



#### REQUEST FOR EXPRESSION OF INTEREST

#### SELECTION OF AN INDIVIDUAL CONSULTANT

## CONSULTANCY SERVICES FOR CAPACITY BUILDING OF NATIONAL REGULATORY AUTHORITIES ON ROLL OUT AND IMPLEMENTATION OF REGULATORY MANAGEMENT INFORMATION SYSTEMS (RIMS)

#### REFERENCE NUMBER: CS/CSTRPSD/08/2025/km

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

CONSULTANCY SERVICES FOR CAPACITY BUILDING OF NATIONAL REGULATORY AUTHORITIES ON ROLL OUT AND IMPLEMENTATION OF REGULATORY MANAGEMENT INFORMATION SYSTEMS (RIMS)

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 <u>INDIVIDUAL CONSULTANTS</u> are eligible to participate under this assignment if they fulfil the following eligibility criteria:
  - a) 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:
  - b) 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);
  - c) they have not been declared guilty of grave professional misconduct proven by any means which COMESA Secretariat can justify.
  - d) 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.
  - e) 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' financial interests; or
  - f) 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 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/08/2025/km: INDIVIDUAL CONSULTANCY - CONSULTANCY SERVICES FOR CAPACITY BUILDING OF NATIONAL REGULATORY AUTHORITIES ON ROLL OUT AND IMPLEMENTATION OF REGULATORY MANAGEMENT INFORMATION SYSTEMS (RIMS)

"should be e-mailed to the following address: kmiti@comesa.int and copied to <a href="mailto:s.mwesigwa@comesa.int">s.mwesigwa@comesa.int</a>; procurement@comesa.int

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

#### 28th October 2025 at 16:00 hours

- 6. <u>Physical submission of applications is NOT allowed.</u>
- 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: 7<sup>th</sup> October 2025

#### ANNEX 1: Terms of Reference

# TERMS OF REFERENCE FOR AN INDIVIDUAL CONSULTANT FOR CAPACITY BUILDING OF NATIONAL REGULATORY AUTHORITIES ON ROLL OUT AND IMPLEMENTATION OF REGULATORY MANAGEMENT INFORMATION SYSTEMS (RIMS)

#### **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. This intervention is in line with continental and international initiatives such as the New Public Health Order, the Pharmaceutical Manufacturing Plan for Africa and promotion of local manufacturing for medical products by WHO.

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 African Medicines Regulatory Harmonization programme seeks to strengthen regulatory harmonization initiatives on the continent working closely with relevant stakeholders, Member States and Regional Economic Communities (RECs). In collaboration with the COMESA Secretariat, the AMRH programme is building capacity in Regulatory Information Management Systems among COMESA Member States to improve information exchange and sharing at regional and continental levels.

## 2.0 Objectives of the COMESA Support Towards Regional Pharmaceutical Sector Development 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 institutionalization 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 one. Institutionalization of the PMPA and AMRH Programmes in the Region.
- (ii) Component two. Institutional Support for Strengthening Medicines and Pharmaceutical Regulatory Bodies & Institutions in the Region.
- (iii) Component three. Capacity Development of Stakeholders and Support for Trans-Regional Research & Development Programmes
- (iv) Component four. Project Management, Coordination & Reporting

COMESA through the CSTRPSD Project is therefore seeking the services of an individual consultant to support the roll out of the AMRH Regulatory Information Management Systems (RIMS) through capacity building of Member State's National Medicines Regulatory Authorities in line 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 build capacity of COMESA Member States and facilitate adoption and domestication of the Regulatory Information Management System (RIMS) Digitalisation Strategy, implement the AU Model RIMS, and integrate their RIMS with the Regulatory Information Sharing Platform (RISP) system for data-sharing.

#### 5.0 Scope of Work

- Assess the specific support needs of the COMESA Member States
- Prioritize the level of support needed by various Member States and categorise them
- Develop the support strategy for each category
- Support COMESA Member States to adopt and domesticate the Regulatory Information Management System (RIMS) Digitalisation Strategy

- To support COMESA Member States to implement the AU Model RIMS through relevant trainings
- Follow up on the collection of registers from COMESA Member States to update RISP.
- Support country-level RIMS integration with RISP by engaging COMESA NRAs that are ready to integrate their RIMS with RISP
- Provide support to Member States' M&E experts to implement AMRH M&E framework.
- Establish a support network where COMESA Member States IT and M&E officers can share experiences, seek advice, and continue learning collaboratively to ensure sustainability.
- Organise a workshop with COMESA Member States to share experiences on lessons learned.

#### 6.0 Specific Tasks Expected by the Consultant

The consultant is expected to undertake the following:

- Produce an inception report that includes a detailed methodology and work plan for supporting the NMRAs with clear timelines and estimated cost.
- Create a priority matrix ranking Member States by urgency and impact and categorize Member States according to similar support requirements.
- Design tailored support plan for each category of Member States.
- Support Member States in implementing the African Union Model RIMS.
- Provide technical assistance for system configuration, data migration and system integration.
- Update Regional Information Sharing Platform (RISP) with new data.
- Compile relevant capacity building activities and reports.

#### 7.0 Deliverables

Item	Deadline - Calendar Weeks after contract commencement	Comments
Inception Report	2 weeks	To include a comprehensive approach to the assignment
Consolidated assessment report on the RIMS needs of COMESA Member States		Report to cover the following among others;  - COMESA MS implementing the AU Model RIMS List of priority countries to support based on duration of the assignment

	6 weeks	<ul> <li>List of countries with Registers for inclusion into RISP highlighting information available and information not collected by NMRA.</li> <li>Report on countries integrated into RISP through RIMS and countries integrated without RIMS.</li> <li>Recommendations on operationalization of RIMS in</li> </ul>
Report on established network of COMESA NMRA's IT and M&E officers.	10 weeks	COMESA  Detailed report on network framework of COMESA NMRA's IT and M&E officers including a sustainability plan
Update meetings  Final assignment report	Every 2 weeks 24 weeks	Recurring  Detailing all capacity building activities
i mai assignment report	ZT WOOKS	carried out, success stories and recommendations for further interventions

#### 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 Consultants

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

#### **10.0 Contract Duration**

The total number of days allocated for this assignment is 180 calendar days inclusive of travel days where required. The Consultant will be required to have completed the assignment and submitted the Final Report within this period.

#### 11.0 Duty Station

The Consultancy will be home based, with travel to the COMESA Secretariat in Lusaka, Zambia, as and when required.

#### 12.0 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.

#### 13.0 Education Qualifications, Professional Skills, and Experience

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

#### 13.1 Education Qualifications

- Master's degree in any of the following areas; Public health, Pharmaceutical Sciences, Databases Conceptualization or Analysis, Big Data, or Information Technology.
- Additional qualifications (degree or certificate) in Health Systems Management, or Digital Health Systems would be advantageous.

#### 13.2 Professional Experience, Required References and Skills

- i. At least **10 years** of experience in health regulatory affairs, health information systems, or data base conceptualisation or database analysis.
- ii. Demonstrated experience of devising at least two needs assessment report or two capacity building plans at Regional Economic Community (REC) level over the past ten years with evidence of completed assignments as proof.
- iii. Proven experience in user training for regulatory information systems and databases used in Africa such as the Regulatory Information System Portal (RISP) with evidence of two completed assignments as proof.
- iv. Good knowledge of the **AMRH initiative** and other regional harmonization initiatives (e.g.: Attending meetings; receiving training; facilitating; etc).
- v. Exposure and ability to work in a multi-cultural and multi stakeholder environment and proven experience in **moderating**, **leading**, **or facilitating Workshops/Seminars** over the last five (5) years.

#### 14.0 Payment

The consultant shall be paid according to the following schedule

- i. Submission of and approval of Inception Report (2 weeks after contract commencement) 20% of contract value
- ii. Consolidated needs assessment report on the RIMS needs of COMESA Member States (6 weeks after contract commencement) 40% of contract value
- iii. Report on established network and Final assignment report (24 weeks after contract commencement)- 40% of contract value

**ANNEX 2**: EXPRESSION OF INTEREST FORMS

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

REFERENCE NUMBER: CS/CSTRPSD/08/2025/km

REQUEST FOR SERVICES TITLE: INDIVIDUAL CONSULTANT SERVICES FOR CAPACITY BUILDING OF NATIONAL REGULATORY AUTHORITIES ON ROLL OUT AND IMPLEMENTATION OF REGULATORY MANAGEMENT INFORMATION SYSTEMS (RIMS)

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To: COMESA Secretariat

Dear Sirs:

I, the undersigned, offer to provide the consulting services for the "CS/CSTRPSD/08/2025/km": INDIVIDUAL CONSULTANT SERVICES FOR CAPACITY BUILDING OF NATIONAL REGULATORY AUTHORITIES ON ROLL OUT AND IMPLEMENTATION OF REGULATORY MANAGEMENT INFORMATION SYSTEMS (RIMS) " 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:
[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 [indicate the name of the professional body]

bodies:

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 assignme nt	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 longterm 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 above<sup>1</sup>, 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:	<ol> <li>Proof of qualifications indicated at point 9</li> <li>Proof of working experience indicated at point 15</li> </ol>

<sup>&</sup>lt;sup>1</sup> 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.