



## **TERMS OF REFERENCE**

# **CONSULTANCY TO CONDUCT RESEARCH ON EVERGREENING PRACTICES AT THE ARIPO LEVEL AND ITS IMPACT ON ACCESS TO ESSENTIAL MEDICINES IN KENYA**

### **Introduction**

The Kenya Legal and Ethical Issues Network on HIV and AIDS (KELIN) is a human rights non-governmental organisation 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 improved the lives of people living with HIV. However, access to

affordable antiretroviral medicines continues to be impacted negatively by intellectual property barriers, specifically patents which enable prohibitive costs of medicines. Pharmaceutical companies often apply for multiple patents in connection with pharmaceutical compounds based on strengths, salts used for the compound, manufacturing process, use, or the combination in which it was provided with other medicines, etc. The practice known as *evergreening* focuses on minor changes to or derivatives of existing products to indirectly extend the life of the original patent over an active ingredient. This keeps the medicine free from completion and enables high pricing. Regionally, the African Regional Intellectual Property Organisation (ARIPO) provides an avenue among member states for cooperation in intellectual property matters. As Kenya is a contracting party to the Harare Protocol on Patents and Industrial Designs, it is possible to register patents either nationally or through ARIPO. Regional registration provides multi-country protection of intellectual property rights.

### **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 research on evergreening practices at the ARIPO level and their impact on access to essential medicines in Kenya.

### **Specific Objectives**

The specific objectives of this consultancy are to:

- i. Research on evergreening practices at the ARIPO level and their impact on access to essential medicines in Kenya.
- ii. Develop a research report.

### **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 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 and a comparative analysis of findings through secondary data sources.

### **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 in line with the 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 comprehensive research.
- v. Develop a draft and final report highlighting findings; and
- vi. Finalize and submit the final report.

### **Time Frame**

The assignment should be completed within 1 month of signing the Agreement. The consultant will be engaged for a period of 20 consultancy days in accordance with the

work plan. 15 days shall be dedicated to the research on evergreening practices at the ARIPO level and their impact on access to essential medicines in Kenya, comparative analysis and development of the draft report and submission 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 medicine, pharmacy, public health, or related discipline.
- ii. Knowledge of human rights national, regional and international legal frameworks.
- iii. Knowledge of the treatment and management of HIV and access to essential medicines in Kenya, regionally and internationally.
- iv. Experience in pharmaceutical research and development within the line of value maximization and repurposing/reprofiling of pipelines and products including formulations, routes of delivery, chemical modifications (salts) and enantiomer switches.
- v. Excellent and proven research experience in the development of similar literature.
- vi. Ability to produce high-quality output in a timely manner while understanding and anticipating the evolving client needs.
- vii. Strong organizational skills; and
- viii. Ability to work independently and produce high-quality output.

### **Required skills and experience**

- i. Minimum of 7 years of relevant experience is required.
- ii. Language: Excellent written and spoken English.

**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 24<sup>th</sup> February 2023 at 5.30 p.m. to [info@kelinkenya.org](mailto:info@kelinkenya.org) and copy [gaudencewere@kelinkenya.org](mailto:gaudencewere@kelinkenya.org)

While submitting your application be sure your email subject line is  
CONSULTANCY TO CONDUCT RESEARCH ON EVERGREENING PRACTICES  
AT THE ARIPO LEVEL AND ITS IMPACT ON ACCESS TO ESSENTIAL  
MEDICINES IN KENYA - (Your Name)