

6 January 2014

Mr. John L. Bishop
Chief Executive Officer
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089 USA

OPEN LETTER Re: Cartridge prices, extended warranties and business in Russia and the People's Republic of China

Dear Mr. Bishop,

GeneXpert MTB/RIF has contributed to advances in the diagnosis of tuberculosis (TB) and drug-resistant-TB (DR-TB) around the world. We recognize the use of Xpert MTB/RIF as a critical diagnostic tool in the fight against TB. In various settings, such as South Africa, GeneXpert MTB/RIF has contributed to an increase in multidrug-resistant tuberculosis (MDR-TB) diagnosis,ⁱ increasing the chance of appropriately treating and curing more people.

Civil society is at the forefront of advocating for the use of new tools such as GeneXpert MTB/RIF as an integral diagnostic tool in national programs. Yet we also have several concerns for your attention, including 1) high cartridge and instrument concessional pricing; 2) costs associated with warranty; 3) high pricing in the public sector in Russia; and 4) the costs of the GeneXpert modules and cartridges, lack of registration of the Xpert MTB/RIF cartridges, and greater efforts to broaden access to Xpert MTB/RIF particularly in all CDC, TB Control and Prevention Centers and infectious diseases hospitals in China.

In August 2012, the TB community welcomed the negotiated “buy down” of cartridge prices to US \$9.98. This has led to over 4.2 million cartridges,ⁱⁱ with more than 2 million cartridges sold in South Africa alone, procured under concessional pricing. At the Supply Chain Stakeholder meeting on Xpert in Paris, France on October 28, 2013, you projected that Cepheid will produce about 7–8 million cartridges in 2014. In November 2013, the WHO recommended that GeneXpert MTB/RIF should be utilized as the initial diagnostic test in adults presumed of having TB.ⁱⁱⁱ We are confident that this will generate increased sales of GeneXpert MTB/RIF for Cepheid. The negotiated cartridge “buy down,” as outlined in the UNITAID Resolution,^{iv} does not preclude further price decreases of the cartridges.

More than a year after the initial but insufficient price reduction, and with sales increasing exponentially, **we urge you to decrease the price of cartridges below US \$9.98 based on volume-related thresholds.**

As instrument sales have similarly risen, with over 1,800 instruments purchased under concessional pricing, we urge you to lower the price of GeneXpert instruments as well.^v Following up on previous communication in April 2012,^{vi} we remain disappointed that the price of GeneXpert instruments has not been reduced as requested from the high price of US \$17,000 and \$17,500.^{vii}

Data presented by the National Health Laboratory Services in South Africa in March 2013 show module failure rates of 7.94% within two years. According to these data, 6.62% of modules failed within 1 year of operation and the median time to failure was 219 days.^{viii} For high burden disease countries (HBDC), Cepheid recently proposed an extended three-year warranty for an additional price of US \$6,800-7,900 for the GX IV 4 and US \$18,500-20,950 for the GX XVI 16^{ix}. Though the Foundation for Innovative New Diagnostics' (FIND) website indicates that "the new warranty options have been negotiated by a number of implementers and donors at several stakeholder meetings,"^x this is not correct. We spoke to donors who were key to the buy-down for cartridge prices and they were unaware of any consultations and civil society was certainly not included. Cepheid is using the extended warranties as a way to lock in buyers for the next few years, knowing that new technologies and potential fast followers are only 3-5 years away. **We find it unacceptable that Cepheid should profit from extended warranties in high burden countries due to high module failure rates and for a technology partly developed by public funds. Cepheid must remove any additional warranty costs.**

Of serious concern are the reports we have heard about Cepheid in Russia. Cepheid provides data to the WHO on the number of cartridges and modules sold globally each quarter. In the last quarter there was a discrepancy in the figures from Russia. Cepheid indicated that Russia has 15 GeneXpert machines and procured 12,000 cartridges. In a presentation given by Marina Shulgina at the *Health systems in transition: TB control in the countries of the former Soviet Union* (FSU) session at the International Lung Union Conference, Russia indicated they had 67 machines. **Can you please clarify this discrepancy and confirm whether this means that 50 machines were purchased by the private sector at full price?**

We have also discovered that TB dispensaries in the Russian public sector are paying US \$60 per cartridge instead of the negotiated buy-down price of US \$9.98 per cartridge. We also understand that TB dispensaries have the added challenge of paying Cepheid up front for 100% of the costs. As they cannot pay in US dollars they are forced to procure through your chosen third party entities such as SAGE.

Why are cartridges, which should cost US \$9.98, being sold to TB dispensaries for US \$60 each? After researching the public procurement of GeneXpert cartridges in Russia, we discovered that a pack of 10 cartridges can cost around US \$600 or more. There are several suppliers, including SAGE, which cite similar prices.

We are concerned that machines and cartridges purchased for public institutions, but outside of the existing public procurement mechanism, are now subject to extortionate prices. **We call on you to ensure that all public institutions go through the public procurement mechanism to ensure access to the negotiated buy-down price.**

With regard to Xpert MTB/RIF in China, there are two issues we would like to get clarification on from you. The first is the price of modules. Your sales agent in China, Yimei SCI indicates that GeneXpert IV costs RMB1,100,000 (US \$180,623.97) and GeneXpert II costs RMB700,000 (US \$114,942.53) and that the cartridges are being sold for RMB300 (US \$49.26). We would like to know why the modules are at such exorbitantly high costs when the FIND negotiated instrument price is US \$17,000 for the GeneXpert IV-module with desktop and US \$17,500 for the GeneXpert IV-module with laptop and China is one of the countries eligible for concessional pricing for modules. **Like for Russia, we would also like to know why cartridges are almost five times the concessional price?**

The second issue is registration, we understand that the GeneXpert I, GeneXpert IV, GeneXpert XVI were all registered in 2011 at the Chinese Food and Drug Administration but to date the Xpert MTB/RIF cartridges have not been registered. We would like to know your projected timeframe and plans for registration of the cartridges in China?

We respectfully request that you:

1. further decrease the price of cartridges given the large volume already purchased and increased procurement projections for 2014 and beyond, particularly in light of the new WHO policy update;
2. decrease the price of GeneXpert instruments from US\$17,000-17,500 for high burden countries;
3. provide extended warranties free of charge due to the impact your proposed price increases will have on national TB and HIV programs;
4. clarify the differential pricing for cartridges in Russia and outline your plans to rectify the situation to ensure that the Russian public sector can access the negotiated buy-down price of US \$9.98 per cartridge;
5. clarify the differential pricing for modules and cartridges in China; and
6. provide us with details on your plans to register Xpert MTB/RIF cartridges in China.

We look forward to receiving your response to this letter, in addition we would like to schedule a teleconference with you at your earliest convenience to discuss these matters in more detail. We are positive that you will consider our requests in our united endeavor to ensure zero TB deaths, infections and suffering in our lifetime.

Please contact Colleen Daniels at colleen.daniels@treatmentactiongroup.org if you have any questions and to schedule the teleconference.

Best regards,

Global Tuberculosis Community Advisory Board (TB CAB)
Treatment Action Group (TAG)

cc:

The Hon. Li Bin, Minister of National Health and Family Planning Commission,
People's Republic of China

Denis Broun, UNITAID

Catharina Boehme, FIND

Margaret Chan, WHO

Lucica Ditiu, Stop TB Partnership

Philippe Douste-Blazy, Board Chair, UNITAID

Deborah von Zinkernagel, PEPFAR

Mark Dybul, Global Fund

The Hon. Aaron Motsoaledi, Minister of Health, South Africa

Mario Raviglione, WHO, Geneva

Rajiv Shah, USAID

Nelson Otwama, UNITAID Board

The Hon. Veronika Skvortsova, MoH Russia

Tido von Schoen-Angerer UNITAID Board

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- ⁱ Stevens, W. GeneXpert Implementation in South Africa Public Sector: One year later: Lessons Learnt. National Health Laboratory Service South Africa. Presentation at the 4th WHO/GLI meeting, April 2012. (Accessed November 29, 2013) [http://www.stoptb.org/wg/gli/assets/html/day%203/Stevens%20-](http://www.stoptb.org/wg/gli/assets/html/day%203/Stevens%20)
- ⁱⁱ World Health Organization. WHO monitoring of Xpert MTB/RIF roll-out. Accessed November 29, 2013 <http://who.int/tb/laboratory/mtbrifrollout/en/>
- ⁱⁱⁱ World Health Organization. Automated real -time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF system for the diagnosis of pulmonary and extrapulmonary TB in adults and children. November 2013. Accessed November 29, 2013 <http://www.stoptb.org/wg/gli/assets/documents/WHO%20Policy%20Statement%20on%20Xpert%20MTB-RIF%202013%20pre%20publication%2022102013.pdf>
- ^{iv} UNITAID. Draft Resolution Number 5: Scaling up access to contemporary diagnostics for tuberculosis (TB) with a focus on HIV-associated TB, drug resistant TB and early TB case detection: A 'technology push/demand pull' approach based on economies of scale and innovative interventions. June 2012 (Accessed November 29, 2013) http://www.unitaid.eu/images/EB16/R05_proposal-WHO-Cepheid.pdf
- ^v World Health Organization. WHO monitoring of Xpert MTB/RIF roll-out. Accessed November 29, 2013 <http://who.int/tb/laboratory/mtbrifrollout/en/>
- ^{vi} Global TB Community Advisory Board. Open Letter to Cepheid on Pricing of GeneXpert <http://www.treatmentactiongroup.org/tb/publications/2012/open-letter-cepheid-pricing-genexpert>
- ^{vii} Stevens, W. National Health Laboratory Services South Africa Presentation at the Advanced Tuberculosis Diagnostics Course, McGill University. July 2013.
- ^{viii} World Health Organization. WHO monitoring of Xpert MTB/RIF roll-out. Accessed November 29, 2013 <http://who.int/tb/laboratory/mtbrifrollout/en/>
- ^{ix} Cepheid, GeneXpert Procurement Stakeholder Meeting, slides 12 and 14. Presentation at 2013 October 28, Institut Pasteur Paris.
- ^x FIND. Negotiated prices for Xpert® MTB/RIF and FIND country list. October 2013 Update. Accessed December 12, 2013 http://www.finddiagnostics.org/about/what_we_do/successes/find-negotiated-prices/xpert_mtb_rif.html