

**Secretary-General's meeting with pharmaceutical and diagnostic companies  
working on HIV, United Nations, New York, October 9th, 2008**

**'Current gaps in scaling up access to diagnostics and treatment'  
Interlocutor for the UN, Dr. Catherine Hankins, Scientific Adviser to UNAIDS**

Dr. Peter Piot of UNAIDS, Ms. Anne Veneman of UNICEF, CEOs and other representatives of the pharmaceutical and diagnostics companies, fellow UN colleagues and others, I will be brief, as it is important that everyone be given a chance to intervene on the current gaps in scaling up access to diagnostics and treatment and on proposed actions to address the gaps. It is not possible to address all the gaps so I will highlight a few that I hope will help set the stage for stimulating and constructive discussions on the way forward.

First and foremost, it is critical that we all stay focused on our mutual objectives of increasing access to treatment and care beyond the 3 million people currently on antiretroviral treatment in low- and middle-income countries. A key piece of the work towards Universal Access by 2010 and Millennium Development Goal 6 to halt and reverse the HIV epidemic by 2015 is continued strong investment in research and development of first- and second-line antiretroviral medicines and combinations of these, as well as in diagnostic technologies that are appropriate to resource-limited settings. We are living in times of immense financial turmoil but we all must stay focused on these goals, confronting rather than condoning the status quo.

I will highlight four broad gap areas for discussion. They are the need for renewed efforts in biomedical prevention, the very real gaps in paediatric HIV diagnosis and treatment, the need for concerted efforts on second-line therapy, and the importance of intensifying work on diagnostics and monitoring.

After compelling evidence in 2005 and 2006 from three randomised controlled trials conducted in South Africa, Kenya and Uganda showing a 60% reduction in HIV acquisition among heterosexual men who became circumcised, biomedical prevention has sailed on troubled waters. Studies of the most promising HIV vaccine candidate Merck's Adenovirus 5 trivalent gag/pol/nef vaccine were halted in September 2007 due to lack of a trend towards protection. Several early-generation microbicides either have shown no protective effect or were stopped for safety concerns. A trial of the female diaphragm and trials of acyclovir treatment for herpes simplex virus type 2 failed to demonstrate an added benefit in protecting against HIV acquisition. Hope is being held out for positive results in the current trials of both oral pre-exposure prophylaxis and topical pre-exposure prophylaxis with antiretroviral-containing microbicides. With five people being infected for every two that go on treatment it is clear that we are mortgaging the future and we need to invest now for a long term solution to the epidemic – an effective HIV vaccine.

Second, we need to focus on infants and children – they have tended to be left behind as we worked for solutions to keep their parents alive. The new WHO recommendations for initiation of antiretroviral treatment in infants as soon as infection can be confirmed call out for improved technologies for infant diagnosis – and not just for the reference laboratory in the capital city. We need further

development of viral load techniques that can be used at point of care on dried blood spot specimens that are collected so easily from infants. We need further development of technologies appropriate to resource-constrained settings for CD4 count and CD4 percentage determination in children. And we need to ensure that a full range of infant treatment products are in development, with specific attention to formulations that are heat-stable and kid-friendly, including with simplified dosing schedules and easy dosing forms, such as granules, films, and sprinkles. With the number of children living with HIV in 2007 having reached 2 million, we are talking about leaving many kids behind if we do not up the ante now on paediatric HIV diagnosis and treatment.

Third, concerted efforts are needed now on second-line therapy. A surprisingly low 3% of all people on treatment in low- and middle-income countries are on second line therapy. As the epidemic evolves and treatment programmes mature, we can expect the demand for second-line treatment to rise. In 2007 the median price paid for first-line regimens continued to decline in both low- and middle-income countries, as it did for the majority of second line medications recommended by WHO. However, second-line regimens are still eight to thirteen times more expensive than first line treatment in both low- and middle-income countries. But not just price reductions are needed. We need more widespread registration of second-line drugs in low- and middle-income countries and we need companies to work together to co-formulate heat stable once daily fixed dose combinations of boosted protease inhibitors.

Finally, we will never increase demand and lower prices without greater efforts on diagnostics. This means intensifying the work on diagnostics and monitoring for HIV and for tuberculosis in people living with HIV. Simplified CD4 count and viral load techniques for management of treatment failure are needed if we are to avoid both increasing prevalence of drug resistance at the population level and premature death at the individual level. The bar is high. These have to be techniques that are appropriate to rural and remote settings – HIV is there and increasingly HIV treatment is there too. Dried blood spot technologies for point-of-care application are what we should be aiming for. And not so far down the line, we need to be thinking beyond treatment failure and toxicity monitoring to point-of-care drug level testing, particularly for women.

Women have not been enrolled in treatment clinical trials in sufficient numbers to draw adequate conclusions about sex differences and their clinical implications. On the one hand, we have to make sure that new clinical trials strive for adequate power to draw statistically significant conclusions about women and on the other hand, we need to work on techniques for monitoring drug levels at point of care for already licensed drugs for which we have little or no information about sex differences.

Beyond the gaps in biomedical prevention, paediatric diagnosis, second-line regimens, and diagnostics, there are many gaps that I have not addressed, but all is not gloom and doom. We are standing on firm ground – and I predict that our discussions will be lively as we see how we can collaborate more closely to move this agenda forward.

Thank you for your attention.