**TERMS OF REFERENCE FOR A CONSULTING FIRM**

**CONSULTANCY SERVICES FOR ASSESSMENT OF (i) MANUFACTURING CAPACITY OF THE PHARMACEUTICAL INDUSTRY; (ii)** **PHARMACEUTICAL TRADE PERFORMANCE AND SUPPLY CHAIN INTEGRITY IN COMESA REGION, AND (iii) THE POLICY, REGULATORY AND INSTITUTIONAL FRAMEWORKS FOR TRADE IN PHARMACEUTICAL INPUTS AND PRODUCTS**

1. **Background**

The Common Market for Eastern and Southern Africa (COMESA) is a regional economic community comprising of 21 Member States[[1]](#footnote-1). The region commands a largest market in Africa with an estimated total population of more than 583 million people and Gross Domestic Product of USD 805 billion. COMESA’s objective is to create a large economic and trading bloc capable of overcoming the constraints faced by individual Member States. The region also carries a disproportionate burden of communicable and non-communicable diseases, necessitating the need to have stable and reliable medical and pharmaceutical supply chains to ensure commodity security.

COMESA’s pharmaceutical industry is nascent and growing[[2]](#footnote-2) boasting of a few countries with large numbers of domestic pharmaceutical manufacturing plants such as Egypt, Tunisia, and Kenya. The growing industry is characterised by limited technical and financial capacity to locally manufacture enough essential medicines and medical supplies to meet domestic and regional demand.

The COVID-19 experience highlighted the necessity of countries to ensure at least a minimum level of security of supply for health products. Like many governments globally, several governments in Africa are developing their local pharmaceutical industries, not only for security of supply but to reduce the pressure on the balance of payments, and to create wealth more broadly. The development of the pharmaceutical industry in the COMESA region is limited by structural challenges such as low-capacity utilisation, small and fragmented markets, logistical constraints, tariff, and non-tariff barriers, and limited technical know-how.

Strengthening Africa’s medicines regulatory framework, regional quality management systems, trade policies, training institutions and investing in research and development centres will contribute positively towards regional pharmaceutical manufacturing through the development of an enabling environment. Improved regulatory systems will reduce the prevalence of fake and counterfeit medicines, while better trade policies foster regional integration and enhance self-sustainability within the region.

Therefore, to reduce external dependence and promote intra-COMESA trade in pharmaceutical products and inputs (eg Active Pharmaceutical Ingredients - APIs, excipients, and other raw materials), it is critical to assess manufacturing capacity, identify and address the underlining factors to limited capacity utilisation, fragmented markets, logistical constraints, prohibitive tariff, and non-tariff barriers, access to market information and limited investments in the sector. Continental initiatives such as Africa CDC Pooled Procurement, and the African Continental Free Trade Area will be taken into consideration.

**1.1 Regional Pharmaceutical Sector Development Project**

COMESA has received support towards regional pharmaceutical sector development from the African Development Bank (AfDB). The overall objective of the project is to provide institutional support for the development of the pharmaceutical industry through strengthened capacities of the region’s pharmaceutical regulatory bodies, quality control and management systems, research, and development institutions for effective manufacturing of safe and quality pharmaceutical products in the region.

The specific objectives include:

1. The institutionalization and domestication of the pharmaceutical manufacturing plan for Africa (PMPA) and the African Medicines Regulatory Harmonization programme
2. Strengthening of the region’s medicines and pharmaceutical regulatory bodies/institutions in the region
3. Building the capacity of key stakeholders and support trans-regional research and development programmes.

The project is comprised of four main components:

**Component 1:** Institutionalization of the PMPA and AMRH Programmes in the region. This component aims at supporting COMESA region in the implementation of the continental strategies on pharmaceutical manufacturing and streamline medicines registration harmonization processes as well as ensuring that the region has access to essential medical products and technologies. It will address the challenges faced by national medicines regulatory authorities, including, weak or non-coherent legislative frameworks, redundant processes, sluggish medicines registration processes, and inefficiency and limited technical capacities, among others, through regulatory harmonization. The target beneficiaries include, COMESA Secretariat, National Pharmaceutical Policy Institutions such as NMRAs/FDAs.

**Component 2**: Institutional Support for Strengthening Medicines and Pharmaceutical Regulatory Bodies & Institution in the Region. This component concerns providing technical support to strengthen the institutions and bodies responsible for pharmaceutical sector development in the region, including, the National Medicines Regulatory Authorities (NMRAs), the COMESA Pharmaceuticals Committee, institutions responsible for trade facilitation and the quality infrastructure for standardization and testing pharmaceutical products. The target beneficiaries include NMRAs, COMESA pharmaceutical committee, standards and certification labs and collaborations with other regional economic communities on pharmacovigilance.

**Component 3:** Capacity Development of Stakeholders and Support for Trans-Regional Research & Development Programmes. This component aims at strengthening the capacities of pharmaceutical stakeholders, including research institutions and create an information platform for pharmaceutical manufacturers, importers, and exporters in the region. It will also establish pharmaceutical industry collaborations with universities to address skills mismatch and shortages in the sector. The objective is to improve the requisite capacities of stakeholders as well as increase efficiency, effectiveness, and improve service delivery to the pharmaceutical industry in the region.

**Component 4:** Project Management, Coordination & Reporting. This component entails the general management and implementation of the project. It aims to complement the capacity of COMESA Secretariat for the effective and efficient implementation of the project. This includes setting up of a Project Implementation Unit and staffing it with the required human resources that would be responsible for the implementation of the project activities and delivering of the outputs.

**2.0 Rationale of the Consultancy**

The pharmaceutical industry in COMESA is heavily dependent on imports and fragmented due to factors such as low operational capacity which has the potential to be harnessed, weak supply chains, and inconsistencies in trade policies as indicated in a 2022 market study on the supply of COVID-19 Related Pharmaceutical Goods. The 2024 Africa CDC Vaccine Manufacturing Supply Chain Forum proposed three strategies to address supply chain challenges on the continent namely localization of production of key materials, establishment of a regional access and supply consortium and the simplification and harmonization of trade regulations, policies, and procedures[[3]](#footnote-3).

To address this, the assignment will analyse capacity constraints in the COMESA pharmaceutical manufacturing industry using selected tracer final products and inputs, evaluate pharmaceutical inputs trade performance and supply chain integrity and assess current pharmaceutical trade policies, regulations, and frameworks to inform relevant policy changes.

**3.0 Objectives of the Consultancy**

The consultancy has three main objectives, with emphasis on stakeholder engagement during the process (eg industry associations, manufacturers, policy makers etc). Each objective is linked to a work package.

**Work Package 1** - to assess the capacity constraints in pharmaceutical manufacturing in the COMESA region.

**Work Package 2** - to assess the pharmaceutical input and final products trade performance and supply chain integrity in the COMESA region.

**Work Package 3** - to assess policy, regulatory and institutional frameworks governing trade in pharmaceutical products and come up with a model policy for trade facilitation in the region.

**3.1 Specific objectives of the Consultancy**

The objectives of the consultancy for Work Package 1 are to:

1. Using primary and secondary data sources, analyze the capacity utilization, size, industrial organizational structure, contribution to the economy, contribution to trade of the pharmaceutical manufacturers in the COMESA region relative to installed capacity;
2. Determine current COMESA Member States pharmaceutical industry policy orientation (import substitution or export promotion) in relation to capacity utilization by manufacturers;
3. Identify the key policies, regulations, initiatives and institutions (public and private) in the pharmaceutical sector in the COMESA region ;
4. Determine the bottlenecks and enablers to production, productivity, sophistication, and export orientation of the pharmaceutical sector in COMESA; and
5. Propose policy recommendation to enhance investment, local manufacturing, optimize capacity utilization, and enhance supply integrity of the pharmaceutical industry in COMESA region.

The objectives of the consultancy for Work Package 2 are to:

1. Assess and map the traded pharmaceutical inputs for three tracer antibiotics and painkillers included on the WHO List of Essential Medicines[[4]](#footnote-4) and three pharmaceutical inputs (pharmaceutical starch, porcine gelatin and one API) commonly used in the COMESA region over the last 10 years;
2. Determine the key drivers of pharmaceutical input and product trade in the COMESA region;
3. Determine the border and beyond the border constraints/barriers to pharmaceutical input and product trade in the COMESA region;
4. Evaluate the integrity and security of the regional supply chain of pharmaceutical input and products; and
5. Propose strategies/measures/policy reforms to enhance trade, integrity, and security of regional supply chains of pharmaceutical input and products in COMESA.

The objectives of the consultancy for Work Package 3 are to:

1. Review the policy, regulatory and institutional frameworks and thereby determine their role in facilitating trade in pharmaceutical products and intermediate goods (eg Active Pharmaceutical Ingredients, excipients and other raw materials);
2. Identify the challenges in policy, regulatory and institutional frameworks, and the need for harmonization at regional and continental levels; and
3. Propose recommendations on policy and regulatory formulation and/or reform options as well as institutional reforms or establishments that can support trade in pharmaceutical products, inputs, and intermediate goods.

**4.0 Scope of Work**

Work Package 1

i. Review the status of COMESA pharmaceutical industry including installed capacity and utilization, investment structure/ownership, number of manufacturers, importers, percentage of country pharmaceutical need met by local production and size of pharmaceutical market;

iii. Assess the COMESA pharmaceutical value chain, policies, regulatory, procurement and institutional frameworks;

iv. Identify opportunities and constraints (eg infrastructure, maintenance costs, regulatory compliance costs, research and development) in the value chain for local production and the availability of inputs (eg Active Pharmaceutical Ingredient (APIs); excipients and other raw materials) in COMESA;

v. Propose measures for addressing identified constraints and exploiting the opportunities

vi. Identify incentives and best practices to enhance investment, sustained supply, and local production;

Work Package 2

1. Guided by the ITC Trade Performance Index[[5]](#footnote-5), compute various indicators that describe the trade performance of Pharmaceutical inputs for three tracer medicines (antibiotics and analgesics listed on the WHO Essential Medicines List and commonly used in COMESA) and three pharmaceutical inputs (pharmaceutical starch, porcine gelatin and one API). Imports, intra-imports, exports and intra-exports should be flagged out in the analysis;
2. Identify and evaluate the key drivers of, and at the border and beyond the border constraints/barriers to pharmaceutical input and products trade in the COMESA region.
3. Give technical definitions and scope of “supply chain integrity and security” as they relate to pharmaceuticals supply chains and evaluate the integrity and security of pharmaceuticals supply chains in the COMESA region using three tracer antibiotics and painkillers included on the WHO List of Essential Medicines[[6]](#footnote-6) and three pharmaceutical inputs (pharmaceutical starch, porcine gelatin and one API).
4. Evaluate tariffs on imported raw materials and other inputs for pharmaceutical manufacturing based on the above-mentioned six tracer commodities commonly used in COMESA or Africa;
5. Conduct a mapping and analysis of customs systems and procedures, including use of the Harmonized System (HS) codes for the six tracer commodities and come up with recommendations on their optimization
6. Based on the findings of this study, propose strategies; initiatives, (including trade facilitation reforms); and other policy reforms to enhance pharmaceutical input and final products trade in the COMESA region.

Work Package 3

1. Assess the policy and regulatory framework of COMESA Member States in view of emerging issues such as globalization, technology advancement, pharmacovigilance, and prevalence of pandemics;
2. Assess the national pharmaceutical institutional frameworks and capacities (human and financial resources, infrastructure, and information management systems);
3. Identify the pharmaceutical policy orientation (import substitution or export promotion), regulatory and institutional challenges in COMESA;
4. Propose measures for addressing the challenges and strengthening the policy, regulatory and institutional frameworks as well as for harmonization at regional and continental levels to promote trade.

**5.0 Expected Deliverables**

For Work Packages 1 and 2 and 3, the key outputs will be the following,

1. **Inception Report** – This will provide details of how the assignment will be executed, including the interpretation, and understanding of the terms of reference, approach, methodology and a proposed workplan.
2. **Draft Study Reports** – This will be a technical report providing details on methodology implementation, preliminary findings contextualized within the literature, field work/ consultations and the key recommendations (12 weeks after the study is commissioned/contract signed).
3. **Validation workshop** – The Consulting Firm will present the draft report to stakeholders for validation. The comments received during the workshop will be incorporated in the final study report.
4. **Final Study Reports** – This will be a refined version of the draft report incorporating the comments from the COMESA Secretariat and other stakeholders.
5. **A Policy Brief** – this will be a high-level summary, presenting the key findings and actionable policy implications or recommendations of the study.
6. **Model Policy on pharmaceutical trade in COMESA**

**NB: All the work packages will contribute to the development of a Model Policy on pharmaceutical trade in COMESA. Each work package has its own set of reports.**

The work schedule for the assignment is broken down in the table below. The consulting firm is allowed to apportion the working days for each expert accordingly in line with the assignment needs. The assignment duration is 180 calendar days.

|  |  |  |  |
| --- | --- | --- | --- |
| **Item**  | **Estimate Duration** **- Working Days** | **Deadline - Calendar Weeks after contract commencement**  | **Comments**  |
| Inception Report  | 10 | 2 weeks  | Inception report to cover all three work packages. Consulting firm to allocate the working days accordingly to each expert. |
| Update meetings with COMESA |  06 | Bi-weekly | Ongoing throughout the assignment |
| Draft report on capacity constraints in the pharmaceutical manufacturing industry  | 25 | 10 weeks |  |
| Draft report on assessment of policy, regulatory and institutional frameworks governing trade in pharmaceutical products. | 25 | 12 weeks |  |
| Draft report on assessment of the pharmaceutical input and final products trade performance and supply chain integrity in the COMESA region.  | 40 | 14 weeks  |  |
| Draft model policy for pharmaceutical trade facilitation in the region. | 15 | 16 weeks |  |
| Preparation for a validation workshop for the three studies | 04 |  |  |
| Validation workshop      | 03 | 18 weeks |  |
|  |  |  |  |
| Stakeholder engagements for Work packages 1,2 and 3 (virtual and site visits) | 35 | 14 weeks | Ongoing throughout the assignment. Allocation of days is at the discretion of the Consulting Firm. |
| Short workshop report  | 02 | 19 weeks  |  |
| Final report on capacity constraints in the pharmaceutical manufacturing industry. | 03 | 21 weeks  |  |
| Final report on assessment of the pharmaceutical input and final products trade performance and supply chain integrity in the COMESA region.  | 04 | 22 weeks  |  |
| Final report on assessment of policy, regulatory and institutional frameworks governing trade in pharmaceutical products.  | 04  | 23 weeks |  |
| Final model policy for pharmaceutical trade facilitation in the region. | 04 | 24 weeks |  |
| **TOTAL WORKING DAYS (for all experts)** | **180** |  |  |

**6.** **Payment Schedule**

Payments will be paid according to the following milestones.

1. Inception Report (20%)
2. Draft report on capacity constraints in the pharmaceutical manufacturing industry (30%)
3. Draft report on assessment of the pharmaceutical input and final products trade performance and supply chain integrity in the COMESA region and draft report on assessment of policy, regulatory and institutional frameworks governing trade in pharmaceutical products (30%)
4. Final reports and model policy for pharmaceutical trade facilitation in the region (20%)

**7.0 Location, Duration, and travel arrangements**

The total number of days allocated for this assignment is one hundred and eighty (180) calendar days inclusive of travel days. The Consulting Firm is required to complete the assignment and submit the Final Report within this period. Travel to the COMESA Secretariat and 6 Member States

All travel arrangements for the assignment will be organized by the Consulting Firm in line with the ToRs to accomplish the deliverables of the assignment and these costs should be included as part of the total financial proposal Arrangements for the validation workshop will be made by COMESA and the associated expenses **should not be included** in the costing.

Below are the anticipated travels.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Anticipated Travels and Related Cost Items**  | **Travel****Yes/No**  | **# of Experts** | **Travel Frequency/# of countries**  | **# of days per travel**  | **Reason for Travel**  |
| Flights for 2 experts (Travel to COMESA Secretariat) | Yes  | 2 | 2 | 2 | Kick-off meetings and final meeting  |
| Stakeholder engagement meetings (2 Experts only)  | Yes | 2 | 6 | 2/mission | 2 days engaging stakeholders within one country  |

**15. Requirements and Qualifications of the Consulting Firm**

The Consulting firm/organization/entity must have professional experience in pharmaceutical manufacturing, regulatory sciences, pharmaceutical policy and trade at regional/continental level or similar experience outside Africa. The following minimum requirements are required:

* Company Profile (including any other material relevant to the services being requested), nature of business, field of expertise, licenses and certifications.
* Business licenses-registration papers, tax payment certification, etc.
* Demonstrated 20 years of combined experience in delivering similar and relevant assignments in the sector (list of projects’ details including the scope, location, and clients)
* Organizational Team of experts with competencies in the key areas of assignment such as pharmaceutical manufacturing, regulatory sciences, program design, business development, trade, policy formulation etc.
* The consulting firm presence (offices) in any Global Location and understanding of trade aspects in pharmaceutical manufacturing, challenges, and capacity gaps of pharmaceutical small and medium size enterprises in the region.

**8.0 Qualifications and Experience of Key Experts**

**Team Lead**

1. A Masters degree in Chemistry, Pharmacy, Chemical and Process Engineering; Biotechnology, Operations Management and Health Economics or related disciplines.
2. A minimum of fifteen (15) years’ experience in pharmaceutical industry value chain and manufacturing.
3. Experience in COMESA pharmaceutical sector will be an added advantage.
4. A good knowledge of the pharmaceutical manufacturing sector and the operating and policy environment.
5. Experience in organizing meetings and interacting with personnel at the Regional Economic Community (REC) level.
6. Good report writing skills and strong computer skills and experience in policy formulation and advocacy.
7. Strong interpersonal, facilitating and negotiating skills.
8. Fluency in both written and spoken English. Ability to communicate in French, Arabic or any of the local languages in COMESA member states will be an added advantage.

**Trade Expert**

1. A minimum of a Master’s degree in Economics, Health Economics, International Economics, International Trade, International Trade and Law, and Development Economics.
2. A minimum of ten (10) years’ experience in the areas of trade policy analysis, and regional integration research.
3. Demonstrated thorough knowledge and understanding of the COMESA regional integration agenda and pharmaceutical industry.
4. Proven experience and skills in conducting trade policy research and analysis, ***using both quantitative and qualitative analysis*** relating to trade flows.
5. Proven experience in formulating policy briefs and advocacy frameworks, particularly those related to regional integration or trade policy issues.
6. Strong interpersonal and communications skills.
7. Strong computer skills especially in Microsoft packages and applications; and
8. Fluency in both written and spoken English. Ability to communicate in French, Arabic, or any of the local languages in COMESA member states will be an added advantage.

**Policy Analyst**

1. A Masters degree in Pharmacy, Public Health, Business Administration, Marketing, Economics, Development Economics, Health Economics or related disciplines.
2. A minimum of ten (10) years’ experience in pharmaceutical policy, regulatory affairs, supply chain management, trade and economics.
3. Experience in the COMESA pharmaceutical sector will be an added advantage.
4. Knowledge of supply chains in Africa and experience in policy analysis and development of relevant strategic documents and business plans.
5. Good communication and interpersonal skills, strong report writing skills, and fluent in both written and spoken English. Ability to communicate in French and/or Arabic will be an added advantage.

**9.0 Reporting**

The consulting firm will report directly to the Project Coordinator under the overall guidance of the Director of the Industry and Agriculture Division, COMESA Secretariat. Deliverables will become payable when all tasks are completed and approved by the COMESA Secretariat.

**10. Selection Procedure**

 Eligibility criteria, establishment of the short-list and the selection procedure shall be in accordance with African Development Bank’s “Procurement Framework for Bank Group Funded Operations” dated 2015, which is available on the Bank’s website at: <https://www.afdb.org/en/projects-and-operations/procurement/new-procurement-policy>. The Consultant will be selected under the Quality and Cost Based Selection method.

1. Burundi, Comoros, Democratic Republic of Congo, Djibouti, Egypt, Eritrea, Eswatini, Ethiopia, Kenya, Libya, Madagascar, Malawi, Mauritius, Rwanda, Seychelles, Somalia, Sudan, Tunisia, Uganda, Zimbabwe, Zambia [↑](#footnote-ref-1)
2. https://www.comesa.int/wp-content/uploads/2020/09/Gaps-in-COVID-19-Related-Pharmaceutical-Goods-Services-in-COMESA.pdf [↑](#footnote-ref-2)
3. https://africacdc.org/news-item/africa-cdc-and-cepi-hosts-the-african-vaccine-manufacturing-supply-chain-forum-future-proofing-africas-vaccine-manufacturing-supply-chains/ [↑](#footnote-ref-3)
4. <https://iris.who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf?sequence=1> [↑](#footnote-ref-4)
5. https://tradecompetitivenessmap.intracen.org/Documents/TPI\_Notes.pdf [↑](#footnote-ref-5)
6. <https://iris.who.int/bitstream/handle/10665/371090/WHO-MHP-HPS-EML-2023.02-eng.pdf?sequence=1> [↑](#footnote-ref-6)