



TERMS OF REFERENCE (TOR) FOR A CONSULTANT TO CONDUCT A COMPREHENSIVE AUDIT OF THE STATE OF LOCAL PRODUCTION OF GENERIC MEDICINES FOR PEOPLE LIVING WITH HIV IN KENYA

- Work Description:** Consultant to conduct a comprehensive audit, carry out research and develop a report with recommendations on improving local production of generic medicines for people living with HIV in Kenya.
- Project Title:** The state of local production of generic medicines for people living with HIV in Kenya.
- Duration:** Two months
- Expected Start Date:** 1st March 2023
- Expected End Date:** 30th April 2023

Introduction

The Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN) is a human rights non-governmental organization working to promote and protect health-related human rights in Kenya. KELIN seeks to ensure that by 2024, vulnerable and marginalized communities in Kenya have access to available, accessible, acceptable, and quality health services, their health-related human rights are protected and social justice for health is promoted. This result is to be achieved through interventions aimed at promoting and strengthening rights-based, gender-transformative and enabling legal and policy environments; empowering communities and community structures to demand and promote social justice for health and holding the government accountable

to deliver on the right to health; as well as generating evidence to inform policies, practices, and programs.

Background

Access to safe and affordable medicines is critical to the enjoyment of the highest attainable standard of health as guaranteed in the Constitution of Kenya 2010. Access to medicines entails having safe medicines; continuously available and affordable at both public and private health facilities including medicine outlets. Indeed, antiretroviral medicines have greatly improved the lives of people living with HIV. However, access to these drugs is dependent on their affordability and quality. Local production fills in this gap and provides great benefits including creating a reliable supply of medicines, facilitating technology transfers, facilitating TRIPS flexibilities, and enhancing self-sufficiency.

In 2013, the East African Community developed the East African Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO Flexibilities and the Approximation of National Intellectual Property Legislation. One of the expected outcomes of the policy is to promote pharmaceutical manufacturing and innovation industries in the region. The 2nd East African Community Regional Pharmaceutical Manufacturing Plan of Action (2017-2027) was validated in August 2017 and is a roadmap toward an effective and efficient East African pharmaceutical industry with four high-level targets including: - 1) Reversing dependency on pharmaceutical imports from outside EAC from more than 70% to less than 50%; 2) Support the expansion of product portfolio of EAC firms to cater for more than 90% of disease conditions; 3) At least 50% of purchases by EAC national medicines procurement agencies are to be sourced from EAC pharmaceutical manufacturers; and 4) Support local industry in expanding their portfolio.

The African Union also created a roadmap which has three strategic pillars which include access to medicines, local production and regulatory harmonization where members are encouraged to incorporate TRIPs flexibilities and avoid TRIPs-plus measures in trade agreements. President Uhuru Kenyatta's administration (2017-2022) launched the Big 4 Agenda, a development blueprint of which two of its goals were universal health coverage and increased manufacturing capacity. In November 2022, the Kenyan government expressed its support for the establishment of the African Medicines Agency under the African Union. The government also undertook to lay down structures to support medicine manufacturing in Kenya and regulate the distribution process.

Purpose of Consultancy

The consultancy is constituted under the project titled *“Challenging Intellectual Property Barriers that Prevent Access to Treatment for Persons Living with HIV in Kenya.”*

The main purpose of the assignment is to conduct a status audit of the state of local production of generic medicines for people living with HIV in Kenya.

Specific Objectives

The specific objectives of this consultancy are to:

- i. Conduct a comprehensive audit (through both field and desk research) of the state of local production of generic medicines for people living with HIV in Kenya.
- ii. Develop a research report containing the current status, gaps, challenges and policy recommendations.

Scope of work and Main Tasks

The Consultant shall be required to:

- i. Participate in an inception meeting and prepare an inception report detailing the methodology to be employed and the work plan.
- ii. Finalise a jointly agreed work plan and map out timelines for activities.

- iii. Develop a template for the final report.
- iv. Conduct both desk and field research and develop a draft report.
- v. Participate in a report validation meeting.
- vi. Incorporate comments by KELIN and other stakeholders; and
- vii. Develop a final report highlighting findings.

Proposed Methodology

The proposed research will employ desktop research, a comparative analysis of findings through secondary data sources and to the extent necessary site visits and stakeholder consultation.

Deliverables

The Consultant will complete and submit a draft inception report in soft copy, a draft work plan therein. The Consultant will finalize the report considering comments/suggestions of KELIN. The key deliverables for the assessment are as follows:

- i. Inception report, prepared after an inception meeting, detailing the general understanding of the assignment, approach, work plan, budget and deliverables.
- ii. Final work plan with timelines as agreed on with KELIN.
- iii. Develop a results and resources framework for the plan period.
- iv. Conduct research.
- v. Develop a draft report highlighting findings; and
- vi. Finalize and submit the final report.

Time Frame

The assignment should be completed within 2 months of signing the Agreement. The consultant will be engaged for a period of 45 consultancy days in accordance with the work plan. 40 days shall be dedicated to the conduct of a status audit of the state of local production of generic medicines for people living with HIV in Kenya and the

development of the draft report and submission, validation, and review of the first draft. 5 days will include finalization of the process.

KELIN's Role

KELIN shall provide overall supervisory support for the assignment. The roles will be further defined at the inception meeting.

Qualifications of the consultant

- i. Post-graduate qualification in law, medicine, pharmacy, public health, technology and technology education, statistics, commerce, development studies or related discipline.
- ii. Knowledge of human rights and the legal context of HIV & AIDS is highly desirable.
- iii. Knowledge of the treatment and management of HIV and access to essential medicines is highly desirable.
- iv. Experience working in a research institution, conducting research, and leading or managing research programs or projects.
- v. Excellent and proven research experience in the development of similar literature.
- vi. Fluency in English.
- vii. Ability to produce high-quality output in a timely manner while understanding and anticipating the evolving client needs.
- viii. Strong organizational skills; and
- ix. Ability to work independently and produce high-quality output.

Application instructions:

Send a cover letter, a resume and a detailed proposal to conduct the assignment outlining the consultant's understanding of the task, proposed methodology, work plan and

budget before the application deadline of 24th February 2023 at 5.30 p.m. to info@kelinkenya.org and copy gaudencewere@kelinkenya.org.

While submitting your application be sure your email subject line is
CONSULTANCY TO CONDUCT A STATUS AUDIT OF THE STATE OF LOCAL
PRODUCTION OF GENERIC MEDICINES FOR PEOPLE LIVING WITH HIV IN
KENYA - (Your Name)