

November 4, 2019

RE: OPEN LETTER: Time to Lower the Price of Xpert Cartridges to US\$ 5

Response via email by Warren C. Kocmond, President of Cepheid

Dear Mr. Branigan,

Thank you for your positive words regarding the impact of Cepheid's GeneXpert® System and Xpert® MTB/RIF on the management of tuberculosis (TB) in LMICs. We appreciate feedback from stakeholders in the global health community and continue to be committed to the global fight against TB.

We understand the responsibility that comes with having a platform and test menu so uniquely positioned to help clinicians deliver healthcare to people in need around the world. Our research pipeline reflects our ongoing investment in delivering tests that help fulfill that responsibility. To this end:

- Cepheid recently improved TB test performance with Xpert MTB/RIF Ultra;
- Cepheid expects to release a new cartridge for multi-drug-resistant tuberculosis in 2020 (Xpert MTB XDR); and
- Cepheid continues to make R&D investments related to HIV/AIDS, hepatitis, human papillomavirus and sexually-transmitted infections.

You may be aware that our Xpert Ebola test is central to the response to the outbreak in the Democratic Republic of the Congo. We were able to respond with no delay when the crisis started and continuously supply our tests and systems even in the face of uncertain forecasts for the consumption of our product.

Cepheid understands and shares your desire for even more affordable TB cartridges. The 2012 buy-down agreement referenced in your letter resulted in a 41% reduction to the price negotiated during the subsidized development of the TB cartridge with FIND. However, most of the other compassionately priced products on our HBDC list received little, if any, financial support during their lengthy development phases. In addition, Cepheid supports all costs associated with getting products onto the list of pre-qualified IVD products by the WHO as well as the substantial costs to support these products around the world. Please be assured that if the pricing you are requesting for TB cartridges were possible and sustainable, we would implement it.

Cepheid has been implementing an exceptional set of business tools and processes that are enabling significant, continuous improvements across the company. These efficiencies allowed us to invest in LMIC business, expand our menu of offerings and continue to support and provide a maintenance network for our customers. As we continue on this journey, we hope to find breakthroughs that can enable even more affordable pricing in the future but, we are not able to predict the amount of further reductions or when they may be available.

I would like to take this opportunity to note some unintended challenges faced by national programs in countries where The Global Fund against AIDS, TB and Malaria has started the

transition process to domestic funding. When countries are required to issue domestic tenders, those tenders often incur a set of obligations that actually increase the price of our tests. Domestic funding has created a much less favorable situation than the prior use of global procurement agencies. For example, products that used to receive a tax and duty waiver are now subject to those costs, artificially increasing the price. I encourage the groups and individual signatories of your letter and beyond to advocate for a return to the previous situation. It is interesting to note that in most countries tax and duties on HIV products are waived, but not on other also critical products for global health, an anomaly in the context of Universal Health Coverage (UHC) and the development by WHO of the Essential Diagnostics List (EDL).

Regarding the private sector, we are aware that often more than 50% of patients present to the private sector and may not be correctly diagnosed or treated. Cepheid, working with the Clinton Health Access Initiative and others, implemented IPAQT in India and collaborated closely with projects in Pakistan, the Philippines, and Indonesia. In LMICs we are open to offering public sector pricing to the private sector if the cost savings are passed to the patient and results are reported to the national program. Since Cepheid cannot impose patient pricing or reporting on the private sector, the involvement of a non-profit or governmental organization (e.g. what CHAI has done in India) is essential. We note with interest the signatories to your letter and invite them to contact Cepheid's Global Access team if they are able to facilitate private sector engagement. I also invite you to contact me directly for an open discussion of the issues your groups are seeing first-hand.

Thank you once again for contacting me and sharing the concerns of the civil society groups working to eliminate TB. We value your passion and share your commitment. Cepheid remains dedicated to the development and supply of diagnostic tools that global health leaders need to enable better health outcomes, at a cost that ensures access for all stakeholders and continued sustainability of our programs to reach communities in need.

Best Regards,

Warren Kocmond