



Your Ref: TBA

Our Ref: C/KELIN/18

Date: 19th December 2018

To:

Kenya Medical Supplies Agency (KEMSA),
Pharmacy and Poisons Board (PPB)
National Tuberculosis, Leprosy and Lung Disease Programme, (NTLD-P)
National AIDS & STI Control Programme,
Kenya Bureau of Standards (KEBS)

Cc: Office of The President
Cc: Chairperson Council of Governors
Cc: The 47 Governors
Cc: Cabinet Secretary Ministry of Health
Cc: Cabinet Secretary Industry Trade and Cooperatives
Cc: Cabinet Secretary National Treasury and Planning
Cc: WHO Country Office

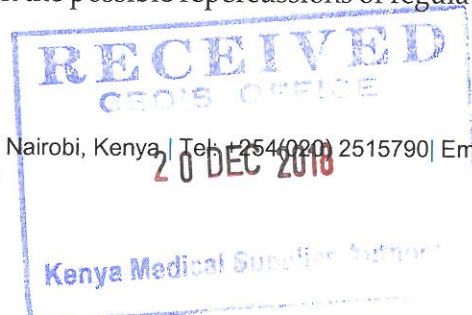
RE: Open Letter on Arresting the National GeneXpert cartridge Stock out in Kenya

We are writing to you as civil society members, TB survivors, those affected by TB and implementing partners.

We are gravely concerned about the prolonged national GeneXpert cartridge stock out in a number of facilities in Kenya; a situation that is both detrimental to the health of those with active TB but remain undiagnosed, which leads to increased TB related mortalities. The lack of TB testing using GeneXpert contributes to increased sickness and suffering, thereby worsening treatment outcomes, if patients eventually get diagnosed.

GeneXpert was recommended for national use for TB diagnosis due to its timely generation of results, which allows quicker initiation of patients onto TB treatment. Additionally, GeneXpert is a more sensitive than microscopy, hence the test diagnoses more people with TB than microscopy. TB diagnosis has now reverted to microscopy, a retrogressive step in the TB response in Kenya.

It is disturbing that the Government has introduced a regulatory requirement (pre-export verification of conformity-PVoC) of inspecting the manufacturing sites for WHO endorsed diagnostic tools; an unnecessary and costly step, which has partly led to the cartridge stock out, thereby creating a barrier to ensuring a steady supply of TB commodities. We demand to understand the delay in KEMSA issuing a certificate of inspection to Cepheid (the manufacturer of GeneXpert), months after inspection. We had foreseen the possible repercussions of regulatory



barriers to implementing diagnostic tools in Kenya and had written [an open letter](#)¹ to the Cabinet Secretary of Health last year, warning about regulatory barriers to implementing TB diagnostic tools in Kenya, which was neither acknowledged nor acted upon. Regulatory barriers such as the PVoC, hinder the steady supply of health commodities and must be removed in order to arrest national stock outs.

The President attended the UN High-level Meeting on TB in September 2018, where he stated; “I commit to provide the necessary support and resources to ensure that TB diminishes as a public health threat in Kenya by 2035 as currently envisioned by the global end TB targets”. This vision involves closing the testing and treatment gaps of those with TB. In light of this prolonged and unnecessary stock out of GeneXpert cartridges, we fear that the country will lose the gains made in the TB response and go against the presidential commitment to ending TB in Kenya by 2035. The lack of TB testing using GeneXpert further violates the constitutional commitment the National and County governments have made to the people to ensure they enjoy the highest attainable standard of health at Article 43(1) a of the Constitution of Kenya 2010.

We have checked several health facilities in various parts of the country and verified that there are no GeneXpert cartridges; therefore, the national stock out still persists in certain counties, even though anecdotal reports indicate the cartridges have arrived in Kenya. Delays in the distribution of GeneXpert cartridges are unacceptable. The absence of the cartridges means more than 40% of people with TB will remain undiagnosed in Kenya.

We are in a compounded emergency TB situation in Kenya and we request a response on or before 14th January 2019 and a joint meeting with KEMSA, PPB, NTLD-P, NASCOP and KEBS on or before 21st January 2018 to discuss the update, next steps and mitigation strategies to avoid future national stock outs of health commodities. Kindly direct your responses to undersigned at info@kelinkkenya.org



Allan Maleche

Signed on behalf of the following organisations and individuals

1. Wote Youth Development Projects
2. Pamoja TB group
3. Talaku TB
4. Stop TB Partnership Kenya
5. Global Coalition of TB Activists TA
6. Treatment Action Group
7. TB CAB
8. KELIN
9. Joyce Matogo
10. Khairunisa Suleiman

1

http://www.tbonline.info/media/uploads/documents/overcoming_barriers_to_implementing_new_tb_diagnostic_tools_in_kenya.pdf

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