KENYA BIOVAX INSTITUTE

Health Emergency Preparedness Response and Resilience (HEPRR) Project

Credit Number: 7405-KE

Project ID: P180127

TERMS OF REFERENCE

FOR

CONSULTING SERVICES FOR PHARMACEUTICAL AND VACCINE MANUFACTURING LEGAL AND REGULATORY FRAMEWORK ANAYSIS FOR THE KENYA BIOVAX INSTITUTE

(FIRMS SELECTION)

PROCUREMENT/CONTRACT REF NO.: KE-KBI-503044-CS-CQS

AUGUST 2025

Client:
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1.0 Introduction

1.1 Project Background

The Government of Kenya, through the State Department of Medical Services, and with support from The World Bank, is implementing the Health Emergency Preparedness Response and Resilience Program (HEPRR) which aims to strengthen health system resilience and multisectoral preparedness and response to health emergencies in Kenya. This is to be achieved through providing support for national and regional systems for health emergency preparedness and response to work in tandem with those strengthening health system resilience, and to develop regional pharmaceutical and vaccine manufacturing and logistical capacities, premised on a strong regulatory ecosystem and a reliable market ecosystem, which is imperative to addressing Africa's reliance on imports.

The Project comprises of the following four (4) components:

Component 1: Strengthening the Preparedness and Resilience of Kenya's Health System to Manage Health Emergencies: (i) Health workforce development including narrowing of gender gaps; (ii) Strengthening of Local Pharmaceutical and Vaccine Manufacturing Capacity, implementation to be conducted in phases, with key conditions to be met before implementing establishment of capacity for F&F of human vaccines; (iii) Information systems for Health Emergencies and the digitalisation of the health sector.

Component 2: Improving the Detection of and Response to Health Emergencies: (i) Collaborative multisectoral gender-disaggregated surveillance and laboratory diagnostics; (ii) Emergency management, coordination, and essential service continuity.

Component 3: Project Management: To support project coordination and activities for program implementation and monitoring and to strengthen management capacity.

Component 4: CERC, to be activated as needed based on established procedures described above. Project scope and beneficiaries

1.2 Rationale

Kenya is strategically positioned to be the regional hub for manufacturing of specialized HPTs, including vaccines for children, adolescent girls, and mothers. Kenya's potential for pharmaceutical manufacturing includes an enabling business environment; the availability of a skilled workforce; the capability to conduct relevant clinical R&D; and its role as a strategic regional hub for commercial and health security initiatives, including conducting of relevant clinical trials. Product development and manufacturing capacity in Kenya for five critical infectious diseases could avert over 4.44 million deaths and 206.27 million disability-adjusted life years in the common market for the AFE region.

The Government of Kenya is committed to strengthening capacity and creating an enabling environment for domestic pharmaceutical, vaccines and biologics manufacturing. To this end, the Government established the Kenya BioVax Institute (BioVax) as a state-owned enterprise in September 2021 with the mandate to manufacture and commercialize vaccines and related

healthcare products and technologies. BioVax is implementing the vaccine manufacturing component with an objective of establishing production capacities for human vaccines to strengthen health commodity security for Universal Health Coverage and self-reliance for pandemic preparedness under Subcomponent 1.3: Strengthening of Local Pharmaceutical and Vaccine Manufacturing Capacity through the following activities:

I. Strengthening Quality Control/Assurance: establishing an internal in-process quality control laboratory;
II. Human resources capacity, learning, and development: Training and knowledge exchange; Creating opportunities for internship and mentorship; Technology transfer; Technical Assistance – WHO accredited GMP; and
III. Establishing capacity for F&F of human vaccines: Purchase and installation of F&F machinery and equipment

BioVax intends to engage a consulting firm to undertake a comprehensive study of the institutional legal and regulatory framework risks as applicable to pharmaceutical and vaccine manufacturing activities. Further, the assessment will identify regulatory gaps and, propose interventions aimed at strengthening regulatory oversight and compliance, while supporting adherence to the World Health Organisation's (WHO) Good Manufacturing Practice (GMP) standards.

2.0 Objective of the Assignment

The primary objective of the consulting services is to undertake a comprehensive review of the national, regional and global legal and regulatory framework environment for pharmaceutical, vaccines and biologics manufacturing and thereafter assess the institutional legal and regulatory framework and attendant risks as applicable to pharmaceutical, vaccines and biologics manufacturing activities.

The specific objectives of this consultancy are to:

1. Undertake a comprehensive analysis of the applicable legal and regulatory framework environment surrounding pharmaceutical, vaccines and biologics manufacturing activities;
2. Identify regulatory and legislative gaps and inconsistencies impacting pharmaceutical, vaccines and biologics manufacturing;
3. Provide actionable proposals for interventions aimed at strengthening institutional regulatory compliance to national, regional and international standards;
4. Provide actionable recommendations on regulatory oversight measures aimed at supporting adherence to the World Health Organisation (WHO) Good Manufacturing Practice (GMP) standards and any other applicable international standards;
5. Coaching on implementation of actionable proposals on strengthening legal and regulatory frameworks.

3.0 Scope of Consulting Services and Specific Tasks

3.1 Scope of the Consulting Services

The scope of the Consulting Services will review legal and regulatory frameworks impacting the pharmaceutical, vaccines and biologics manufacturing environment, assess BioVax's readiness to undertake vaccine manufacturing.

3.2 Specific Tasks

The specific tasks shall be to:

1. Synthesize primary and secondary data and any further relevant information with respect to legal and regulatory frameworks impacting the pharmaceutical, vaccines and biologics manufacturing environment including strategic and development plans, policy and legal documents at national, regional and global level;
2. Comprehensive risk analysis on pharmaceutical and vaccine manufacturing activities in Kenya and the region;
3. Identification of areas where regulations are duplicative, contradictory, or cause significant delays to pharmaceutical and vaccine manufacturing activities
4. Assessment of BioVax's strategic alignment with pharmaceutical, vaccines and biologics manufacturing national and international legal and regulatory frameworks;
5. Developing costed actionable interventions and recommendations aimed at strengthening institutional legal and regulatory compliance to national and international pharmaceutical and vaccine manufacturing standards;
6. Prepare and submit comprehensive technical reports of the consultancy including stakeholder consultations and meetings reports.
7. Undertake in-house coaching of technical officers on implementation of actionable proposals on strengthening legal and regulatory frameworks.

4.0 Duration and Location of the Assignment

The duration of consulting services will be a period of eighty-four (84) calendar days from contract commencement date.

The Consulting services will generally be offered in Nairobi (Kenya) at the BioVax offices. The consulting services may however involve engagement with various stakeholders in the pharmaceutical and vaccine manufacturing ecosystem. All such engagements shall be supported by BioVax.

5.0 Reporting Requirements and Project deliverables timelines

5.1 Reporting

I. The Consultant will report to the Chief Executive Officer through a designated senior manager
All reports shall be submitted to the:
Chief Executive Officer
Kenya BioVax Insititute
Attn: HEPRR Focal Officer
KWFT Centre, Kiambere-Masaba Road Junction, Upperhill, Nairobi
P.O. Box 40779-00100. Nairobi. KENYA
Tel:+254775751639
Email: info@biovax.go.ke cc: procurement@biovax.go.ke heprr@biovax.go.ke

II. BioVax will review the submitted reports and issue official comments and approvals.

5.2. Schedule of deliverables

The consultants will be expected to deliver the following outputs:

Table 1: Reporting Requirements

No	Deliverable/ Reports	Deliverable Description	Timelines after contract commencement	Submission Format
1	Inception Report	Detailed Project Work Plan and methodology to carry out the assignment.	After fifteen (15) days	2 printed copies & an electronic copy
2	Interim Report	Interim progress report as detailed in the key tasks of the assignment. Annexure of minutes and attendance lists of stakeholder/agencies engagements	After forty (40) days	2 printed copies & an electronic copy
3	Draft Final Report	Draft of the final report	After sixty (60) days	Electronic copy
4	Final Report	Final Revised Report incorporating feedback from a validation workshop	After eighty-four (84) days	2 printed copies & an electronic copy

6.0 Payment Schedule

The proposed payment schedules based on satisfactory performance of the contract which will be negotiated with the successful consultant will be as presented in Table 2 below.

Upon submission of every report, the consultant is expected to make a presentation of the submitted report to the Client in a scheduled meeting. The acceptance of the report shall be recorded in the minutes of the meeting.

Table 2: Payment Schedule

S/No	Deliverable/Reports	Timelines for submission of deliverables after contract commencement	Percentage of the contract amount
1	Submission and Acceptance of Inception report	15 Days	20%
2	Submission and Acceptance of the interim report	40 Days	30%
3	Submission and Acceptance of Draft Final Report	60 Days	20%
4	Submission and Acceptance of Final Report	84 Days	30%

7.0 Minimum requirements for Consultants Qualification and Experience

The consulting firm shall have the following minimum qualifications and experience:

7.1 Core business and years in business

The firm shall be registered/incorporated as a consulting firm with core business in legal consulting services or related fields for a minimum period of ten (10) years.

7.2 Relevant experience:

The firm shall demonstrate as having successfully executed and completed at least one (1) assignment of a similar nature, complexity and in a similar operating environment in the last eight (8) years. Details of similar assignments-Name and address of the client, scope, value, and period should be provided in the submitted proposal including enumeration of these similar past assignments.

7.3 Technical and managerial capability of the firm:

The firm shall demonstrate as having the requisite technical capacity and managerial capacity to undertake the assignment in the submitted company profile(s).

8.0 Team Composition, Minimum Qualifications and Experience for Key Experts

The Consulting firm shall have well-qualified and experienced professionals as required and appropriate for completion of the exercise. They should possess necessary resources to undertake services of such nature including equipment and software required to execute the assignment.

The key professionals/experts shall personally carry out (with assistance of other non-key staff deemed appropriate) the services as described in this Terms of Reference.

The key experts shall exhibit extensive knowledge of the Kenyan manufacturing sector and regulatory frameworks; and working knowledge of regional and global frameworks impacting pharmaceutical and vaccine manufacturing sectors, including regional trade agreements and their implications on manufacturing.

The key experts to be provided for this assignment will include qualified personnel with extensive international, regional and national experience are as follows: -

8.1 Legal Consultant- Team Leader

i. Minimum of Masters' degree in law from a university recognized in Kenya;
ii. A minimum of ten (10) years of general experience in legal analysis or policy reform;
iii. A minimum of six (6) years specific experience working with donor funded projects and/or government agencies in legal analysis or policy reform with a focus on the pharmaceutical and vaccine business environment;
iv. Must be validly registered and holding a current annual practicing license from a relevant professional body recognized in Kenya as applicable.

8.2 Regulatory Affairs Consultant – Key Expert

i. Minimum of Masters' degree in Regulatory Affairs, Industrial Pharmacy or Pharmaceutical Manufacturing from a university recognized in Kenya;
ii. A minimum of eight (8) years of general experience in regulatory audits;
iii. A minimum of four (4) years specific experience in legal and regulatory analysis with a focus on pharmaceutical and vaccine environment;
iv. Must be validly registered and holding a current annual practicing license from a relevant professional body recognized in Kenya as applicable.

8.3 Compliance Officer – Key Expert

i. Minimum of Bachelor's degree in Pharmacy, Life Science or Engineering related to pharmaceutical or bio-pharmaceutical technology from a university recognised in Kenya;
ii. A minimum of five (5) years of general experience in a GMP-regulated industry;
iii. A minimum of one (1) year specific experience in regulatory compliance experience;
iv. Must be validly registered and holding a current annual practicing license from a relevant professional body recognized in Kenya as applicable.

The Team Leader will be in charge of reporting and coordination of all activities, and will be the main contact person in the team vis-à-vis the Client

9.0 Estimated Time Inputs for Key Experts

The number of key experts and the estimated time input for each key expert for the assignment are presented in Table 3.

Table 3: Estimated Time Inputs for Key Experts

S/No	Key and Support Staff	No.	Time Inputs (staff- days)
1	Legal Consultant-Team Leader	1	80
2	Regulatory Affairs Consultant	1	80
3	Compliance Officer	1	80
	TOTAL	**3**	**240**

10.0 Management and Accountability of the Assignment

The Kenya BioVax Institute is the Client for these services. The consultant will report to the Chief Executive Officer through a designated senior manager. The designated senior manager will work closely with the HEPRR focal officer to oversee the day-to-day running of the assignment.

11.0 Obligation of the Client

i. The client will provide all relevant information that can assist in this assignment;
ii. Organize meetings with relevant stakeholders as may be required by the consultant;
iii. Review and approve reports

12.0 Obligation of the Consultant

i. The consulting firm will be answerable to the Chief Executive Officer, the Designated Senior Manager and the HEPRR Focal Officer and will work closely with BioVax staff in the execution and delivery of this consultancy.
ii. The consultant will be required to make their own travel and accommodation arrangements during consultations with different stakeholders to ensure the assignment is carried on smoothly and seamlessly within the timeframe provided.
iii. The consulting firm will consult and include inputs from the stakeholders and is responsible for organizing and achieving the evaluation and delivering the final report.

13.0 Proprietary Rights of Client in Reports and Records

i. All the reports, data, and information developed, collected, or obtained from the implementing agencies etc., Client, and other Institutions during this exercise shall belong to the Client. No use shall be made of them without prior written authorization from the Client.

ii. At the end of the Services, the Consultant shall relinquish all data, manuals, reports and information (including the database, codes, and related documentation) to the Client and shall make no use of them in any other assignment without prior written authority from the Client.