**TERMS OF REFERENCE FOR AN INDIVIDUAL CONSULTANT TO SUPPORT THE RE-ESTABLISHMENT AND OPERATIONALISATION OF THE COMESA PHARMACEUTICALS COMMITTEE**

1. **Background and context**

The COMESA region commands the largest market in Africa with an estimated total population of more than 583 million people and Gross Domestic Product of USD 805 billion. COMESA’s objective is to create a large economic and trading bloc capable of overcoming the constraints faced by individual Member States. The treaty establishing COMESA provides for facilitation of movement of pharmaceuticals and control of quality within the region and a meeting of the Council of Ministers meeting in Khartoum held in March 2003 noted variations in legislation and regulations among National Medicines Regulatory Authorities (NMRAs) and emphasised the need of harmonisation of the regulatory environment. The Council further observed that some of these decisions only require policy change and very little or no financing to implement while others require private sector intervention.

In response to the recommendations of the Ministers at the Khartoum meeting, a COMESA Medicine Regulatory Authorities Conference (CMRAC), a multi-disciplinary technical group was created. CMRAC held its first meeting in Lusaka from 13 - 15 June 2005, during which fifteen documents covering Minimum Technical Standards for Harmonisation (MTSH) were accepted to be used as a basis for harmonisation work. During the meeting, CMRAC established a Steering Committee consisting of Kenya, Uganda, Zambia, and Zimbabwe to prepare National Drug/Medicine Regulatory Authorities within member states for the harmonisation process. The steering committee held the first meeting on 4-5 September 2006 during which it reviewed the documents and agreed on a harmonisation programme. This was followed by a sensitisation workshop of the harmonisation programme and a CMRAC meeting in June 2009 and April 2010 respectively. Beyond that, the coordination of pharmaceutical activities within the COMESA Secretariat ceased as the funding envelope that was supporting it came to an end.

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 and one of the outputs of the project is to support re-establishment and operationalisation of the COMESA Pharmaceuticals Committee and ensure that it is sustainable.

**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 institutionalisation and domestication of the Pharmaceutical Manufacturing Plan for Africa (PMPA) and the African Medicines Regulatory Harmonisation (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:

1. **Component 1. Institutionalisation of the PMPA and AMRH Programmes in the Region.**

 This component aims at supporting the COMESA region in the implementation of the continental strategies on pharmaceutical manufacturing and streamline medicines registration harmonisation processes as well as ensuring that the region has access to essential medical products and technologies. It will address the challenges faced by national medicines regulatory authorities, including weak or non-coherent legislative frameworks, redundant processes, sluggish medicines registration processes, and inefficiency and limited technical capacities, among others, through regulatory harmonisation. The target beneficiaries include COMESA Secretariat and National Pharmaceutical Policy Institutions such as (National Medicines Regulatory Authorities (NMRAs)/Food and Drug Administration (FDA) bodies.

1. **Component 2. Institutional Support for Strengthening Medicines and Pharmaceutical Regulatory Bodies & Institutions in the Region.**

 This component concerns providing technical support to strengthen the institutions and bodies responsible for pharmaceutical sector development in the region, including, the NMRAs/FDAs, the COMESA Pharmaceuticals Committee, institutions responsible for trade facilitation and quality infrastructure for standardisation and testing pharmaceutical products. The target beneficiaries include NMRAs, COMESA pharmaceutical committee, standards and certification laboratories and collaborations with other regional economic communities on pharmacovigilance.

1. **Component 3. Capacity Development of Stakeholders and Support for Trans-Regional Research & Development Programmes.**

 This component aims at strengthening the capacities of pharmaceutical stakeholders, including research institutions and create an information platform for pharmaceutical manufacturers, importers, and exporters in the region. It will also establish pharmaceutical industry collaborations with universities to address skills mismatch and shortages in the sector. The objective is to improve the requisite capacities of stakeholders as well as increase efficiency, effectiveness, and improve service delivery to the pharmaceutical industry in the region. Further to strength the implementation of COMESA Health framework (2026) which calls for establishing capacity of Health Research and Development (R&D) and production of medicines and supplies.

1. **Component 4. Project Management, Coordination & Reporting**

 This component entails the general management and implementation of the project. It aims to complement the capacity of COMESA Secretariat for the effective and efficient implementation of the project. This includes setting up of a Project Implementation Unit and staffing it with the required human resources that would be responsible for the implementation of the project activities and delivering of the outputs.

**4.0 Rationale of the assignment**

It was recognised as early as 1987 that for trade to be enhanced in the then Preferential Trade Area (PTA), there was need to harmonise activities of National Drugs/Medicines Regulatory Authorities in the region. Despite the emergence of the COVID-19 pandemic and other public health emergencies which disrupted medical supply chains, there has been no formal coordination of pharmaceutical activities in the COMESA Secretariat. Furthermore, the region needs to align with other regulatory harmonisation initiatives on the continent. The re-establishment of the Pharmaceutical Committee is vital for strengthening and coordination of all pharmaceutical activities in the region and contributing to various continental initiatives.

1. **Objective of Consultancy**

The overall objective of the consultancy is to Support the Re-establishment and operationalisation of the COMESA Pharmaceuticals Committee and ensuring its sustainability thereafter.

**6.0 Specific Objectives**

* Undertake a detailed analysis of the previous structure and activities of the Pharmaceuticals Committee and update them in line with current trends and developments within COMESA and the continent.
* Engage relevant stakeholders including but not limited to Member States, sister Regional Economic Communities eg EAC, ECOWAS, SADC to inform the revival of the Pharmaceuticals Committee and ensure its sustainability.
* Draft Terms of Reference (ToRs) of the role, responsibilities and functions of the Pharmaceuticals Committee as well as its structure within the COMESA system.
* Facilitate meetings of the COMESA Pharmaceuticals Committee and develop relevant strategies for its sustainability.

**7.0 Scope of Work and activities**

The consultant will undertake the following Work / Activities:

1. Review the relevant information on the current and recent initiatives on Medicine Regulatory Harmonisation Procedures, and other relevant activities in the Pharmaceutical Sector in the COMESA Region
2. Compile recommendations on activities of the Pharmaceutical Committee based on the review of current activities in the region
3. Draft the terms of reference outlining the composition, roles and responsibilities of the Pharmaceuticals Committee and recommend its hierarchical structure
4. Facilitate the re- establishment of the COMESA Pharmaceutical Committee including holding an inaugural meeting and a competence building session
5. Develop a strategic plan and workplan of the Pharmaceuticals Committee taking into consideration the current developments in the sector
6. Develop a Communications and Stakeholder Engagement Strategy of the Committee
7. Develop a Sustainability Strategy and Resource Mobilisation Strategy of the Committee
8. Carry out other activities in line with the requirements of the assignment
9. Prepare a Draft End of Assignment Report
10. Prepare a Final End of Assignment Report including relevant recommendations
11. Present the Final End of Assignment Report in a committee meeting validation

**8.0 Deliverables**

|  |  |
| --- | --- |
| **Expected Deliverables** | **Estimated Working Days** |
| Inception Report (Max 15 pages) | 04  |
| Short report on Pharmaceutical activities and Regulatory Harmonisation initiatives in the region and recommended approaches for the Pharmaceutical Committee (Max 15 pages)  | 02 |
| Terms of reference for Re-establishment and Operationalisation of the COMESA Pharmaceuticals Committee | 05 |
| Meetings of the COMESA Pharmaceuticals Committee  |  |
| * Inaugural COMESA Pharmaceuticals Committee (CPC)

meeting held | 05 |
| * Material for competence building session developed
 | 05 |
| * Competence building session held
 | 05 |
| Report of the Inaugural Meeting of the COMESA Pharmaceuticals Committee (CPC) Prepared | 03 |
| Strategic Plan and Workplan of the Pharmaceuticals Committee developed | 08 |
| Communications and Stakeholder Engagement Strategy of the Committee developed | 04 |
| Sustainability and Resource Mobilisation Strategy of the Committee developed | 04 |
| Draft Final Report for the Assignment | 05 |
| Final Report for the Assignment and a Policy Brief | 5 |
| Presentation of the Final Report of the COMESA Pharmaceuticals Committee and the developed strategies in a Validation Workshop  | 05 |
| **TOTAL WORKING DAYS** | **60** |

**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 the Individual Consultant**

The consultancy is open to nationals of any country that have sufficient qualification and experience to undertake this assignment.

**11.0 Duration**

The total number of days allocated for this assignment is one hundred and twenty (120) calendar days inclusive of travel days. The Individual Consultant is required to complete the assignment and submit the Final Report within this period.

**12.0 Duty Station**

The Consultancy will be home based, with travel requirement to the COMESA Secretariat in Lusaka, Zambia and selected Member States in the COMESA Region, where possible.

**13.0** **Reporting**

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

**14.0 Requirements and Qualifications**

The consultant must have the following qualifications, professional skills, and experience:

A Minimum of a Master’s Degree with specialisation in any of the following areas: public health, pharmacy, natural sciences, biomedical sciences, development studies, and management, or related relevant field.

1. At least 5 years of relevant work experience in pharmaceutical/health or related fields
2. Knowledge of the COMESA industrial development agenda, and AfDB or development cooperation in the pharmaceutical sector.
3. Experience in organising meetings at the Regional Economic Community (REC) level.
4. In-depth familiarity with pharmaceutical and regulatory initiatives in Africa
5. Demonstrated experience in domesticating continental/regional frameworks in Member States in the COMESA region.
6. Knowledge of COMESA efforts towards Regulatory Harmonisation of Medicines.
7. Exposure and ability to work in a multi-cultural and multi stakeholder environment.
8. Leadership, creativity, negotiations, and diplomatic skills.
9. Advanced computer literacy skills.

**15.0 Payment Schedule**

Payments shall be paid upon satisfactory accomplishment of the contracted tasks and submission of reports of acceptable standard and quality to COMESA as follows:

1. 20 % of the payment upon submission of an Inception Report;
2. 10% of the payment upon submission of the Report on Regulatory Harmonisation;
3. 40% of the consultancy fee upon submission and approval of the Draft Report; and
4. 30% upon completing the assignment and submission of Final report and Policy Brief.

**ANNEX 1**: EXPRESSION OF INTEREST FORMS

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# A. COVER LETTER FOR THE EXPRESSION OF INTEREST FOR THE PROJECT

REFERENCE NUMBER: CS/CSTRPSD/05/04/km

REQUEST FOR SERVICES TITLE: **CONSULTANCY SERVICES TO SUPPORT THE RE-ESTABLISHMENT AND OPERATIONALISATION OF THE COMESA PHARMACEUTICALS COMMITTEE**

 [*Location, Date*]

To: COMESA Secretariat

Dear Sirs:

I, the undersigned, offer to provide the consulting services for the “**CS/CSTRPSD/05/04/km**”: **CONSULTANCY SERVICES TO SUPPORT THE RE-ESTABLISHMENT AND OPERATIONALISATION OF THE COMESA PHARMACEUTICALS COMMITTEE**

” in accordance with your Request for Expression of Interests number **CS/CSTRPSD/05/04/km***,* dated [*insert date*] for the sum of [*Insert amount(s) in words and figures*]. This amount is inclusive of all expenses deemed necessary for the performance of the contract in accordance with the Terms of Reference requirements.

I hereby declare that all the information and statements made in my CV are true and accept that any misinterpretation contained in it may lead to my disqualification.

My proposal is binding upon me for the period indicated in Paragraph 9(iii) of this Request for Expression of Interest.

I undertake, if my Proposal is accepted, to initiate the consulting services related to the assignment not later than the date indicated in Paragraph 9 of the Request for Expression of Interest, and to be available for the entire duration of the contract as specified in the Terms of Reference.

I understand you are not bound to accept any Proposal you receive.

Yours sincerely,

Signature [*In full and initials*]:

Name and Title of Signatory:

B. CURRICULUM VITAE

*[insert full name]*

|  |  |
| --- | --- |
| 1. Family name:
 | *[insert the name]* |
| 1. First names:
 | *[insert the names in full]* |
| 1. Date of birth:
 | *[insert the date]* |
| 1. Nationality:
 | *[insert the country or countries of citizenship]* |
|  |  |
| 1. Physical address:
2. Postal address
3. Phone:
4. E-mail:
 | *[insert the physical address]**[Insert Postal Address]**[insert the phone and mobile no.]**[Insert E-mail address(es)* |
| 1. Education:
 |  |
|  |  |
| Institution:[Date from – Date to] | Degree(s) or Diploma(s) obtained: |
| *[indicate the month and the year]* | *[insert the name of the diploma and the specialty/major]* |
| *[indicate the month and the year]* | *[insert the name of the diploma and the specialty/major]* |

10. Language skills: (Indicate competence on a scale of 1 to 5) (1 – excellent; 5 – basic)

|  |  |  |  |
| --- | --- | --- | --- |
| Language | Reading | Speaking | Writing |
| *[insert the language]* | *[insert the no.]* | *[insert the no.]* | *[insert the no.]* |
| *[insert the no.]* | *[insert the no.]* | *[insert the no.]* | *[insert the no.]* |

|  |  |
| --- | --- |
| 11. Membership of professional bodies:  | *[indicate the name of the professional body]* |
| 12. Other skills: | *[insert the skills]* |
| 13. Present position: | *[insert the name]* |
| 14. Years of experience: | *[insert the no]* |
| 15. Key qualifications: (Relevant to the assignment)*[insert the key qualifications]* |

16. Specific experience in the region:

|  |  |
| --- | --- |
| Country | Date from - Date to |
| *[insert the country]* | *[indicate the month and the year]* |
| *................* | *......................* |
| *[insert the country]* | *[indicate the month and the year]* |

17. Professional experience:

| Date from – Date to | Location of the assignment | Company& reference person (name & contact details) | Position | Description |
| --- | --- | --- | --- | --- |
| *[indicate the month and the year]* | *[indicate the country and the city]* | *Name of the Company:**Address of the company:**Phone:**Fax:**Email:* *Name and title of the reference person from the company:* | *[indicate the exact name and title and if it was a short term or a long-term position]* | *Name of the Assignment:* *Beneficiary of the Assignment:**Brief description of the Assignment:* *Responsibilities:*  |
| ................ | …………….. | ……………………. | …………… | ………………………………………………………………………….. |
| *[indicate the month and the year]* | *[indicate the country and the city]* | *Name of the Company:**Address of the company:**Phone:**Fax:**Email:* *Name and title of the reference person from the company:* | *[indicate the exact name and title and if it was a short term or a long-term position]* | *Name of the Assignment:* *Beneficiary of the Assignment:**Brief description of the Assignment:* *Responsibilities:*  |

1. Other relevant information: (e.g. Publications)

*[insert the details]*

*19. Statement:*

I, the undersigned, certify that to the best of my knowledge and belief, this CV correctly describes myself, my qualifications, and my experience. I understand that any wilful misstatement described herein may lead to my disqualification or dismissal, if engaged.

I hereby declare that at any point in time, at the COMESA Secretariat’s request, I will provide certified copies of all documents to prove that I have the qualifications and the professional experience as indicated in points 8 and 14 above[[1]](#footnote-1), documents which are attached to this CV as photocopies.

By signing this statement, I also authorize the COMESA Secretariat to contact my previous or current employers indicated at point 14 above, to obtain directly reference about my professional conduct and achievements.

|  |  |  |
| --- | --- | --- |
|  | Date: |  |

ATTACHMENTS: *1) Proof of qualifications indicated at point 9*
 *2) Proof of working experience indicated at point 15*

1. ***The proof of stated qualifications shall be in the form of the copies of the degrees and diploma obtained, while for the professional experience the proof shall be either acknowledgement letters from the previous employers or copies of the Purchase Order/ Contract signed with them.***  [↑](#footnote-ref-1)