REQUEST FOR EXPRESSION OF INTEREST (REOI) -INDIVIDUAL CONSULTANT

FOR

Consultancy to develop the Regional Medicines Regulation Reliance Framework for the Inter-governmental Authority on Development (IGAD) in line with the Africa Continental Medicines Regulation Reliance Framework

BACKGROUND

I. Background and Context

Building and maintaining strong regulatory systems in IGAD member states requires skilled professionals, adequate funding, and efficient processes. The WHO Guidelines on Good Regulatory Practices emphasize that globalization, rapid advancements in health technologies, and increasingly complex supply chains make international cooperation among regulators more important than ever. By working together, regulatory bodies can ensure that medical products used in the region are safe, effective, and of high quality. Given the growing challenges of regulation, National Regulatory Authorities (NRAs) need to adopt smarter, more collaborative approaches. By pooling expertise and resources, they can reduce duplication of efforts and focus on the areas that need the most attention.

Harmonizing and aligning regulations across countries is key to achieving universal health coverage. In Africa, regulatory reliance has become an especially important strategy. This approach makes the regulatory process more efficient by encouraging collaboration, trust, and shared decision-making. It benefits everyone—patients, consumers, governments, healthcare providers, industry, and international partners—by ensuring quicker access to safe and high-quality medical products.

Regulatory reliance means that one country's regulatory authority can use assessments or approvals from another trusted reference authority or international organization when making its own decisions. However, the final responsibility remains with the relying authority, ensuring accountability and independence. By adopting this model, IGAD member states can strengthen their regulatory systems, improve efficiency, and work more closely together in regulating health products.

II. OBJECTIVE

IGAD seeks to engage the service of a consultant to develop a regional reliance framework in alignment with the AMRH Continental Regulatory Reliance Framework to guide the implementation of principles of Good Regulatory Practices for regulation of medical products (GReIP) at the national level in various regulatory activities across all regulatory functions. The specific objective of the assignment is to develop a regional reliance framework and implementation guidelines consisting of practical guides, case studies, and a more comprehensive repository of examples of reliance activities.

The specific objectives for the consultants are as below:

i. Conduct a comprehensive desk review of existing regulatory reliance pathways implemented by IGAD and EAC regions across marketing authorization and regulatory inspection functions for medicines and vaccines and in accordance with Good Reliance Practices for regulation of medical products (GRelP).
ii. Work with the AMRH initiative to localize the continental reliance framework to IGAD and EAC region.
iii. Conduct a pre-development consultation with IGAD technical teams on areas to be considered, barriers and recommendations to enhance reliance on regulatory recommendations and decisions amongst regulators in Africa.
iv. Develop a regional Reliance Framework for marketing authorisation and regulatory inspection function that will promote a more efficient approach to the regulation of medical products as per WHO Global Benchmarking Tool (GBT) plus for medicines and vaccines, and with practical guides, illustrative examples of reliance approaches and their implementation.
v. Conduct a post-development consultation with IGAD technical teams on areas to be considered, barriers and recommendations to enhance reliance on regulatory recommendations and decisions amongst regulators in Africa.
vi. Develop template for assessment of sameness in view of the IGAD/EAC reliance framework
vii. Incorporate inputs/feedback from IGAD technical teams.
viii. Present Localized Regional Reliance Framework to relevant IGAD personnel for validation and adoption.

III. DELIVERABLES

The Consultant is expected to support IGAD to adopt and adapt the AMRH-developed regulatory reliance framework and support IGAD in implementing principles of reliance in regulatory decision-making. The consultant will work closely with IGAD technical staff to develop, validate and roll out the framewo**rk**

IV. LOCATION AND DURATION OF THE ASSIGNMENT

The Consultant will conduct the assignment partially remotely and partially on site in the IGAD region where necessary. The assignment is for twenty (20 days) from the date of the signing of the contract. All work must be completed by 31st July 2025.

V. Required Qualifications, Experience and Skills

Interested individual applicants should possess the following qualifications and experience. Please apply only if you are from the IGAD region.

Education qualifications

Prospective consultants should have a minimum of a master's degree in pharmacy, pharmaceutical sciences, medicine, chemistry, medical laboratory sciences, biomedical engineer, or any other related field.

Experience and Skills

1) At least 10 years as a practitioner or consultant on matters related to implementation of regulatory networks and convergence, regulatory systems strengthening or harmonization initiatives.
2) A candidate with experience working in a medical products regulatory body, Regional Medicines Regulatory Harmonization programme or international harmonization initiatives is highly preferred.
3) Good knowledge on the AMRH Initiative, RECs MRH initiatives and the field of Africa Medical Products Regulation.
4) A professional with exposure to international collaboration; previous experience working with IGAD will be an added advantagee
5) Expert knowledge of English is essential.

The Selection shall follow the IGAD procurement procedures. The Intergovernmental Authority on Development (IGAD) now invites interested and eligible consultants who are members of the IGAD member states to submit Expressions of Interest (EOI) for the above assignment. Detailed terms of reference (TORs) will be shared with shortlisted consultants.

- Interested consultants may obtain further information from Monday to Friday, 8:00am - 4:00pm EAT, by email to Karim.Wanga@igad.int with copies to glory.karimi@igad.int Please note that at this stage, **no PROPOSALS whether TECHNICAL or FINANCIAL are requested.**

HOW TO APPLY

The consultant should submit their Expression of Interest (EOI), Curriculum Vitae (s) and academic credentials to glory.karimi@igad.int with a copy to procurement@igad.int no later than Monday, 1st May 2025, ***at 23:59 Hrs. EAT (GMT+3).***

ANNEX 1 TOR

TERMS OF REFERENCE	
Title of the Consultancy:	Consultancy to develop Reliance Framework in line with the Continental Reliance Framework for Implementation of Regulatory Recommendations and decisions at a regional level by National Regulatory Agencies (NRAs) in IGAD and EAC region
Consultancy type: *(Individual or firm)*	Individual
Directorate & Division	Health and Social Development
Contact Person:	Pharmaceutical Expert

BACKGROUND

Building and maintaining strong regulatory systems in IGAD member states requires skilled professionals, adequate funding, and efficient processes. The WHO Guidelines on Good Regulatory Practices emphasize that globalization, rapid advancements in health technologies, and increasingly complex supply chains make international cooperation among regulators more important than ever. By working together, regulatory bodies can ensure that medical products used in the region are safe, effective, and of high quality. Given the growing challenges of regulation, National Regulatory Authorities (NRAs) need to adopt smarter, more collaborative approaches. By pooling expertise and resources, they can reduce duplication of efforts and focus on the areas that need the most attention.

Harmonizing and aligning regulations across countries is key to achieving universal health coverage. In Africa, regulatory reliance has become an especially important strategy. This approach makes the regulatory process more efficient by encouraging collaboration, trust, and shared decision-making. It benefits everyone—patients, consumers, governments, healthcare providers, industry, and international partners—by ensuring quicker access to safe and high-quality medical products.

Regulatory reliance means that one country's regulatory authority can use assessments or approvals from another trusted body when making its own decisions. However, the final responsibility remains with the relying authority, ensuring accountability and independence. By adopting this model, IGAD member states can strengthen their regulatory systems, improve efficiency, and work more closely together in overseeing health products.

RATIONALE

The COVID-19 pandemic accelerated collaboration between regulators and the healthcare industry, streamlining the approval and distribution of essential medical products such as medicines, vaccines, blood products, and in-vitro diagnostics. Rapid cross-border access to these products is critical for pandemic preparedness and public health in the

IGAD and EAC regions. The crisis underscored the value of regulatory reliance in facilitating access to medical products already approved by mature regulatory systems based on national and international guidelines.

Regulatory reliance enhances efficiency, optimizes resource allocation, builds trust among regulatory authorities, and ensures timely access to life-saving medical products. To support this, a continental reliance framework is being developed to help African Union Member States improve regulatory efficiency, facilitate access to safe and effective products, and strengthen emergency preparedness. The African Medicines Regulatory Harmonization (AMRH), in collaboration with Regional Economic Communities (RECs) and National Regulatory Authorities (NRAs), promotes reliance on trusted regulatory decisions to optimize resources and expertise. This approach enables regulators to focus on critical functions such as pharmacovigilance, market surveillance, and oversight of local manufacturing and distribution, reducing duplication and expediting approvals.

The World Health Organization (WHO) emphasizes that good reliance practices (GRelP) are grounded in good regulatory practices (GRP), ensuring consistency, efficiency, and sound decision-making in medical product regulation. Implementing GRP strengthens regulatory systems, improves public health outcomes, and streamlines processes for IGAD and EAC regulators. Embracing reliance and harmonization, efforts will enhance regulatory agility and improve access to quality medical products in the region.

THE OBJECTIVES OF THE ASSIGNMENT

The IGAD seeks to engage the service of a consultant to develop a reliance framework in alignment with the AMRH Continental Regulatory Reliance Framework to guide the implementation of principles of Good Reliance Practices for regulation of medical products (GReIP) at the national level in various regulatory activities across all regulatory functions. The specific objectives of the assignment to develop a national reliance framework and implementation guidelines consisting of practical guides, case studies and a more comprehensive repository of examples of reliance activities.

SCOPE OF WORK, ACTIVITIES AND TASKS

The Consultant shall deliver on the following tasks:

- Conduct a comprehensive desk review of existing regulatory reliance pathways implemented by IGAD and EAC region across marketing authorisation and regulatory inspection function for medicines, and vaccines in accordance with Good Reliance Practices for regulation of medical products (GRelP).
- Work with the AMRH initiative to localize the continental reliance framework to IGAD and EAC region.
- Conduct a pre-development consultation with IGAD technical teams on areas to be considered, barriers and recommendations to enhance reliance on regulatory recommendations and decisions amongst regulators in Africa.
- Develop a regional Reliance Framework for marketing authorisation and regulatory inspection function that will promote a more efficient approach to regulation of medical products as per WHO Global Benchmarking Tool (GBT) plus for medicines and vaccines an with practical guides, illustrative examples of reliance approaches and their implementation.
- Conduct a post-development consultation with IGAD technical teams on areas to be considered, barriers and recommendations to enhance reliance on regulatory recommendations and decisions amongst regulators in Africa.
- Develop template for assessment of sameness in view of the IGAD/EAC reliance framework
- Incorporate inputs/feedback from IGAD technical teams.
- Develop template for assessment of sameness in view of the IGAD/EAC reliance framework

- Present Localized Regional Reliance Framework to relevant IGAD personnel for validation and adoption.

EXPECTED RESULTS AND DELIVERABLES

The Consultant is expected to help IGAD adopt and adopt the AMRH-developed regulatory reliance framework and support IGAD in implementing principles of reliance in regulatory decision-making. The consultant will work closely with IGAD Technical Staff to develop, validate and roll out the Framework.

LOCATION

The Consultant will complete the assignment partially remotely and on site in IGAD region where necessary.

TIMEFRAME OF THE ASSIGNMENT

It is anticipated that the assignment will be completed within a total of 20 days from the date of the signing of the contract. All work must be completed by 31st July 2025.

DELIVERABLES/REPORTS/MILESTONES SCHEDULE

Milestones	Number of person-days
Project inception report	
This is a report on the review of existing regulatory reliance pathways implemented by IGAD and EAC for the marketing authorisation and regulatory inspection function for medicines and vaccines.	
Report on the pre-development consultation with IGAD technical team	3 person-days
Draft Localized Regional Reliance Framework	10 person-days
Report on the post-development consultation with IGAD Technical team	3 person-days
Final localized regional Regulatory Reliance Framework for IGAD and EAC	4 person-days

SUBMISSION & APPROVAL OF REPORTS

Under the overall guidance of the senior regional program Coordinator -ICEN, the consultant shall submit all reports assigned to the IGAD pharmaceutical expert. The reports will be approved by the Director of Health and Social Development prior to submission to the IGAD.

The consultant will be directly supervised by the IGAD Pharmaceutical Expert. The incumbent will consult with IGAD directly in the development and validation of a reliance framework.

LANGUAGE REQUIREMENTS:

- Expert knowledge of English is essential.

PERSON DAYS/MONTHS

A total of 20 man-days over a period of 4 months.

GOVERNANCE, SUPPORT AND FACILITIES TO BE PROVIDED BY IGAD

Under the overall technical guidance, The Consultant will work under the leadership of the IGAD Pharmaceutical Expert on a day-to-day basis. Work progress will be discussed regularly, at least every fortnight. All reports shall be submitted to IGAD.

The IGAD will support the convening of regional and national consultations for the consultant while undertaking the assignment.

PROPOSED PAYMENT SCHEDULE

(i) 20 % upon submission of report on the review of existing regulatory reliance pathways implemented by NRAs and IGAD and a register of relevant stakeholders
(ii) 40% upon submission of the report on the pre-development consultation and draft IGAD Reliance Framework
(iii) 40% upon submission of the Final IGAD Reliance Framework

QUALIFICATION AND WORK EXPERIENCE REQUIRED FOR KEY EXPERTS

1.1. Qualifications required.

Prospective consultants should have a minimum of a master's degree in pharmacy, pharmaceutical sciences, medicine, chemistry, medical laboratory sciences, biomedical engineer, or any other related field.

1.2. Experience required.

6) At least 10 years as a practitioner or consultant on matters related to implementation of regulatory networks and convergence, regulatory systems strengthening or harmonization initiatives.
7) A candidate with experience working in a medical products regulatory body, Regional Medicines Regulatory Harmonization programme or international harmonization initiatives is highly preferred.
8) Good knowledge on the AMRH Initiative, RECs MRH initiatives and the field of Africa Medical Products Regulation.
9) A professional with exposure to international collaboration.
10) Previous experience working with IGAD will be an added advantage

Proposed Evaluation Criteria

Evaluation Criteria	Points
Educational qualifications: master's degree in pharmacy, pharmaceutical sciences, medicine, chemistry, medical laboratory sciences, biomedical engineer, or any other related field.	20

At least 10 years as a practitioner or consultant on matters related to implementation of regulatory networks and convergence, regulatory systems strengthening or harmonization initiatives.	30
Experience working in a medical products regulatory body, Regional Medicines Regulatory Harmonization initiatives or international harmonization initiative.	10
Previous experience working. With IGAD	10
A professional with exposure to international collaboration.	10
Good knowledge on the AMRH Initiative, RECs MRH initiatives and the field of Africa Medical Products Regulation.	20
Total	**100**

The minimum Shortlisting Sore (St) required to pass is: 70 points.

TOR Prepared By	Title	Signature	Date
TOR Approved By	Title	Signature	Date