

## **TERMS OF REFERENCE**

**Technical Assistance for Preparation of Vaccines Production Capacity Increase Project**

**AA-012824-001**

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## 1. BACKGROUND INFORMATION

### 1.1. Partner country and promoter

The beneficiary is VACSERA (the “**Promoter**” or the “**Company**”), Holding Company for Biological Products and Vaccines SAE, located in the Arab Republic of Egypt.

### 1.2. Contracting Authority and mandate

#### 1.1.1 The Contracting Authority

European Investment Bank  
98-100, boulevard Konrad Adenauer  
L-2950, Luxembourg  
Grand Duchy of Luxembourg

#### 1.1.2 The mandate

The Services covered by this Technical Assistance (TA) are financed through financial support from the Facility for Euro-Mediterranean Investment and Partnership (“**FEMIP Trust Fund**”). The FEMIP Trust Fund was established in 2004 and has been financed – to date – by 17 EU Member States, the United Kingdom and the European Commission (the “**Donors**”). It is intended to promote private and public sector development and bolster socioeconomic infrastructure in the Mediterranean region by financing upstream studies, project preparation and implementation, capacity building and risk capital support.

### 1.3. Relevant country background

Egypt has demonstrated a strong and sustained commitment to immunisation, implementing robust national policies and programmes that have led to high vaccine coverage and effective control of vaccine-preventable diseases.

The foundation of Egypt’s immunisation efforts is the **Expanded Programme on Immunisation (EPI)**, launched in 1984. This initiative provides routine immunisation against key diseases such as diphtheria, tetanus, whooping cough (pertussis), measles, polio, and hepatitis B. Supported by the **World Health Organization (WHO)** and **UNICEF**, the EPI has achieved remarkable results, with national vaccination coverage consistently exceeding 90%, placing Egypt above the global average.

Egypt’s immunisation strategy includes several key components:

- **Routine Immunisation:** The Ministry of Health ensures the provision of high-quality vaccines, maintaining their safety and efficacy through rigorous cold chain management and the use of auto-disable syringes. The national schedule includes essential childhood vaccines as part of comprehensive preventive care.
- **Polio Eradication:** Egypt has remained polio-free since 2006, sustained through regular immunisation campaigns and vigilant surveillance to prevent re-emergence.
- **Measles Elimination:** In 2023, the WHO officially recognised Egypt as having eliminated measles, marking a significant public health milestone.
- **Addressing Vaccine Hesitancy:** Acknowledging that vaccine hesitancy poses a challenge to immunisation efforts, Egypt has introduced targeted communication and community engagement strategies to strengthen public confidence and encourage uptake.

In addition to delivering vaccines, Egypt is also enhancing its domestic vaccine production capabilities. In November 2024, the country launched the **Egyptian Vaccine Manufacturers Alliance (EVMA)** – a strategic initiative aimed at boosting local vaccine manufacturing. The EVMA supports national health objectives and aligns with the **African Union’s goal of producing 60% of Africa’s vaccine needs locally by 2040**. This initiative contributes to both national preparedness and regional health security by promoting vaccine self-reliance.

### 1.4. Current situation in the sector

Vaccine manufacturing in Egypt – much like across the African continent – faces substantial structural and capacity-related challenges. Despite increasing recognition of the importance of local production, the majority of vaccines used in Egypt and neighbouring countries are still imported.

This dependence creates exposure to global supply chain disruptions, inflated procurement costs, and delayed access, as demonstrated during the COVID-19 pandemic.

Infrastructure for large-scale, modern vaccine production remains underdeveloped. There is limited availability of advanced manufacturing facilities, and cold chain logistics are often inadequate. Furthermore, access to sustainable financing for the construction and maintenance of vaccine production sites presents a significant barrier. At the same time, national regulatory systems require further enhancement to meet international standards. In particular, the ability to obtain WHO prequalification is essential for the export and global procurement of locally produced vaccines but remains a key hurdle for many producers. Additionally, there is a clear need to develop a skilled workforce with technical expertise in biomanufacturing, quality control, and regulatory compliance – critical elements for ensuring safety and efficacy throughout the production process.

At the continental level, there is growing momentum to strengthen local vaccine production, with regional institutions such as the Africa CDC playing a key role in supporting this shift. Egypt is well placed to contribute to these efforts, given its institutional legacy in the life sciences and its strategic role within the wider MENA and African regions.

### 1.5. Related programmes and other donor activities

The proposed project which is to establish a multi-product vaccine manufacturing facility at the VACSERA site in Sixth of October City in Egypt (the “**Project**”) is closely aligned with several regional and international initiatives aimed at enhancing vaccine manufacturing capacity in Africa. Most notably, it supports the goals of the **Partnership for African Vaccine Manufacturing (PAVM)**, a flagship initiative of the African Union that promotes local production as a means to strengthen health security and reduce reliance on external suppliers.

The project also complements the objectives of the **African Vaccine Manufacturing Accelerator (AVMA)**, a donor-supported mechanism designed to provide financial and technical assistance to emerging manufacturers committed to achieving WHO prequalification and long-term operational sustainability.

Globally, organisations such as **Gavi, the Vaccine Alliance, UNICEF, the WHO, the European Union, and the Bill & Melinda Gates Foundation** are actively engaged in strengthening vaccine value chains in Africa. These efforts include targeted investments, capacity-building for regulatory authorities, and support for technology transfer and research partnerships.

Given Egypt’s growing role in the regional health landscape, the proposed investment stands to benefit from potential synergies with these programmes and may serve as a model for coordinated public-private collaboration in vaccine manufacturing across the continent.

## 2. OBJECTIVE, PURPOSE & EXPECTED RESULTS

### 2.1. Overall objective

The overall objective of the Project of which this contract will be a part of, is to support the establishment of a multi-product vaccine manufacturing facility in Egypt that strengthens national production capacity, ensures the sustainability of compulsory vaccination programmes, and contributes to regional health security by providing high-quality, WHO-prequalified vaccines in line with Egypt’s Vision 2030 and continental efforts to enhance self-sufficiency.

### 2.2. Purpose/Specific objectives

The specific objective of the TA operation is for a consultant (hereafter, the “**Consultant**”) to support the Promoter (VACSERA) in carrying out a comprehensive feasibility study and market analysis providing evidence-based recommendations on project design, vaccine production priorities, and capacity requirements (the “**TA Assignment**”).

Ultimately the TA Assignment will support the preparation and successful implementation of the Project, thereby reinforcing the Company’s vision to expand production capacity, diversify vaccine manufacturing, and enhance Egypt’s ability to meet national immunisation needs, including for migrants and refugees.

- To enable the Company to achieve competitiveness in vaccine production through the application of advanced technologies, technology transfer, and the attainment of WHO prequalification accreditation, ensuring vaccines of the highest quality, safety, and efficacy

- To strengthen Egypt's vaccine manufacturing capacity and support Egypt's Vision 2030, while enhancing regional health security by reinforcing vaccination programmes, reducing reliance on imports, and establishing the foundation for affordable vaccine exports to the Middle East and African Union countries.

### **2.3. Results to be achieved by the Consultant**

The TA Assignment should have a positive, long-term impact in a number of fields and will achieve the following results

- A comprehensive feasibility study and market analysis providing evidence-based recommendations on project design, vaccine production priorities, and capacity requirements.
- A defined set of project components, technologies, and resource requirements, including detailed specifications for the development of the multi-product facility.
- Preparation of an Environmental and Social Impact Assessment (ESIA) and associated management plans in line with international best practice.
- Development of procurement, implementation, and operational plans, ensuring alignment with WHO standards and international regulatory requirements.
- A WHO Prequalification (PQ) roadmap outlining the steps, quality systems, and timelines necessary to achieve accreditation.
- Knowledge transfer and capacity-building support for the Company to strengthen its technical, regulatory, and managerial capabilities.
- Clear decision-support tools enabling the Company and the Egyptian government to make informed choices on design, investments, and prioritisation of vaccine production pipelines.

## **3. ASSUMPTIONS & RISKS**

### **3.1. Assumptions underlying the project**

The successful implementation of this assignment assumes the following:

- Close and constant communication and coordination among the Consultant, the Bank, project stakeholders, and other relevant parties.
- Timely availability and accessibility of all necessary project information.
- Ongoing commitment and prompt responsiveness from stakeholders at the decision-making level.

### **3.2. Risks**

It is acknowledged that the work carried out under this Assignment may be subject to certain risks, including but not limited to:

- The risk of providing generic advisory support that fails to address the unique characteristics and specific needs of this project.
- The risk of producing vague recommendations that do not adequately guide the creation of a comprehensive information package for technical due diligence.
- The risk of delays arising from insufficient cooperation by project stakeholders, limited access to necessary information, or incomplete data.

## 4. SCOPE OF THE WORK

### 4.1. General

#### 4.1.1. Description of the assignment

The TA Assignment consists of providing **TA services** to the Promoter to support the preparation, design, and successful implementation of the Project. The advisory support provided by the Consultant will contribute across all phases of the Project, including feasibility analysis, technical and operational planning, regulatory compliance, and strategic prioritisation of vaccine production pipelines.

The scope of the TA Assignment includes:

- Conducting a **comprehensive feasibility study** and market research to evaluate vaccine demand, production requirements, and commercial opportunities in Egypt and regional markets.
- Defining **project components, technologies, and required resources** for the development of a modern, multi-product vaccine facility.
- Supporting the preparation of an **ESIA** and associated management plans in line with international standards.
- Developing **procurement, implementation, and operational plans**, ensuring compliance with WHO prequalification requirements and international best practices in vaccine manufacturing.
- Facilitating **technology transfer and application of advanced manufacturing processes**, including guidance on adopting cutting-edge equipment, production workflows, and quality assurance systems.
- Providing **decision-support tools and capacity-building measures** to enable the Company and the Egyptian government to make informed, evidence-based decisions regarding facility design, production priorities, and strategic investments.

This TA will ensure the Project aligns with **Egypt's Vision 2030**, national vaccination targets, and regional efforts to strengthen vaccine self-sufficiency, including the African Union's strategic goal of increasing local vaccine production.

#### 4.1.2. Geographical area to be covered

The Assignment will be implemented primarily in **Egypt**, with a focus on the **VACSERA facility in Sixth of October City**. A number of **field missions to the facility and relevant government institutions in Cairo will be** needed, to gather data, hold stakeholder consultations, and validate project plans - please also refer to §5.1 hereafter.

- **Field missions:** At least four on-site visits are anticipated to conduct workshops and hold consultations with the Promoter, as well as with national and regional stakeholders – for more details, please refer to §5.1.
- **Contextual considerations:** Egypt is a politically stable country, but the Consultant should remain aware of potential regional sensitivities regarding public health data, regulatory processes, and coordination with international partners. The assignment may involve engagement with multiple governmental agencies, international organisations (WHO, UNICEF), and regional partners.

#### 4.1.3. Target groups

The TA will primarily benefit the following groups:

- **National population of Egypt**, including children, adults, and vulnerable populations such as migrants and refugees, by ensuring sustainable access to essential vaccines.
- **VACSERA and associated staff**, through knowledge transfer, training, and capacity building in advanced vaccine production processes, quality assurance, and regulatory compliance.
- **Government authorities and policymakers**, by providing evidence-based recommendations for strategic decisions on vaccine production, resource allocation, and regulatory oversight.

- **Regional stakeholders and partner countries**, indirectly benefiting from enhanced vaccine self-sufficiency and the potential for export of high-quality vaccines to neighbouring countries and African Union member states.

Socio-demographic factors relevant to this TA include:

- High demand for vaccines among children, at-risk populations, and migrants/refugees.
- Need to address inequalities in vaccine access across socio-economic groups.
- Importance of gender-inclusive workforce planning and training in the vaccine manufacturing sector.

## 4.2. Specific work

### 4.2.1. Specific activities

To ensure the successful planning and implementation of the Project, the Consultant will carry out a series of essential tasks. These are structured to support thorough project development, informed decision-making, and smooth execution throughout all phases.

#### - Task 1: Feasibility Study

Task 1 involves conducting an in-depth analysis of vaccine demand across local, African, and Middle Eastern markets, reviewing the competitive landscape, and identifying export opportunities. The Consultant will evaluate the regulatory frameworks relevant to the Company's products, pinpoint potential barriers to market entry, and develop strategies aligned with EU and WHO standards. The assessment will cover infrastructure and resource requirements, including estimated costs, staffing needs, and timelines, as well as budget allocation for each phase of the Project. A detailed supply chain analysis will identify logistical challenges and mitigation strategies. The study will also include clinical trials design, cold chain development at the VACSERA facility, and identification of workforce needs and capacity-building requirements. Finally, the study will prioritise project components and technology platforms based on local and export needs, evaluate capital investment and operating costs, and explore potential strategic partnerships and technology transfer approaches.

##### Deliverables Task 1

- Draft Feasibility Study (draft version + final version)
- Inputs to Power point presentation, draft Action Plan and Final Report requested under Components 4 and 5

#### - Task 2: Environmental and Social Impact Assessment

Starting from the existing environmental conditions, Task 2 will examine the impact of the Project on resource consumption, pollution, biodiversity, health and safety, and socio-economic factors. It will ensure regulatory compliance and recommend any necessary mitigation measures to minimise negative environmental and social effects.

##### Deliverable Task 2

- ESIA
- Inputs to Power point presentation, draft Action Plan and Final Report requested under Components 4 and 5

#### - Task 3: Procurement Plan

In Task 3, the Consultant will develop a comprehensive procurement plan to support the Company in selecting contractors for works on the facilities and infrastructure, suppliers of equipment and machinery, as well as providers of raw materials, consumables, logistics, and distribution services. This plan will outline a stepwise selection process that considers regulatory requirements and associated risks, alongside budget management and financial oversight.

Deliverable Task 3

- Procurement Strategy report
- Inputs to Power point presentation, draft Action Plan and Final Report requested under Components 4 and 5

- **Task 4: Implementation Plan**

Task 4 will provide a phased roadmap for project execution, detailing the schedule for infrastructure development, equipment procurement, and workforce planning. It will define key milestones and timelines to guide project progress. Additionally, the plan will incorporate a compliance and quality assurance framework, providing clear guidance on securing regulatory approvals – including WHO prequalification – and ensuring the highest standards in vaccine production and distribution are maintained. Furthermore, the Service Provider will assist the Promoter in developing an Action Plan aimed at enhancing the Company’s portfolio and business strategy.

Deliverable Task 4

- Input to Power point presentation, draft Action Plan and Final Report requested under Components 4 and 5

**4.2.2. Technical deliverables to be produced**

The following table presents an estimated timetable for the accomplishment of the tasks foreseen in these Terms of reference. Based on this recommendation and his experience, the Consultant should develop its own proposal:

Task	Months	Deliverables	Timing estimate
<b>Component I – Feasibility Study</b>			
<b>Task 1</b>	1-2	<p>The Consultant will prepare a <b>draft Feasibility Study</b> and cost estimate based on a detailed demand analysis, forming the foundation for Project planning and decision-making. The study will include preliminary financial and economic assessments and cover the following aspects:</p> <ul style="list-style-type: none"> <li>• Market research evaluating vaccine demand across Egypt, Africa, and the Middle East, including an overview of the competitive landscape and export opportunities.</li> <li>• Assessment of regulatory frameworks in target markets, identifying key requirements and potential barriers to entry.</li> <li>• Development of initial strategies to address regulatory challenges, with alignment to EU and WHO standards to ensure international market compatibility.</li> <li>• Analysis of existing infrastructure and manufacturing capacity, including scalability of production facilities and alignment with vaccine manufacturing plans.</li> <li>• Clinical trial design, cold chain development at the VACSERA facility, and identification of workforce needs along with capacity-building requirements</li> </ul> <p>Preliminary supply chain assessment, addressing sourcing, logistics, and potential distribution constraints for vaccine exports.</p>	No later than 2 months after the start of implementation

Task 1	3-4	<p>The Consultant will finalise the <b>Feasibility Study</b> by integrating the most up-to-date information and findings gathered during the course of the assignment. Building on the draft version, the final study, in the form of a report, will present a comprehensive and validated analysis, including:</p> <ul style="list-style-type: none"> <li>• Final figures for capital investment requirements, operating costs, and projected revenues for each phase of the Project.</li> <li>• Identification and prioritisation of key project components and technology platforms, based on technical, market, and financial feasibility.</li> <li>• Assessment of potential strategic partnerships to support technology transfer, production scalability, and market access.</li> </ul> <p>This finalised Feasibility Study will serve as a solid foundation for decision-making and further steps in project implementation</p>	No later than 4 months after the start of implementation
<b>Component 2 - Environmental and Social Impact Assessment</b>			
Task 2	1-2-3-4	<p>The Consultant will prepare a comprehensive <b>Environmental and Social Impact Assessment report</b> that includes:</p> <ul style="list-style-type: none"> <li>• Review of existing Environmental &amp; Social Impact Assessment (ESIA): Determine whether the existing ESIA meets EIB standards and adequately covers any potential expansion and assess if amendments are required to address new or increased environmental &amp; social impacts.</li> <li>• Additional Resource Consumption: Assess the anticipated increases in water, energy, and raw material usage resulting from the expansion of manufacturing capacity.</li> <li>• Increased Emissions and Waste: Identify and quantify any additional emissions and waste generated by the expanded operations, including pollutants affecting air, water, and soil quality.</li> <li>• Impact on Local Biodiversity: Examine potential effects on local flora and fauna, including any disruptions or habitat displacements caused by the expansion.</li> <li>• Health and Safety: Evaluate new risks to human health and safety, such as exposure to hazardous materials or pathogens associated with the expansion.</li> <li>• Socio-Economic Impact: Analyse how the expansion may affect the local economy, employment opportunities, and overall community well-being, considering both positive and negative outcomes.</li> <li>• Regulatory Compliance: Ensure that the expanded facility complies with all applicable environmental and social regulations and</li> </ul>	No later than 4 months after the start of implementation

		standards. Mitigation measures: Recommend strategies to minimize adverse environmental and social effects, including improved pollution control technologies and enhanced waste management practices	
<b>Component 3 – Procurement Plan</b>			
<b>Task 3</b>	1-2-3-4-5	<p>The Consultant will prepare a comprehensive <b>Procurement Strategy report</b> that includes the following areas:</p> <ul style="list-style-type: none"> <li>• Stepwise Selection Process: Clear criteria and procedures for selecting contractors and suppliers, ensuring compliance with regulatory requirements, risk mitigation, and adherence to project timelines.</li> <li>• Regulatory Compliance Framework: Guidance ensuring all procurement activities and procured items meet applicable laws, industry standards, and quality and safety requirements.</li> <li>• Budget Management and Financial Oversight: Detailed budgeting and cost management plan for procurement activities, including cost estimates, financial controls, and expenditure monitoring.</li> <li>• Risk Assessment and Mitigation: Identification of procurement risks, such as supply chain disruptions, and strategies to mitigate these risks to prevent delays and cost overruns.</li> <li>• Material Requirements: Identifying and sourcing raw materials, reagents, and consumables essential for vaccine production.</li> <li>• Equipment, Machinery and Facility Infrastructure: Planning for the procurement of specialized equipment for manufacturing, quality control, and packaging as well as any further upgrades or modifications needed for the adaptation and expansion of essential infrastructure, including HVAC systems, clean rooms, and storage facilities.</li> </ul> <p>Logistics and distribution planning: Organising transportation, storage, and distribution of raw materials and finished products, ensuring supply chain integrity</p>	No later than 5 months after the start of implementation
<b>Component 4 - Workshops with the Promoter to present and receive feedback on the Reports provided</b>			
Tasks 1, 2, 3, 4	5-6	<b>Power point presentation and draft Action Plan</b> for discussions, including recommendations on what to do and how to do it in order to complement and achieve the Development plan	No later than 6 months after the start of implementation period.

<b>Component 5 - Final Report, including the revised version of all Report and results on all activities</b>			
Tasks 1, 2, 3, 4	7-8	<p><b>Final versions of all reports</b> produced under Tasks 1, 2, and 3, along with a comprehensive and implementable Action Plan as outlined in Task 4. These deliverables will serve to inform decision-making by the Company’s management and board regarding future changes, investments, or developments.</p> <p>These documents constitute the <b>final results of the assignment.</b></p>	No later than 8 months after the start of implementation period.
<b>Reporting requirements</b>	As foreseen in Section 7 – Reporting requirements of these ToR’s		

### 4.3. Project management

#### 4.3.1. Responsible body

The European Investment Bank, through the Consultant Procurement and Contract Management Division (CPCM), will act as Contracting Authority and will be responsible for managing this TA operation.

#### 4.3.2. Management structure

##### *Contracting Authority*

At the European Investment Bank, the Projects Directorate (PJ) and EIB Global (GLO) or, when applicable, the Portfolio Management & Monitoring Directorate (PMM) are responsible for the management and technical follow up of the contract. The CPCM Unit of the Advisory Division (ADV) is responsible for contractual and administrative matters.

##### *Promoter*

The Promoter is VACSERA, responsible for overseeing the TA operation, on the Promoter’s side, and the development of the multi-product vaccine facility. A Project Management Unit (PMU) handles day-to-day coordination with the Consultant, while a Steering Committee of senior VACSERA executives and relevant stakeholders provides strategic oversight, approves key decisions, and ensures alignment with national vaccination strategies and Vision 2030. The PMU manages the project schedule and integrates TA outputs into overall implementation.

##### *Consultant*

The Consultant should nominate a **TA operation director** (the “**TA Operation Director**”) from its head office with sufficient authority to commit the necessary resources, and to take overall responsibility for the performance of the consultancy team. The TA Operation Director should have a minimum of 5 years of professional experience at a level of senior responsibility and be fully fluent in English (**CV to be submitted**).

#### 4.3.3. Support to be provided by the Contracting Authority and/or other parties

##### *Contracting Authority*

The Contracting Authority will provide the Consultant, upon request, with all information relevant to the TA operation which is available to it and not covered by any confidentiality agreements and will fully cooperate with the Consultant in order to achieve the best results.

##### *Promoter*

The Promoter or Contracting Authority will facilitate access to project-related documents and coordinate with local stakeholders as needed.

The Promoter undertakes to ensure that its employees co-operate at all times with the Bank and the Consultant in relation to the provision of the Technical Assistance. The Promoter shall promptly provide the Consultant with such information and documents at its disposal which may be relevant and necessary to the provision of the Technical Assistance. Such documents shall be returned to the Promoter on completion of the Technical Assistance.

The Consultant may request the assistance of the Promoter in obtaining copies of local laws, regulations and information which may affect the Consultant in the performance of its obligations under the Service Contract in the country where the services are to be provided.

The Consultant might be exempt from direct and indirect taxes in Egypt as a result of this project financed through EC funds. The Consultant should verify that this tax exemption applies to their activities with the Government of Egypt. The Promoter will be able to support the Consultant regarding the administrative requirements upon his establishment in Egypt. The EIB has no influence in this matter.

EIB benefits from VAT exemption on its purchases in Member States of the European Union, which means that the Consultant's activities performed in the EU (e.g. home office) can be exempt of VAT.

Subject to the laws and regulations on foreign labour in relevant country, the Promoter shall use its best endeavours to ensure that the Consultant's employees and their dependants obtain the required visas and permits, including work and residence permits.

## **5. LOGISTICS AND TIMING**

### **5.1. Location**

The Services will be carried out primarily from the Consultant's own professional premises, or from any other place of its choice. However, both key and non-key experts assigned to the Assignment must remain available for in-person meetings, phone calls, and video conferences as required.

As indicated in §4.1.2, the Consultant will be expected to conduct **field missions to the VACSERA facility in Egypt, and relevant government institutions in and around Cairo**, if and as needed, to gather data, hold stakeholder consultations, and validate project plans. At least four (4) on-site visits, each with an average duration of three (3) days, are anticipated to conduct workshops and hold consultations with the Promoter, as well as with national and regional stakeholders. The cost related to those travels should be included in the financial proposal.

The kick-off meeting will be held at VACSERA headquarters and/or remotely (to be agreed after contract signature).

### **5.2. Start date & Period of implementation of tasks**

The TA is intended to start in Q1/Q2 2026 and the period of implementation of the contract will be **twelve (12) months** from this date. Please see Articles 3 and 4 of the Special Conditions for the actual start date and period of implementation.

## **6. REQUIREMENTS**

### **6.1. Staff**

The Consultant shall provide the adequate staff (in terms of expertise and time allocation), in order to complete efficiently all the activities required under the scope of the TA operation and to finally achieve the specific and the overall objectives of his contract in terms of time, costs and quality.

The Consultant is free to propose whatever team he may consider appropriate for the provision of the required services, in addition to the "key" positions presented below. An estimate for the level of effort of the Consultant's team is 280-man days. This estimate is provided as a guideline only.

Note that civil servants and other staff of the public administration of the beneficiary country cannot be recruited as experts, unless prior written approval has been obtained from the Contracting Authority, on a case-by-case basis. The justification should be submitted with the tender and shall include information on the added value the expert will bring as well as proof that the expert is seconded or on personal leave.

#### **6.1.1. Key experts**

All experts who have a crucial role in implementing the contract are referred to as key experts. Only key-experts are approved before the contract signature. The profiles of the key experts for this contract are as follows:

### **Key expert 1: Team Leader**

#### **Qualifications and skills**

- At least a Master's degree (or academic equivalent) in pharmaceutical sciences, life sciences, or a closely related field.
- Internationally recognised project management certification, preferably Lean Six Sigma
- Proficient working command of English.

#### **General professional experience**

- At least 15 years of international experience in the pharmaceutical industry, including a minimum of 5 years in the vaccines sector.
- At least 5 years of experience in the Middle East or Africa.

#### **Specific professional experience**

- At least 5 years' experience in vaccine product development, market access, and regulatory strategy.
- Experience with global health actors (e.g., WHO, Gavi, UNICEF) and knowledge of international vaccine procurement and tendering requirements, as demonstrated by the submission of at least one (1) vaccine tender application.
- Having been involved for at least 3 years as a project manager, with multiple complex projects simultaneously, demonstrating strong organizational and multitasking skills, including managing stage gate decision making.
- Participation in at least one (1) project for large-scale commercial Good Manufacturing Practice (GMP) vaccine production or successful completion of commercial vaccine technology transfer.
- Project financial and budget management experience demonstrated by the successful delivery of at least two (2) projects on or under budget

### **Key expert 2: Business Process Management Expert**

#### **Qualifications and skills**

- At least a Bachelor's degree (or academic equivalent) in pharmaceutical sciences, life sciences, business administration, engineering, or pharmaceutical manufacturing.
- A Master's degree in relevant fields such as industrial engineering, supply chain management, biotechnology, or business administration is desirable.
- Proficient working command of English.

#### **General professional experience**

- At least 10 years of international experience in the pharmaceutical industry, including a minimum of 5 year specifically in a consultancy role.

#### **Specific professional experience**

- At least three (3) international assignments involving business or industrial process management in the pharmaceutical sector, preferably linked to manufacturing, quality systems, or supply chain optimisation.
- Demonstrated experience in developing or improving innovation-driven processes within pharma companies, ideally in GMP-compliant environments.

**All experts must be independent and free from conflicts of interest in the responsibilities they take on.**

#### **6.1.2. Non-key experts**

The Consultant should provide the total number of working days and specify the number of experts having national or international experience

CVs for experts other than the key experts should not be submitted in the tender but the tenderer will have to demonstrate in their offer that they have access to experts with the required profiles.

The Consultant shall select and hire other experts as required, according to the profiles identified in the Organisation & Methodology and/or these Terms of Reference.

**All experts must be independent and free from conflicts of interest in the responsibilities they take on.**

For the purposes of this contract, the classification of the experts as senior/junior is entirely the decision of the Consultant, but should nevertheless be communicated to the Contracting Authority when requesting the approval of the experts, for contract management purposes.

The selection procedures used by the Consultant to select these other experts shall be transparent, and shall be based on pre-defined criteria, including professional qualifications, language skills and work experience. The findings of the selection panel must be recorded. The selected experts must be subject to approval by the Contracting Authority before the start of their implementation of tasks.

The key experts are expected to be supported by non-key experts with qualifications and experience that complement those of the key expert team. The profiles of the non-key experts may include, but are not limited to, the following:

Profile	Minimum Qualifications and skills	Minimum General & specific professional experience	Indicative number of working days
<b>Experts in R&amp;D for innovative technologies (vaccine/pharma)</b>	<ul style="list-style-type: none"> <li>- Advanced degree (MSc or PhD) in Biotechnology, Pharmaceutical Sciences, or related field</li> <li>- Strong analytical and scientific research skills</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum 8 years in R&amp;D, with at least 3 years in vaccine or pharmaceutical tech innovation</li> <li>- Proven track record of leading or contributing to R&amp;D projects</li> </ul>	8
<b>Regulatory Specialists (national, regional, international)</b>	<ul style="list-style-type: none"> <li>- Degree in Pharmacy, Regulatory Affairs, or related field</li> <li>- In-depth knowledge of WHO, EMA and Egyptian regulatory requirements</li> </ul>	<ul style="list-style-type: none"> <li>- At least 7 years in regulatory affairs</li> <li>- Experience with product registration, licensing, and GMP inspections</li> </ul>	8
<b>Pharmaceutical Production &amp; Manufacturing Professionals</b>	<ul style="list-style-type: none"> <li>- Degree in Pharmaceutical Sciences, Chemical Engineering, or related field</li> <li>- Certified training in GMP</li> </ul>	<ul style="list-style-type: none"> <li>- 10+ years in pharma manufacturing, with 5+ years in GMP-compliant environments</li> <li>- Familiarity with validation, quality control, and production planning</li> </ul>	10
<b>Business Process Management / Business Development Specialists</b>	<ul style="list-style-type: none"> <li>- Degree in Business Administration, Industrial Engineering, or Life Sciences</li> <li>- Knowledge of process optimization tools</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum 6 years in business process analysis or pharma business development</li> <li>- Experience in pharma or biotech sector preferred</li> </ul>	6
<b>Other Technical or Sectoral Experts</b>	<ul style="list-style-type: none"> <li>- Relevant academic and professional qualifications tailored to the Assignment</li> <li>- Specialized knowledge in assigned technical area</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum 5 years in relevant technical field</li> <li>- Experience contributing to donor-funded or technical assistance projects is an asset</li> </ul>	8

It is recommended that some of the non-key experts to possess a working command of the Arabic language, in particular Egyptian Arabic, to facilitate communication and coordination with local stakeholders, but it is not mandatory.

### **6.1.3. Support staff & backstopping**

The Consultant shall supply all support staff (administrators, secretaries, interpreters, and head office back-up, drivers etc.) as necessary for the proper fulfilment of his obligations. The costs of the support staff must be included in the fee rates of the experts and the financial proposal.

Backstopping costs for logistical and management support (including the activity of the TA operation director designated by the Consultant) of the team must also be included in the fee rates of the experts.

The Consultant should identify and describe in his offer the arrangements for the provision of the support staff and backstopping facilities.

**Note that the support/backstopping staff cannot be assigned as short or long-term experts while still maintaining their original assignment. The two responsibilities must be kept separate and double budgeting under the project should be avoided.**

### **6.2. Travel and associated costs**

International (including mobilisation and demobilisation) and local transport and associated costs (vehicles incl. drivers if considered necessary, per diem, etc.) of Key and Non-Keys experts posted on site should be included in the financial offer.

### **6.3. Office accommodation**

Office accommodation of a reasonable standard and of approximately 10 square metres for each expert working on the contract and reasonably accessible by phone, fax and e-mail over the duration of the assignment is to be provided by the Consultant.

### **6.4. Facilities to be provided by the Consultant**

The costs of the facilities should be included in the tenderer's financial offer. The Consultant shall ensure that experts are adequately supported and equipped. In particular it must ensure that there is sufficient administrative, secretarial and interpreting provision to enable experts to concentrate on their primary responsibilities. It must also transfer funds as necessary to support their work under the contract and to ensure that its employees are paid regularly and in a timely fashion.

The Consultant is required to provide all necessary office supplies, IT equipment, communication tools, and access to relevant documentation and databases. Logistical support such as transportation arrangements, meeting facilities, and translation/interpretation services must also be ensured and be included in the financial proposal.

### **6.5. Equipment**

**No** equipment is to be purchased on behalf of the Contracting Authority and/or Promoter as part of this service contract or transferred to the Contracting Authority and/or Promoter at the end of this contract. Any equipment related to this contract which is to be acquired by the Promoter must be purchased by means of a separate supply tender procedure.

## **7. REPORTS**

### **7.1. Reporting requirements**

In addition to the ones mentioned in 4.2, the Consultant will submit the following reports:

- **Inception Report** to be produced after one month from the start of implementation. In the report the Consultant shall describe e.g. initial findings, progress in collecting data, any difficulties encountered or expected in addition to the work programme and staff travel. It shall confirm the aims of this technical assistance contract. If there are any proposed modifications to the original Terms of Reference due to changed circumstances after arrival on site, these are to be discussed and agreed in principle with the Contracting Authority and the Promoter before the submission of the Report.

This Report will describe the Consultant's proposed establishment, personnel, and where they will be based, as well as the Consultant's proposed approach to the project, taking into consideration the situation at the starting date of the assignment. It will also set out a detailed work plan for completion of the activities in the remaining TA operation period of execution, together with a detailed work plan for interrelated, sequential and complex activities with an agreed project log-frame matrix. The expected achievement of the outputs listed in the Terms of Reference should be clearly identified, with any milestones, and the confirmation of the counterpart staff and other commitments to be made by the recipient counterparts. The inputs to support key activities in each beneficiary should be based on a thorough needs assessment taking account of individual circumstances.

- **Draft final report.** This report shall be submitted no later than one month before the end of the period of implementation of tasks. It shall consist of a narrative section. It shall, *inter alia*:
  - Describe the overall status of the project, including a critical study of any major problems which may have arisen during the performance of the project;
  - Describe the status and results for the assistance given to each project beneficiary;
  - Incorporate as an annex the overall Training Report;
  - Present any recommendations the Consultant wishes to make in view of improving the design and implementation of any future similar activities.

The report shall contain a sufficiently detailed description of the different options to permit an informed decision on any recommendations made. The detailed analyses underpinning these recommendations will be presented in annexes to the main report.

- **Final report** with the same specifications as the draft final report, incorporating any comments received from the parties on the draft report. The deadline for sending the final report is 30 days after receipt of approval on the draft final report.
- **All reports** will be written in concise, clear and well-edited Standard English. All reports shall be produced in A4 size and printed on both sides of the paper. Spreadsheets and schedules shall be produced in a maximum of A3 size for reporting purposes and may be printed single-sided. File origins shall be clearly identifiable in a header or footer. A list of essential contact persons is to be included. The reports should have a title page, which should include project name, project code or reference, report title, date issued and period covered, and the name and address of the Consultant. **The Contracting Authority shall provide the Consultant, after the starting date of the assignment, with a recommended structure of the Reports.** The Consultant may propose changes to this structure, which must be agreed with the Contracting Authority in advance.

## **7.2. Submission and approval of reports and deliverables**

One copy of the reports and deliverables referred to above must be submitted to the Contracting Authority.

The Contracting Authority is responsible for approving the reports **after consultations with the Promoter**, and shall be kept informed by the Consultant of the dates of submission of the reports to the other recipients indicated below. It should be noted that the Promoter will provide comments on each report submitted within 2 weeks after submission. The Promoter may request an extension by no more than one week. After this period, the EIB will consider that the Promoter has no comments on the reports. Please also refer to Article 27.2 of the General conditions for the procedures and deadlines for the approval of reports.

The contact details of EIB's staff members to which the reports shall be submitted will be communicated to the Consultant during the kick off meeting. The draft of the reports must be sent in e-copy to these staff members. Following the comments received, the Consultant will send a revised version, with the operated changes highlighted, via the same contact, before formally submitting the final version. Once this report is agreed to by the EIB, a final version shall be submitted as follows:

- in e-copy to the EIB's staff members mentioned above, and
- in e-copy and one hard copy

### 7.3. Visibility requirements

The Consultant must also comply with the latest Communication and Visibility Manual for EU External Actions concerning acknowledgement of EU financing of the project.

The technical assistance operation is financed by the European Union under the FEMIP Trust Fund. To ensure EU visibility, the EU flag, the FEMIP Trust Fund logo and the EIB logo should appear on the cover page of reports produced under the TA contract. THE EIB LOGO MAY NOT BE USED FOR ANY OTHER PURPOSE.

The following text should also be included in all documents produced: “*The technical assistance operation is financed under the FEMIP Trust Fund.*”

The following disclaimer should also be included: “The authors take full responsibility for the contents of this report. The opinions expressed do not necessarily reflect the view of the European Union, the FEMIP Trust Fund or the European Investment Bank”.

## 8. MONITORING AND EVALUATION

### 8.1. Definition of indicators

The TA outcome will be measured using a set of quantitative and qualitative indicators reflecting the quality, relevance, and impact of the outputs produced:

- **Studies and Technical Documents:** A single comprehensive report will cover the feasibility study, market scoping, ESIA, procurement strategy, and include a workshop. In addition, three technical documents – the feasibility report, procurement strategy, and ESIA – will provide detailed analyses to support project design and implementation.
- **Stakeholder Consultation:** Engagement with stakeholders is critical and will be extensive, ensuring that feedback informs project design, operational planning, and risk management.
- **Environmental and Social Impact:** The TA will perform an ESIA gap analysis and update environmental and social aspects as needed, ensuring the project aligns with EIB Environmental & Social (E&S) standards. The expected impact is significant for both environmental and social outcomes.
- **Use of Outputs in Decision-Making:** The studies and technical outputs are expected to be critical for project appraisal by the EIB and other financiers. Recommendations from pre-feasibility studies will guide feasibility studies and enhance the quality of project design, including social and environmental aspects.

### 8.2. Special requirements

None

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