



REQUEST FOR EXPRESSION OF INTEREST

SELECTION OF AN INDIVIDUAL CONSULTANT

TO DEVELOP A COMESA MEDICINES REGULATORY HARMONIZATION PROGRAMME ALIGNED TO THE CONTINENTAL PROGRAMME AND TAKING INTO CONSIDERATION EXISTING PROGRAMMES FROM SISTER (REGIONAL ECONOMIC COMMUNITIES) RECS

REFERENCE NUMBER: CS/CSTRPSD/05/2025/km

1. The COMESA Secretariat is inviting Individual Consultants to submit their CV for the following services:

CONSULTANCY SERVICES TO DEVELOP A COMESA MEDICINES REGULATORY HARMONIZATION PROGRAMME ALIGNED TO THE CONTINENTAL PROGRAMME AND TAKING INTO CONSIDERATION EXISTING PROGRAMMES FROM SISTER (REGIONAL ECONOMIC COMMUNITIES) RECS

The Terms of Reference defining the minimum technical requirements for the service is attached as Annex 1 to this Request for Expression of Interest.

2. Only INDIVIDUAL CONSULTANTS are eligible to participate under this assignment if they fulfil the following eligibility criteria:
 - a) *they are a national of an AfDB Member country and have sufficient experience to undertake this assignment.*
 - b) *they are not bankrupt or wound up, are not having their affairs administered by the courts, have not entered into arrangements with creditors, have not suspended business activities, are not being subject of proceedings concerning those matters, or are not in any similar situations arising from similar procedures provided for in the national legislation or regulations of the COMESA member states;*
 - c) *they have not been convicted of offences concerning their professional conduct by a judgment which have the force of res judicata; (i.e., against which no appeal is possible);*
 - d) *they have not been declared guilty of grave professional misconduct proven by any means which COMESA Secretariat can justify.*
 - e) *they have fulfilled obligations related to the payments of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those countries where the contract is to be performed.*

- f) *they have not been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the COMESA Secretariat's financial interests; or*
 - g) *they are not being currently subject to an administrative penalty.*
3. The maximum consultancy fee for this consultancy is USD20,000 (exclusive of travel) for a duration of 180 Calendar Days.
 4. Your Expression of Interest must be presented as per Expression of Interest Forms attached as Annex 2 to this Request for Expression of Interest, in the English language and be accompanied by copies of all the indicated supporting documents. If the supporting documents are not in English, these shall be accompanied by a certified translation into English.

Your application documents clearly marked and email bearing the subject "CS/CSTRPSD/05/2025/km: INDIVIDUAL CONSULTANCY - TO DEVELOP A COMESA MEDICINES REGULATORY HARMONIZATION PROGRAMME ALIGNED TO THE CONTINENTAL PROGRAMME AND TAKING INTO CONSIDERATION EXISTING PROGRAMMES FROM SISTER (REGIONAL ECONOMIC COMMUNITIES) RECS", should be e-mailed to the following address: kmiti@comesa.int and copied to s.mwesigwa@comesa.int; procurement@comesa.int

5. The deadline for submission of your application, to the address indicated in Paragraph 4 above, is:

19th May 2025 at 16:00 hours

6. Physical submission of applications is NOT allowed.
7. Your CV will be evaluated against the following criteria.

	Criteria	Maximum points allocated
1	Applicant's Educational qualifications	30
2	Relevant Experience and skills	60
3	Experience in the African Region	10
	Total	100

8. Your proposal should be submitted as per the following instructions:

(i) EVALUATION AND AWARD OF THE CONTRACT:

Expressions of Interest determined to be formally compliant to the requirements will be further evaluated technically.

An Expression of Interest is considered compliant to the requirements if it fulfils the formal requirements (see Paragraphs 2,3,4,5,6 and 7 above),

The award will be made to the applicant who obtains the highest technical score. Expressions of Interest not obtaining a minimum score of 70% will be rejected.

(ii) VALIDITY OF THE EXPRESSION OF INTEREST:

Your Expression of Interest should be valid for a period of 90 days from the date of deadline for submission indicated in Paragraph 5 above.

9. The assignment is expected to commence within two (2) weeks from the signature of the contract.
10. Additional requests for information and clarifications can be made until 3 working days prior to deadline indicated in paragraph 5 above, from:

The Procuring entity: *COMESA Secretariat*
Contact person: Kondanani Miti (*Mr*)

E-mail : *kmiti@comesa.int*; procurement@comesa.int ;

The answers on the questions received will be sent to the Consultant and all questions received as well as the answers to them will be posted on the COMESA Secretariat's website at the latest 2 working days before the deadline for submission of applications.

ANNEXES:

ANNEX 1: Terms of Reference
ANNEX 2: Expression of Interest Forms

Sincerely,

NAME: SILVER MWESIGWA
TITLE: HEAD OF PROCUREMENT
Date: **05th May 2025**

TERMS OF REFERENCE FOR AN INDIVIDUAL CONSULTANT TO DEVELOP A COMESA MEDICINES REGULATORY HARMONIZATION PROGRAMME ALIGNED TO THE CONTINENTAL PROGRAMME AND TAKING INTO CONSIDERATION EXISTING PROGRAMMES FROM SISTER (REGIONAL ECONOMIC COMMUNITIES) RECS

1.0 Background and context

The COMESA region commands the largest market in Africa with an estimated total population of 640 million people and Gross Domestic Product of USD 1.0 trillion. 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 harmonization of the regulatory environment. The Council further observed that some of these decisions only require policy change and very little or no financing requirement to implement while others require private sector intervention.

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 develop a COMESA Medicines Regulatory Harmonization Programme aligned to the continental programme, the African Medicines Regulatory Harmonization (AMRH) programme and taking into consideration existing programmes from sister Regional Economic Communities (RECs).

In line with the AMRH initiative, the COMESA Medicines Regulatory Harmonization (COMESA MRH) Programme aims to streamline and align regional medicine regulatory processes with the African Union's continental ones.

Working under the umbrella of the COMESA Pharmaceuticals Committee, the COMESA MRH Programme seeks to enhance access to safe, effective, and quality-assured medicines across the COMESA region by harmonizing regulations and leveraging existing programs from other regional economic communities.

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:

- (i) The institutionalisation and domestication of the Pharmaceutical Manufacturing Plan for Africa (PMPA) and the African Medicines Regulatory Harmonization (AMRH) programme;
- (ii) Strengthening of the region's medicines and pharmaceutical regulatory bodies/institutions in the region; and

- (iii) Building the capacity of key stakeholders and support trans-regional research and development programmes.

3.0 Project Components

The Project comprises four (4) components:

- (i) **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 harmonization 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 harmonization. The target beneficiaries include COMESA Secretariat and National Pharmaceutical Policy Institutions such as (National Medicines Regulatory Authorities (NMRAs)/Food and Drug Administration (FDA) bodies.

- (ii) **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.

- (iii) **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.

- (iv) **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

The re-establishment of the COMESA Pharmaceutical Committee is vital for strengthening and coordination of all pharmaceutical activities in the region and contributing to various continental initiatives. The AMRH programme is currently supporting the operationalisation of the African Medicines Agency and in line with this development, the COMESA Secretariat is aligning with these initiatives by building the capacity of its Member States.

5.0 Objective of Consultancy

The overall objective of the consultancy is to develop a comprehensive MRH Programme for COMESA that aligns with and complements the AMRH initiative and incorporates best practices and lessons learned from existing medicines regulatory systems across Africa and globally.

6.0 Scope of Work and Activities

The consultant will undertake the following Work / Activities:

- i. Review and analyse existing policies, regulations and frameworks relating to medicine regulation among COMESA Member States and other relevant institutions. This includes medicines registration, marketing authorization, price structure and price adjustment, handling expired medicines and pharmacovigilance, among others.
- ii. Engage with Member States and relevant continental and international organizations and other stakeholders (eg COMESA institutions, industry representatives, advocacy groups, National Regulatory Authorities and health care professionals) involved in medicines regulation to inform the COMESA MRH programme
- iii. Develop a comprehensive MRH Programme for COMESA that aligns with the AMRH programme and incorporates best practices and lessons learned from existing regulatory systems across Africa.
- iv. Drafting a roadmap for regulatory harmonization and a position paper for the COMESA region.
- v. In close collaboration with the AMRH, design implementation plans, including timelines, resource requirements, and monitoring and evaluation mechanisms.
- vi. Identify skill needs, propose plans for capacity building and training for regulatory authorities within the COMESA region.
- vii. Roll out relevant capacity building activities in consultation with the COMESA Secretariat and AMRH

7.0 Deliverables

Expected Deliverables	Estimated Expert-Days
Inception Report (Max 15 pages)	15

Report on regulatory harmonization in the COMESA region with relevant capacity building recommendations including an implementation and monitoring plan based on current activities in the region	25
Final assignment report including capacity building reports (eg trainings, peer to peer learning, mentorship) and a regulatory harmonization roadmap and a position paper for the COMESA region	50
TOTAL WORKING DAYS	90

8.0 Working Language Requirements

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

9.0 Eligibility of the Individual Consultant

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

10.0 Duration

The total number of days allocated for this assignment is one hundred and eighty (180) calendar days inclusive of travel days. The level of effort for the assignment is 90 expert-day as specified in Section 7.0. The Individual Consultant is required to complete the assignment and submit the Final Report within this period.

11.0 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. Travel costs will be borne by the COMESA Secretariat.

12.0 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.

13.0 Requirements and Qualifications

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

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

- a) At least 10 years of relevant work experience in medicines regulation and policy development
- b) Good knowledge of the AMRH initiative and other regional harmonization initiatives
- c) Experience in organising meetings and trainings at the Regional Economic Community (REC) level.
- d) Demonstrated experience in domesticating continental/regional frameworks in the pharmaceutical sector in Member States in the COMESA region with evidence of at least two assignments.

- e) Exposure and ability to work in a multi-cultural and multi stakeholder environment and proven experience in moderating, leading, and facilitating Workshops/Seminars over the last five (5) years
- f) Leadership, creativity, negotiations, and diplomatic skills.

14.0 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:

- i. 10 % upon submission and approval of an Inception Report;
- ii. 30% upon submission and approval of a report on regulatory harmonization in the COMESA region with relevant capacity building recommendations
- iii. 60% upon submission and approval of a Final assignment report including capacity building reports

ANNEX 1: EXPRESSION OF INTEREST FORMS

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

REFERENCE NUMBER: **CS/CSTRPSD/05/2025/km**

REQUEST FOR SERVICES TITLE: CONSULTANCY SERVICES TO DEVELOP A COMESA MEDICINES REGULATORY HARMONIZATION PROGRAMME ALIGNED TO THE CONTINENTAL PROGRAMME AND TAKING INTO CONSIDERATION EXISTING PROGRAMMES FROM SISTER REGIONAL ECONOMIC COMMUNITIES (RECs)

[Location, Date]

To: COMESA Secretariat

Dear Sirs:

I, the undersigned, offer to provide the consulting services for the “CS/CSTRPSD/05/2025/km”: **CONSULTANCY SERVICES TO DEVELOP A COMESA MEDICINES REGULATORY HARMONIZATION PROGRAMME ALIGNED TO THE CONTINENTAL PROGRAMME AND TAKING INTO CONSIDERATION EXISTING PROGRAMMES FROM SISTER REGIONAL ECONOMIC COMMUNITIES (RECs)**

” in accordance with your Request for Expression of Interests number CS/CSTRPSD/05/2025/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]*
2. First names: *[insert the names in full]*
3. Date of birth: *[insert the date]*
4. Nationality: *[insert the country or countries of citizenship]*
5. Physical address: *[insert the physical address]*
6. Postal address
7. Phone: *[Insert Postal Address]*
8. E-mail: *[insert the phone and mobile no.]*
[Insert E-mail address(es)]
9. Education:

Institution: [Date from – Date to]	Degree(s) or Diploma(s) obtained:
<i>[indicate the month and the year]</i>	<i>[insert the name of the diploma and the specialty/major]</i>
<i>[indicate the month and the year]</i>	<i>[insert the name of the diploma and the specialty/major]</i>

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

Language	Reading	Speaking	Writing
<i>[insert the language]</i>	<i>[insert the no.]</i>	<i>[insert the no.]</i>	<i>[insert the no.]</i>
<i>[insert the no.]</i>	<i>[insert the no.]</i>	<i>[insert the no.]</i>	<i>[insert the no.]</i>

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
<i>[insert the country]</i>	<i>[indicate the month and the year]</i>
.....	
<i>[insert the country]</i>	<i>[indicate the month and the year]</i>

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:

18. 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 above¹, 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.*