AUDA - NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

TERMS OF REFERENCE	
Title of the Consultancy:	Consultancy Services to Support Operationalization of the Network of African Reliance Laboratories (NARL)
Consultancy type: *(Individual or firm)*	Individual
Directorate & Division	Human Capital and Institutional Development
Contact Person:	Principal Programme Officer – Policy Specialist
Procurement Number (from procurement plan)	52/AUDA/HCID/ID/ICS/2024

BACKGROUND

African National Quality Control Laboratories (NQCLs) have over the last decade made significant advances in the quality control (QC) of small molecule drugs. However there still remains a significant capacity gap in bio-analytical testing of large molecule drugs (biologicals) including vaccines comparable with international best practices. As the continent steps up efforts for local manufacturing of vaccines with the announcement of new vaccine manufacturing initiatives by 17 African countries, their national regulatory authorities (NRAs) and associated NCLs would need support to build capacity for vaccine regulatory oversight.

Lot release (LR) is a regulatory function specific to biological products, such as vaccines, with the purpose of ensuring a product's quality in comparison with defined specifications through a system of regulatory release. A component of LR may include independent quality control (QC) testing of the product. QC testing can also be a requirement for product registration, investigations of adverse events, vigilance (checking and confirming the quality of products placed on the market), and for detecting substandard and falsified medical products.

To advance regulatory harmonisation and operationalisation of the African Medicines Agency (AMA), there is a need to build African regulatory systems in general, and laboratory capacity, specifically. The development and operationalization of a Network of African Reliance Laboratories (NARL) one of the identified priorities for the African Medicines Regulatory Harmonisation (AMRH) in support of AMA operationalisation.

RATIONALE

The AMRH, Initiative through its African Medicines Quality Forum Technical Committee (AMQF-TC), plays a key role in assuring the quality of medicines, vaccines, biologics and health technologies circulating on the African markets. AMQF was established in 2017 as one of TC of AMRH programme that support the operationalisation of the AMA to build and strengthen the capacity of African countries in medicines quality control and post market surveillance to curb sub-standard and falsified (SF) medical products in Africa. The main roles and responsibilities of AMQF-TC is to drive harmonization of Quality Control (QC) standards and practices and, ultimately the mutual recognition of QC tests among African countries and supporting them to prevent, detect and respond to SF medical products.

During public health emergencies, timely access to quality, safe, and effective vaccines and therapeutics is essential to prevent and respond to national, regional, and global crises like COVID-19 pandemic, that led to 14.9 million deaths in 2020 and 2021.National regulatory authorities (NRAs) and NQCLs must be functional to effectively support regulatory lot release (LR) functions to expedite the availability of and access to effective vaccines.

In November 2022, the AMRH Secretariat commissioned a consultancy to assess the capacity for biological product testing and lot release (LR) among selected NQCLs in Africa and develop a framework for an African reliance laboratory network. One of the key recommendations of the assessment was establishment and operationalization of the NARL. This will develop and strengthen the NQCLs' capabilities, thereby enabling NRAs RECs and AMRH, and eventually the AMA to fulfil their mandate, better safeguard public health and build trust. Through reliance and recognition, a well-functioning NARL will reduce redundant product testing, establish more cost-effective testing practices, promote harmonized testing standards and best practices and contribute to greater efficiency in regulatory oversight. The AMRH Secretariat therefore intends to commission services of a consultant to support operationalization of the ANCL-RN.

THE OBJECTIVES OF THE ASSIGNMENT

The consultancy is aimed at supporting the AUDA-NEPAD's AMRH Secretariat to operationalize NARL in line with the framework and 5-year strategy.

Specifically, the consultancy has the following objectives:

a) To establish and operationalize ANCL-RN including finalisation of governance structure, reporting mechanisms and technical committees.
b) To support development and domestication of harmonized guidelines, procedures, protocols, regulatory frameworks, standards and tools for the NARL.
c) To develop roadmaps to address capacity gaps in infrastructure, equipment's, supplies, personnel, trainings and emergence preparedness to enhance reliance.

SCOPE OF WORK, ACTIVITIES AND TASKS

The Consultant shall work with the AUDA-NEPAD AMRH Secretariat to deliver on the following tasks:

a) Develop and administer an Expression of Interest (EOI) among African NQCLs to facilitate the membership within the various categories of the ANCL-RN (full members, associate members and observers).
b) Define the Central Coordination Unit (CCU) of the NARL in alignment with the AMRH governance structure within the AUDA-NEPAD and AMRH Secretariat including recommendation on competencies, job description, reporting channel and job description of CCU staff.
c) Facilitate the launch of NARL during AMRH governance meetings.
d) Guide NARL in development and domestication of harmonized guidelines, regulatory frameworks, standards and tools.
e) Support the CCU to facilitate the first annual meeting of the NARL to constitute the Assembly of Member, the Steering Committee and initial working groups.
f) Establish outreach programs of NARL, monitor and report progress and impact.
g) Establish peer review mechanisms for processes and conduct mock audit programs for the NARL.
h) Develop a comprehensive roadmap to address capacity gaps in facilities, equipment's and supplies, personnel, trainings and emergence preparedness.

EXPECTED RESULTS AND DELIVERABLES

The deliverables of the consulting firm will include:

a) Central Coordination Unit (CCU) designed, governance and reporting system defined
b) Outreach programs for ANCL-RN established and bi-annual reporting mechanism instituted
c) Roadmap for reliance laboratories developed in alignment with the continental regulatory reliance framework.
d) Capabilities and competencies for participating laboratories mapped and comprehensive report disseminated to stakeholders.
e) Harmonized guidelines, procedures, protocols and tools for the network finalised and approved by the AMRH governance.

LOCATION

The consultant will complete the assignment remotely with frequent visits to the AUDA-NEPAD's AMRH Secretariat in Midrand, South Africa.

TIMEFRAME OF THE ASSIGNMENT

It is anticipated that the assignment will be completed within a total of 80 man-days spread over six months.

DELIVERABLES/REPORTS/MILESTONES SCHEDULE

Deliverable	Delivery date/period
Central Coordination Unit (CCU) designed, governance and reporting system defined	15 person-days
Outreach programs for ANCL-RN established and bi-annual reporting mechanism instituted	10 person-days
Roadmap for reliance laboratories developed in alignment with the continental regulatory reliance framework	15 person-days
Capabilities and competencies for participating laboratories mapped and comprehensive report disseminated to stakeholders	15 person-days
Harmonized guidelines, procedures, protocols and tools for the network finalised and approved by the AMRH governance	25 person-days

SUBMISSION & APPROVAL OF REPORTS

The consultant shall work under the direct supervision of the Principal Programme Officer – Policy Specialist or her designate, who shall receive and approve all reports before submitting for payments. All documents developed under this consultancy shall be reviewed by the AMQF-TC before submitting to the AMRH Secretariat.

LANGUAGE REQUIREMENTS:

- Ability to work in any of the AU working languages.

PERSON DAYS/MONTHS

A total of 80 man-days.

GOVERNANCE, SUPPORT AND FACILITIES TO BE PROVIDED BY AUDA-NEPAD

The Consulting firm will work under the AUDA-NEPAD's AMRH Secretariat. The work will be overseen by the AMQF Technical Committee which reports to the AMRH Steering Committee. Work progress will be discussed on a regular basis with the AMRH Secretariat within the AUDA-NEPAD, at least bi-monthly. The AUDA-NEPAD will directly support travel costs for the consultant related to the delivery of the assignment where necessary.

PROPOSED PAYMENT SCHEDULE

(i) 25% upon submission of Central Coordination Unit (CCU) design, finalised governance and reporting system.
(ii) 20% upon submission of outreach programs design and bi-annual reporting mechanism
(iii) 25% upon submission of the report on capabilities and competencies mapping for participating laboratories and comprehensive dissemination report
(iv) 30% upon the approval of the harmonised guidelines, procedures, protocols and tools for the network finalised by the AMRH governance

QUALIFICATION AND WORK EXPERIENCE REQUIRED FOR KEY EXPERTS

Basic Qualifications

Master's degree in pharmacy, biopharmaceutics, biochemistry, biology, microbiology, regulatory sciences, pharmaceutical sciences or Health Economics with more than 10 years project management experience in pharmaceutical industry or development cooperations sector.

- At least 10 years' experience working in leading regulatory and/or laboratory systems strengthening and medical products in Africa.
- Experience in the implementation of Laboratory Quality Management Systems, analytical test methods, laboratory readiness, and technology transfer activities such as qualification/validation, assay development and verification to support testing of vaccines and biological products.
- Experience and knowledge of regulatory requirements related to vaccines and biological products.
- Experience in conducting risk analysis, audits and inspections of testing facilities to determine compliance with ISO/IEC 17025 and WHO Good Practices for Pharmaceutical

Additional Skills Required

- Defining medical product quality and testing requirements.
- Quality assurance and control in the manufacture, supply and distribution of medical products.
- Laboratory accreditation, quality management systems, and building laboratory capabilities.

- Strengthening of national quality control laboratory capacities.
- Capacity building in quality assurance and quality control of medical products at the national or regional level, particularly in Africa.
- Establishment of quality management systems in accordance with ISO/IEC 17025 and WHO Good Practices for Pharmaceutical Control Laboratories
- Medical products regulatory systems strengthening.

Proposed Evaluation Criteria

Evaluation Criteria	Points
A consultant with a minimum of a Master's degree in pharmacy, biopharmaceutics, biochemistry, biology, microbiology, regulatory sciences, pharmaceutical sciences or Health Economics	20
At least 10 years' experience working in leading regulatory and/or laboratory systems strengthening and medical products in Africa.	20
Experience in the implementation of Laboratory Quality Management Systems, analytical test methods, laboratory readiness, and technology transfer activities such as qualification/validation, assay development and verification to support testing of vaccines and biological products.	20
Experience and knowledge of regulatory requirements related to vaccines and biological products.	20
Experience in conducting risk analysis, audits and inspections of testing facilities to determine compliance with ISO/IEC 17025 and WHO Good Practices for Pharmaceutical	20
Total	**100**

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TORS Approved by:
Director:

Signature:_____

Date:_____