

TERMS OF REFERENCE

TOR - CONSULTANCY TO CONDUCT A FEASIBILITY STUDY FOR PHARMACEUTICAL PROJECT

A. TITLE OF THE PROJECT:

A Feasibility Study for Pharmaceutical Project

B. BACKGROUND

The Lesotho National Development Corporation (LNDC) has the core mandate to “initiate, promote and facilitate the development of manufacturing and processing industries, mining and commerce in a manner calculated to raise the level of income and employment in Lesotho.” This mandate stems from the LNDC Act No. 20 of 1967, as amended by LNDC Act No. 13 of 1990 and LNDC Act No. 7 of 2000.

In line with this mandate, the Corporation developed a five-year Strategic Plan, which seeks to drive economic development and diversification by creating sustainable pharmaceutical manufacturing and distribution industry in Lesotho. The Corporation initiated establishment of Maluti Pharmaceutical (PTY) LTD. in partnership with Battal Holdings Incorporation and Interglobe IEG.

Project Description:

Maluti Pharmaceutical (PTY) LTD. aims to establish an integrated pharmaceutical project in Mafeteng District. The project focus area is the production of medical human drugs, nutritional serum and biotechnological (vaccine), health products, health technology transfers, and medical consumables. The following are the envisaged business activities of the Company:

- a. pharmaceutical product manufacturing,
- b. laboratory establishment in terms of basic analytical test and quality assurance,
- c. laboratory services to private and public hospitals and
- d. Contract manufacturing (CMO)

The Corporation is expected to apply commercially sound principles in executing its mandate, and to prepare projects to determine their viability and bankability. To effectively deliver on this mandate, the Corporation seeks to engage services of a reputable and capable consulting firm to determine the feasibility of establishing a GMP (Good Manufacturing Practices) certified pharmaceutical production facility by testing its commercial, market and technical feasibility.

C. SCOPE OF WORK

The objective of this assignment is to undertake a comprehensive feasibility study and business plan to inform the development of a GMP (Good Manufacturing Practices) certified pharmaceutical production facility in Mafeteng. The consultant will be expected to undertake the following:

1. MARKET FEASIBILITY

- a. Conduct a market study to determine pharmaceutical products and consumables that Lesotho can manufacture competitively in the African Continent.
- b. Unpark pharmaceutical value chains, market linkages and inputs supplies required to enhance and maintain industry competitiveness.

- c. Assess legislative and industry governance framework required to establish an export led pharmaceutical industry.
 - d. Conduct a market study to determine domestic and regional demand for the pharmaceutical products and related value chains.
 - e. Conduct a market study to determine market entry requirements for exporting pharmaceutical products to the African market under the African Continental Free Trade Agreement (AfCFTA) (including certification and accreditations requirements).
2. TECHNICAL FEASIBILITY
- a. Develop a master plan for the Pharmaceutical Park
 - b. Assess state of readiness of existing manufacturing and bulk infrastructure.
 - c. Conduct an assessment of suitable technology for the manufacturing facility.
 - d. Unpack the project external (Supply Chain) and internal (Production Chain) value chains (Production, Processing, Packaging, and distribution).
 - e. Conduct key stakeholder analysis.
 - f. Conduct a skills and training needs assessment.
 - g. Identify general and technical challenges for development of the project and recommend solutions.
 - h. Conduct an audit of existing policies and legislations for the project.
 - i. Develop an implementation plan and advise on realistic timelines.
3. FINANCIAL FEASIBILITY
- a. Assess project capital investment requirements, cashflow requirements and profitability potential.
 - b. Based on clear assumptions, develop a financial model for the project.
4. BUSINESS PLAN
- Develop a comprehensive business plan the project by addressing the following major areas:
- a. Industry Analyses
 - b. SWOT Analysis
 - c. Products and Services
 - d. Sales, Marketing and Brand Development
 - e. Management and Skills requirements
 - f. Develop a suitable business model and process designs.
 - g. Develop a comprehensive financial model to determine financial viability of the project. State project key assumptions.

D. EXPECTED OUTCOMES AND DELIVERABLES

<i>Stage</i>	<i>Deliverables</i>
Market Feasibility	Detailed Market feasibility Report entailing the following: <ul style="list-style-type: none"> • Competitor Analysis • legislative and industry governance • Inputs Suppliers Analysis • Market Demand • Market entry requirements • Etc.
Technical Feasibility	A detailed technical feasibility report encompassing the following: <ul style="list-style-type: none"> • Project Master Plan.

	<ul style="list-style-type: none"> • State of readiness of manufacturing and bulk infrastructure Report. • Pharmaceutical Value Chain Analysis Report • Stakeholders Analysis Report • Skill Analysis Report • Regulatory Analysis Report • Implementation Plan • Etc.
Financial Feasibility	<p>A detailed financial model encompassing the following:</p> <ul style="list-style-type: none"> • Key Assumptions • Capital investment analysis. • Cashflow Projections Analysis • Income Statement • Projected Balance Sheet • Etc.
Business Plan	<p>A detailed business plan entailing the following:</p> <ul style="list-style-type: none"> • Products and Sales Analysis • Competitor Analysis • Marketing Plan • Sales Plan • SWOT Analysis. • Production, Processing, and distribution plan • Risk Analysis Report • Business Model • Business Processes and technology • Financial Model • Etc.
<p>E. <u>REPORTING AND COORDINATION</u></p> <p>The consultant(s) will report to the General Manager, Development Finance at LNDC throughout the assignment.</p>	
<p>F. <u>QUALIFICATIONS AND EXPERIENCE/COMPETENCY OF CONSULTANT</u></p> <ul style="list-style-type: none"> • The feasibility studies team should be led by a Team Leader, who is knowledgeable and experienced with the pharmaceutical industry. The team leader should have a minimum of an MSc in health sciences and pharmaceuticals sciences or related fields, with at least 15 years of general industry experience and 5 years in management in the pharmaceuticals sector. • All the experts should have proven experience in conducting feasibility studies in general. • The feasibility report will be written based on collected data and analyses and submitted to the client within 90days from appoint. 	
<p>G. <u>DURATION OF WORK</u></p> <p>Three (3) months (90 days) after final appointment of preferred consultancy.</p>	
<p>H. <u>QUOTE</u></p> <ul style="list-style-type: none"> - Quote to indicate the costs broken down in categories and quantified, clearly indicating basic fee and reimbursable expenses (e.g. subsistence, transport etc.) etc. - The payment terms. - The timelines. - The regularity of progress reports. - References, especially contacts in institutions that contracted similar services from consultant and were involved in the work or witnessed the final product and its successful implementation. 	