 2013 and 2017, 42 per cent of all reports sent to the WHO Global Surveillance and Monitoring System on SFMP worldwide came from Africa[[2]](#footnote-2). The fight against substandard and falsified medical products requires coordination across sectors locally, nationally, regionally, and internationally. To that effect, the African Medicines Regulatory Harmonization (AMRH) established the African Medicine Quality Forum (AMQF) as a technical committee to lead capacity strengthening of National Quality Control Laboratories (NQCL) for laboratory control of medical products.

National medicines testing laboratories that test suspect falsified medical products should preferably be ISO/IEC 17025 accredited by a recognized accreditation body (affiliated, for example, to the International Laboratory Accreditation Cooperation, etc.) to perform the appropriate analytical procedures that are listed in their scope of accreditation. Alternatively, they should be WHO-prequalified with the capability to test suspect falsified medical products through an appropriate array of analytical techniques[[3]](#footnote-3).

There are 11 WHO pre-qualified medicines Quality Control Laboratories in Africa[[4]](#footnote-4) and only four of these are in the COMESA region. Therefore, laboratories in the region should be capacitated to be competent in testing and certification of pharmaceutical products to combat SFMP.

The COMESA Secretariat is therefore seeking the services of a Consulting Firm to assess capacity and competence for testing and certification of pharmaceutical products in the COMESA region as one approach to reducing the circulation of SFMP.

**2.0 Objectives of the Project**

The principal objectives of the project are to provide institutional support for the development of the pharmaceutical industry through strengthened capacities of the region’s pharmaceutical regulatory bodies, quality control and management systems, research, and development institutions for effective manufacturing of safe and quality pharmaceutical products in the region.

The specific objectives include:

1. The institutionalization and domestication of the Pharmaceutical Manufacturing Plan for Africa (PMPA) and the African Medicines Regulatory Harmonization (AMRH) programme;
2. Strengthening of the region’s medicines and pharmaceutical regulatory bodies/institutions in the region; and
3. Building the capacity of key stakeholders and support trans-regional research and development programmes.
4. **Project Components**

The Project comprises four (4) components as outlined below:

1. **Component 1. Institutionalization of the PMPA and AMRH Programmes in the Region.**
2. **Component 2. Institutional Support for Strengthening Medicines and Pharmaceutical Regulatory Bodies & Institutions in the Region.**
3. **Component 3. Capacity Development of Stakeholders and Support for Trans-Regional Research & Development Programmes.**
4. **Component 4. Project Management, Coordination & Reporting.**
5. **Objective of Consultancy**

The overall objective of the consultancy is to assess capacity and competence for testing and certification of pharmaceutical products in the COMESA region, recommend capacity building initiatives to address SFMP, quantify and cost key infrastructure needed.

**5.0 Specific Objectives**

The Consulting Firm will undertake a comprehensive assessment on testing and certification capacity in the COMESA in consultation with relevant stakeholders in the sector (eg AUDA NEPAD, USAID PQM plus, WHO) and taking into consideration current initiatives within NMRAs such as WHO Benchmarking with the following specific objectives:

1. Assess the capacity and competence of laboratories involved in testing and certifying pharmaceutical products at National Medicines Regulatory Authorities (NMRAs) in line with relevant certification standards (eg ISO 17025 or WHO PQ) focusing on laboratory infrastructure, equipment, expertise etc.
2. Identify areas of capacity-building to rectify identified needs and fortify NMRA laboratory capabilities
3. Recommend interventions to improve reliability and accuracy while ensuring compliance with international standards, thereby combatting counterfeit pharmaceuticals, and promoting public health and safety.
4. Implement selected relevant interventions to address identified gaps, eg capacity building, technical assistance, and guidance on equipment procurement, aimed at enhancing regulatory oversight and quality assurance capabilities to combat the circulation of sub-standard and counterfeit pharmaceuticals.

**6.0 Scope of Work and expected tasks**

The Consulting Firm will undertake the following tasks

1. Prepare an inception report outlining the execution of the consultancy the methodological approach, tools, and proposed approaches to capacity building.
2. Conduct a comprehensive assessment of laboratory capacity and competence within NMRAs across the COMESA region using ISO 17025 and WHO PQ criteria, encompassing the evaluation of infrastructure, equipment, personnel expertise, and testing methodologies available for combating SFMP. The assessment should accommodate Member States where physical visits are not possible.
3. Develop a tailored capacity-building program based on the assessment aimed at strengthening laboratory capabilities within NMRAs, with a focus on enhancing quality assurance protocols, regulatory compliance measures, and surveillance techniques for pharmaceutical products.
4. Develop an action plan outlining interventions to address identified gaps in laboratory capacity and competence, including prioritized strategies for training workshops, technical assistance programs, and equipment procurement initiatives etc
5. In consultation with the COMESA Secretariat, formulate and implement selected targeted interventions to address identified gaps in laboratory capacity and competence, including the provision of training workshops, ongoing technical assistance, and strategic equipment procurement initiatives aimed at enhancing regulatory oversight and product quality assurance measures.
6. Conduct a costing exercise for the prioritized equipment
7. Collaborate with stakeholders, including other RECs, AMRH, AMA leadership, AU’s development partners, academia, business, and international organizations in formulation of capacity building initiatives.

The consulting firm will participate in regular update meetings with the COMESA Secretariat.

**7.0 Deliverables**

|  |  |  |  |
| --- | --- | --- | --- |
| **Item**  | **Estimate Duration** **- Working Days** | **Deadline - Calendar Weeks after contract commencement**  | **Comments**  |
| Inception Report  |  10 | 2 weeks  | To include assessment tools, proposed schedule of visits and anticipated feasible interventions |
| Draft assessment report on the current state of laboratory capacity and competence |   45 | 8 weeks | Activities such as site visits and stakeholder engagement are included in this deliverable. |
| Tailored Capacity building program and action plan for combating SFMP |  20 | 10 weeks |  |
| Costing report for the prioritized items to combat SFMP |  10 | 12 weeks  |  |
| Update meetings  |  5 | Bi-weekly  | Ongoing throughout the assignment |
| Roll out of selected interventions  |  20 | 15 weeks | Feasible interventions to be discussed with the COMESA Secretariat |
| Report on selected capacity building initiatives (eg workshops and trainings)  |   10 | 17 weeks | The nature of the capacity building exercise will be determined by assessment findings |
| Final assignment report and policy brief  |  10 | 18 weeks  |  |
| **TOTAL WORKING DAYS (for all experts)** |  **130**  |  |  |

**8.** **Payment Schedule**

Payments will be paid according to the following milestones.

The Consulting Firm shall be paid the consultancy fee upon completion of the following milestones.

* 30% after completion, submission and acceptance of the Inception Report;
* 20% after completion, submission, and acceptance of the proposed Tailored Capacity building program and action plan for combating SFMP
* 20% after completion, submission, and acceptance of the Report on selected capacity building initiatives (eg workshops and trainings)
* 30% after completion of the final assignment report and policy brief

**9.0 Working Language Requirements**

1. The working language shall be English. Therefore, applicants must be fluent in both spoken and written English.
2. A combination of knowledge and use of English with either French or Arabic will be an added advantage.

**10.0 Eligibility of Consulting Firm**

The consultancy is open to all consulting firms with sufficient qualifications and experience to undertake the assignment.

**11.0 Location, duration, and travel arrangements**

The total number of days allocated for this assignment is One Hundred and Thirty (130) calendar days inclusive of travel days. The assignment is home based, and the Consulting Firm is required to complete the assignment and submit the Final Report within this period. Travel to the COMESA Secretariat and 6 Member States will be required.

All travel arrangements for the assignment will be organised by the Consulting Firm in line with the ToRs to accomplish the deliverables of the assignment. The table below provides guidance on travel arrangements.

Below are the anticipated travel and other related costs.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Anticipated Travels and Related Cost Items**  | **Travel****Yes/No**  | **# of Experts** | **Travel Frequency/# of countries**  | **# of days per travel**  | **Reason for Travel**  |
| Flights for 2 experts (Travel to COMESA Secretariat) | Yes  | 2 | 2 | 2 | Kick-off meeting and close off meeting  |
| Laboratory assessments (1 Expert per country)  | Yes | 3 | 2 | 2/mission | 2 days conducting assessments within one country |

**12.** **Reporting**

The Consulting firm shall report to the Director of Industry and Agriculture, under the overall supervision of the Assistant Secretary General for Programmes of the COMESA Secretariat.

**13. Requirements and Qualifications of the Consulting Firm**

The Consulting firm/organization/entity must have professional experience in pharmaceutical manufacturing, quality assurance of pharmaceuticals and regulatory affairs preferably in Africa.

The following minimum requirements are required:

* Company Profile (including any other material relevant to the services being requested); nature of business, field of expertise, license and certifications.
* Business licenses-registration papers, tax payment certification, etc.
* Demonstrated 20 years of combined experience in delivering similar and relevant assignments on testing and certification of pharmaceutical products (list of projects’ details including the scope, location, and clients)
* Organizational Team of experts with competencies in the key areas of assignment such as; pharmaceutical manufacturing, quality assurance in pharmaceuticals or food manufacturing, regulatory sciences, capacity building in relevant quality standards.
* The consulting firm presence (offices) in any Global Location and understanding of challenges and capacity gaps of pharmaceutical small and medium size enterprises in the region.
* Experience supporting NMRAs, Ministry of Health, Quality Control Laboratories or experience working on SFMP issues eg conducting investigations on SFMP incidents, capacity building on SFMP.

**14. Key Experts:**

The Firm shall provide three experts for the assignment with the following educational background and experience:

**Team Lead:**

* A minimum of a Master’s degree in pharmacy, medicine, engineering, public health, or other health, science and management related-discipline.
* 10 years’ experience in the regulation of food and medical products including laboratory analysis an advantage.
* Experience in developing relevant Quality Assurance Standards for laboratories and manufacturers and assessing conformity.
* Possess capacity building skills including conducting relevant assessments on sub standard and falsified medical products
* Interacting with Member States and project management
* Knowledge of the range of pharmaceutical tests
* Experience in regional, continental, or global networks on medical products regulation or quality assurance issues

**Quality Assurance Expert:**

* A minimum of a Master’s degree or equivalent in the fields of pharmaceutical sciences, natural sciences, engineering, chemistry and business management.
* 10 years’ work experience in quality assurance and regulation of medical products, including sub-standard and falsified medical products a major plus.
* Proven experience in pharmaceutical and medical manufacturing and the associated Quality Assurance Standards .
* Experience in pharmaceutical quality assurance assessments and capacity building .
* Knowledge of regional, continental, and global practices on quality assurance for medical and pharmaceutical products.
* Practical experience working within the pharmaceuticals sector at a management level.

**Regulatory Expert:**

* A minimum of a Master’s degree or equivalent in the fields of pharmaceutical sciences, public health, regulatory sciences, biotechnology, engineering and related disciplines .
* 8 years work experience in regulation of medical products, including SFMP a major plus.
* Knowledge of the range of tests conducted during and post manufacturing of medical products
* Practical experience in monitoring and conducting inspections and operations to combat SFMP at national or regional level
* Competence in capacity building initiatives for Regulatory Agencies and pharmaceutical manufacturers.
* Knowledge of regional, continental, and global collaborations on combating SFMP.

**15. Selection Procedure**

Eligibility criteria, establishment of the short-list and the selection procedure shall be in accordance with African Development Bank’s “Procurement Framework for Bank Group Funded Operations” dated 2015, which is available on the Bank’s website at: <https://www.afdb.org/en/projects-and-operations/procurement/new-procurement-policy>. The Consulting Firm will be selected under the Consultants’ Qualifications Selection (**CQS**).

1. <https://www.usp.org/sites/default/files/usp/document/about/public-policy/combatting-substandard-and-falsified-medicines-policy-position.pdf> [↑](#footnote-ref-1)
2. https://au.int/sites/default/files/documents/40875-doc-Africas\_2nd\_Continental\_Health\_Agency-\_Africa\_Medicines\_Agency\_AMA\_English\_.pdf [↑](#footnote-ref-2)
3. https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/quality-control/trs1010-annex5-testing-suspect-samples.pdf?sfvrsn=df47cb5\_2&download=true [↑](#footnote-ref-3)
4. <https://extranet.who.int/prequal/medicines/prequalified/quality-control-labs> [↑](#footnote-ref-4)