

11<sup>th</sup> December 2017

To:  
The Cabinet Secretary,  
Ministry of Health, Afya House, Cathedral Road,  
P.O. Box 30016– 00100, Nairobi, Kenya.  
cs@health.go.ke

Dear Dr. Cleopa Mailu, EGH,

**RE: Overcoming Regulatory Barriers to Implement New TB and HIV Diagnostic Tools in Kenya**

We write to you as concerned technical partners, civil society and communities to urge you and the Kenyan government to fast track implementation of all World Health Organization (WHO) endorsed TB and HIV diagnostic tools in Kenya.

In Kenya, there is no publicly available policy detailing the registration requirements of new diagnostic tools from the KMLTTB<sup>1</sup>; the Kenyan board responsible for registering diagnostic tools. Relatedly, as technical partners, our efforts to facilitate rapid implementation of TB-LAM and GeneXpert Viral Load - (VL) for almost two years have been hindered by some board representatives citing a complex diagnostic registration policy which has not been availed to us. KMLTTB members stipulate that in-country validation studies<sup>2</sup> are required before diagnostic tools can be used in the country, even when the diagnostic tools are endorsed by the WHO. These validation studies are to determine test sensitivity and specificity data in Kenya. KMLTTB members also say that they would require the companies producing diagnostic tools to conduct in-country validation studies as well as the Government to independently conduct its own in-country validation and operational research (OR), resulting in the body of evidence needed to decide on diagnostic product registration. We would emphatically advise against the need for in-country validation studies for WHO endorsed diagnostic tools that have already been studied in similar environments or in-country already and by several independent partners, as these repeat studies are capital and resource intensive. Repeat validation studies of tests endorsed by the WHO are unnecessary and delay the implementation of new diagnostic tools critical to the rapid diagnosis of patients. While the KMLTTB continues to enforce unwarranted barriers to implementing new, validated, and WHO-endorsed diagnostic tools, patient care is delayed resulting in unnecessary deaths and suffering

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<sup>1</sup> Kenya Medical Laboratory Technicians & Technologists Board

<sup>2</sup> Validation studies involve testing the sensitivity and specificity of a diagnostic test which do not change irrespective of the disease burden or setting

The National TB program under the current leadership has taken a bold decision to implement TB LAM, which is laudable because about 683 deaths per year will be averted in Kenya through use of the TB LAM test<sup>3</sup>. However, we fear that the current registration process for diagnostic tests will hinder the efforts of the National TB and HIV programs as well as other national health programs.

We urge you;

1. to simplify and rapidly publicly avail the diagnostic registration policy.
2. to provide expedited registration for GXP VL and TB LAM.
3. to provide us with a memo on the registration process of new diagnostic tools by early January 2018, in the interim of policy development around the same issue. In the absence of in country operational research, we recommend the memo make provision of conducting in-country OR studies after the accelerated approval of these diagnostic tests. We are willing to provide further input into the development of a simple, robust and patient centric diagnostic registration policy.

Before 22<sup>nd</sup> December 2017, we look forward to a response detailing how the KMLTTB will facilitate pre-approval access to essential rapid diagnostic tools, including whether a memo will be issued on registration of diagnostic policies, and address our concerns regarding the existing policy for registering new diagnostic tools in Kenya. To further discuss any of the points raised in this correspondence in the meantime, please direct your response to Khairunisa Suleiman ([Khairunisa.suleiman@gmail.com](mailto:Khairunisa.suleiman@gmail.com), +254 727 289 223).

Respectfully submitted:

Stop TB Partnership Kenya

KELIN

Kenya Medical Association (KMA)

Global TB Community Advisory Board (TB CAB)

Treatment Action Group (TAG)

NEPHAK

KANCO

CC:

Julius Korir, Permanent Secretary of Ministry of Health

Dr. Maureen Kamene, Head of National Tuberculosis, Leprosy and Lung Disease Program

Jeremiah Ogoro, NTLD-P Xpert Implementation Coordinator

Abel Onyango, Chairman of Kenya Medical Laboratory Technicians & Technologists Board

Mamo Umuro, Head of National Public Health Laboratory

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<sup>3</sup> Assuming that there is 60% ART coverage, 113 753 people with advanced HIV and 15% (17 063) of them with presumptive TB