**TERMS OF REFERENCE FOR AN INDIVIDUAL CONSULTANT TO DEVELOP A REGIONAL PHARMACOVIGILANCE AND COMMUNICATION AND VISIBILITY STRATEGY FOR COMESA IN ALIGNMENT WITH OTHER REGIONAL ECONOMIC COMMUNITIES**

* 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) project which seeks to strengthen institutional capacity among relevant institutions in the Member States to manufacture quality, safe and efficacious medicines, and medical products locally.

COMESA has made sustainable economic and social progress in all Members States through increased regional economic cooperation and integration in all fields of sustainable development. In addition, the COMESA Secretariat has a Health Framework through which initiatives in the health sector are operationalized. The Health Framework recognizes the importance of local manufacturing to reduce dependence on imports, localize pharmaceutical value chains, and strengthen the supply chain of medical and pharmaceutical products.

The pharmaceutical sector is one of the largest industries globally and in the COMESA region and is one building blocks for health systems according to the World Health Organisation (WHO) given its role in ensuring availability of medicines and medical products for preventive and curative health services. The continued growth of the industry needs to be accompanied with strong monitoring systems in line with the ever-increasing concerns for product safety. The World Health Organisation defines pharmacovigilance as “the science and activities relating to the detection, assessment, understanding and prevention of medicine adverse effects or any other medicine related problem”.

The growing population of Africa needs to be safeguarded against the adverse effects of medical and pharmacological interventions and one way of ensuring this is the development of relevant policies and frameworks which take into consideration developing trends such as the use of social media and effective communication in public health emergencies[[1]](#footnote-1) .

Against this background, there is a need to develop a Regional Pharmacovigilance Strategy and align it with ECOWAS, SADC, and EAC, and a Regional Pharmacovigilance and Communication Strategy.

**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.

**3. 0 Project Components**

The Project comprises four (4) components:

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**

COMESA through the CSTRPSD Project is therefore seeking the services of a consultant to develop a pharmacovigilance strategy and plan for the region along with a communication, visibility, stakeholder engagement and resource mobilisation strategy with regards to medicines and medical products safety. The plan will align with global and continental initiatives from other Regional Economic Communities (RECs).

**4.0 Objective of the Consultancy**

The main objective of this consultancy is to develop a Pharmacovigilance Strategy and associated Monitoring, Evaluation and Accountability Plan to promote implementation of Pharmacovigilance programs in the COMESA region. The consultancy will focus on the health system and pharmaceutical industry in the COMESA region while leaning heavily on functional pharmacovigilance systems in Member States and globally. The strategy will be supported by a communication, visibility, stakeholder engagement and resource mobilisation strategy.

**5.0 Scope Of Work**

* Review of relevant policies, laws, regulations and institutional frameworsk on pharmacovigilance in Africa and globally eg WHO, FDA, EAC, SADC, ECOWAS.
* Review of in -country pharmacovigilance systems, structures, and regional pharmacovigilance coordination in the region.
* Engage relevant stakeholders in the region and globally to inform the development of a contextually relevant Pharmacovigilance Strategy for the COMESA region encompassing sustainability, communication, and visibility aspects.

**6.0 Specific Tasks Expected by the Consultant**

The consultant is expected to undertake the following:

1. Develop an appropriate methodology for the assignment and outline it in the inception report;
2. Review the international, regional and sub regional policy, legal, regulatory, and institutional frameworks on pharmacovigilance to identify good practices, bottlenecks, and strengths.
3. Conduct a comparative analysis and benchmarking exercise with other successful frameworks and initiatives outside the region to identify gaps in policies, strategies and performance as well as draw reform lessons.
4. Develop a comprehensive regional Pharmacovigilance Strategy with elements such as capacity-building, resource mobilization, among others, for achieving a fully functional and sustainable medicine and medical products safety system.
5. Organize an expert group meeting to interrogate the COMESA Pharmacovigilance Strategy and the Communication and Visibility Strategy.

**7.0 Deliverables**

1. An inception report within two weeks (14 working days) of signing the contract. The inception report should specifically outline the understanding of the scope of the consultancy. It should also define methodology, data sources and identify and list the key stakeholders to be consulted. The inception report must also incorporate a work plan indicating the phases in the assignment, key deliverables, and milestones. It should also contain a report format/structure.
2. Concept paper detailing the situational analysis of pharmacovigilance systems in the COMESA region and strategies to strengthen pharmacovigilance systems in accordance to the situational analysis
3. A Stakeholder Validation workshop report
4. Final Draft strategic framework that provides guidelines to promote a robust pharmacovigilance system in the COMESA pharmaceutical industry and healthcare systems incorporating comments and perspectives from the stakeholder validation workshop.
5. A Stakeholder Validation workshop report
6. A Communication and Visibility and Resource Mobilization Strategy for pharmacovigilance in the COMESA region.

**7.0 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.

**8.0 Eligibility of Consultants**

The consultancy is open to all applicants that have sufficient qualifications and experience to undertake this assignment.

**9.0 Contract Duration**

The total number of days allocated for this assignment is 120 calendar days inclusive of travel days. The Consultant will be required to have completed the assignment and submitted the Final Report within this period.

**10. Duty Station**

The Consultancy will be home based, with travel requirement to the COMESA Secretariat in Lusaka, Zambia and at least five Member States in the COMESA Region, as required.

**11. Reporting and Accountability**

The 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.

**12. Education Qualifications, Professional Skills, and Experience**

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

**Education Qualifications**

The preferred candidate should meet the following criteria:

* Bachelors’ Degree in Medicine, Pharmacy, Biomedical Sciences or other related fields.
* Master’s degree in Public Health, Pharmacology, Regulatory Affairs or any other relevant clinical science discipline.

**Professional Skills, and Experience**

1. At least 15 years of experience in clinical practice, post marketing surveillance, developing and implementing public health programs, policy frameworks, strategic plans, roadmaps, and advocacy in health systems.
2. A very good understanding of the health systems and pharmaceutical sector including policy developments in Africa and the COMESA region.
3. Experience in product safety and pharmacovigilance with good knowledge of African systems.
4. Demonstrated evidence of skills in research, analysis of qualitative and quantitative data as well as good report writing.
5. Ability to engage stakeholders efficiently and effectively to collect relevant information for the assignment.
6. Familiarity with the developmental organizational work environment and dynamics.
7. Good interpersonal skills and ability to work independently as well as within interdisciplinary teams.
8. Advanced computer literacy skills

**13.Payment**

The consultant shall be paid in three (3) tranches as follows:

1. 10% upon submission of an inception report
2. 40% upon submission of the draft report
3. 50% upon submission of the final report to the COMESA Secretariat.

**ANNEX 1**: EXPRESSION OF INTEREST FORMS

#

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

REFERENCE NUMBER: CS/CSTRPSD/01/08/km

REQUEST FOR SERVICES TITLE: **CONSULTANCY SERVICES TO DEVELOP A REGIONAL PHARMACOVIGILANCE AND COMMUNICATION AND VISIBILITY STRATEGY FOR COMESA IN ALIGNMENT WITH OTHER REGIONAL ECONOMIC COMMUNITIES**

 [*Location, Date*]

To: COMESA Secretariat

Dear Sirs:

I, the undersigned, offer to provide the consulting services for the **“CS/CSTRPSD/01/08/km CONSULTANCY SERVICES TO DEVELOP A REGIONAL PHARMACOVIGILANCE AND COMMUNICATION AND VISIBILITY STRATEGY FOR COMESA IN ALIGNMENT WITH OTHER REGIONAL ECONOMIC COMMUNITIES”**

” in accordance with your Request for Expression of Interests number **CS/CSTRPSD/01/08/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[[2]](#footnote-2), 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. https://cdn.who.int/media/docs/default-source/medicines/pharmacovigilance/unmasking-safety-signals-in-an-infodemic\_technical-report.pdf?sfvrsn=5890874b\_1&download=true [↑](#footnote-ref-1)
2. ***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-2)