SPEECH 10

BY: Michel Sidibé, Executive Director of UNAIDS
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Beautiful Music: Bringing Africa's Drug Regulations in Harmony with Human Health

Good morning

This is an exciting time to be with you—experts in health, science and technology and pharmaceutical regulation—as you strive to bring the commitments of the African Union leaders in harmony with the aspirations of African peoples. Today we are seeing a resurgence of political will in Africa to push farther, faster, against the spread of preventable diseases, including HIV/AIDS.

I want to begin by offering heartfelt thanks to Dr. Ibrahim Assane Mayaki, Chief Executive Officer of NEPAD, for convening this path-breaking Meeting on Pharmaceutical Innovation in Africa.

Harmony is the theme for these next days. I am convinced that at the end of this meeting you will have identified practical steps to provide better access to affordable quality medicines in Africa, with a view to establishing a single African Drug Agency to regulate the pharmaceutical sector on this Continent. This is the music we will be making together.

I am pleased to note the participation of the Regional Economic Committees in this effort. I urge them to continue their great work in building consensus and coordinating Member States of the African Union on various aspects of harmonization of drug regulatory processes. I see a major role for them as we move stepwise from national to regional to Continental action.

By bringing elements of a strong cross-Continent drug industry in accord, we as Africans become the authors of our own economic and health care transformation. An African pharmaceutical industry could reflect our pan-African vision for development: meeting the needs of Africans; putting Africans in control of their destiny.

Harmonization for Human Rights

Dear friends, I have been to all of the front lines of the AIDS response, and have a clear vision of how the future can look.

I envisage a world where Africans do not suffer stigma and discrimination, or even worse, criminalization, because of their sero-status, sexual orientation, religion or gender.

I envisage a world where Africans can realise their right to health by actively preventing diseases that are clearly avoidable.

I envisage a world where Africans have access to affordable, quality-controlled, essential drugs for the acute and chronic diseases that affect them, including the antiretrovirals (ARVs) that provide health and longer lives to people living with HIV.

Such a world is within our grasp, but only if we acknowledge the bottlenecks and find innovative ways to address them. We know that amazing progress is possible, because we have done it within the AIDS response.

Today, over 4 million people in low- and middle-income countries are receiving life-saving treatment for HIV—10 times more than just five years ago.[1] Impressive, yes, yet another estimated 10 million people would benefit from the drugs under the World Health Organization's newest guidelines on when treatment should be started.[2]

Then there is the matter of those who, over time, can no longer rely on the efficacy of first-line treatment for HIV and have to switch to more powerful and expensive second-line treatment. First-line treatment costs can be procured for less than $100 per patient per year—but second-line treatment can cost four to ten times more. In Africa, less than 4% of patients are on second-line therapy, which is likely far below the number in need.[3] We should also anticipate the need for second-line pediatric formulations.

As we welcome WHO's new treatment recommendations, we now need to find the most cost-effective way to roll them out. With millions of HIV-positive people at risk of untimely deaths, access to treatment has once again become a development issue and—if not handled appropriately—may lead to a breakdown of the social fabric, with more children becoming heads of households and more institutions depleted of their workforce in the highest-burden countries.

Creating Fertile Conditions for an Industry Made in Africa, Owned by Africans

Looking at it another way though, assuring treatment for all who need it presents a huge potential win for Africa.

The AIDS response has already transformed the global health agenda by triggering fundamental shifts in our thinking. A shift in realising the right to health—through sustained advocacy for universal access. A shift in approaches to sustainability and country ownership.

The AIDS response has provoked unprecedented price reductions in first-line treatment as well as innovation within the pharmaceutical industry—such as encouraging companies to produce fixed-dose combinations and conducting innovative clinical trials. Above all, the AIDS response has successfully engaged an array of partners to respond innovatively to a public health crisis and deliver results for people.

Local production of high-quality pharmaceuticals must be within our sights. But it requires a strong regulatory environment that can attract private sector investments for the manufacture of medicines within Africa. Domestic production could flourish, just as we have seen in Asia and Latin America.

I recognize the good efforts already underway in several African countries to do this. An African Drug Agency would support them by enforcing the same regulations for all African countries—giving all a level playing field with the possibility to compete and market their products across the whole of Africa and beyond.

I commend the African leaders who have acknowledged the urgent need to improve access to affordable, quality, safe, efficacious, essential medicines across the Continent. The 2005 Gaborone Declaration calls on member states of the African Union to pursue local

production of generic medicines, making full use of the flexibilities as outlined in the Doha Declaration on TRIPS Agreement and Public Health and other WTO Decisions.

I also congratulate the African Union for developing and adopting the Pharmaceutical Manufacturing Plan for Africa in 2007—a step that should prove to be extremely helpful in this dialogue on the best approaches to the production of medicines in the Continent.

Another step is the coordinating framework set out in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Rights. It was signed in 2008 by 192 countries, including member states of the African Union. I commend my friends Drs. Chan, Sambo and Gezairy for the leadership they are exercising to ensure that stated aspirations are realized in Africa.

Five Strategies for Moving Forward

Recognizing the excellent work undertaken by the African Union and NEPAD and the different Regional Economic Committees, including EAC, SADC and ECOWAS, I would like to propose that you consider five general strategies during this meeting—strategies which build on the AIDS response and address challenges laid bare by the AIDS response.

I believe that the Global Strategy and Plan of Action I just mentioned can serve as a framework for bringing these strategies to fruition.

First, and in supporting the United Nations Secretary-General Ban Ki-moon's call for greater innovation and development of HIV drugs,[4] there is need for aggressive movement towards one harmonized drug regulatory system—a single African Drug Agency to regulate the pharmaceutical sector on this Continent. This will be achieved through cross-country networking and by pooling resources available across national drug regulatory authorities and institutions. Partnering with organizations such as European Medicines Agency, the WHO Prequalification of Medicines Programme will not only reduce the burden on individual countries, but also cut the time needed for the registration of life-saving drugs.

Second, ensuring quality assurance and drug safety—in all their dimensions—is critical. We cannot allow substandard practices that always result in poor quality, fake or toxic drugs. This damages the health of Africans and the credibility of Africa's drug regulators and the private sector and deters investment.

I call on partners to expand their support for health systems strengthening to include capacity building of regulatory bodies. In this context, I would like to recognize the excellent work of the Chirac Foundation for Sustainable Development and Cultural Dialogue in combating fake and substandard drugs—for example, their support for the Benin quality-control laboratory for medicines.

Third, there is need to maximize efficiencies within national drug supply and procurement systems. In parallel, there is a need to strengthen WHO Prequalification of locally produced drugs so that national buyers can use domestic and external funds for their procurement—with a guarantee of quality for patients. Another is to eliminate the need for expensive ad-hoc procurements in the case of stock-outs. In the medium-term, full use of flexibilities inherent in the TRIPs Agreement, as well as the HIV Patent Pool, once functioning, could generate even more efficiencies for both producers and buyers.

Fourth, we must aggressively pursue state-of-the-art drug production in Africa and expand the number of local producers of quality medicines. We must establish and enforce international Good Manufacturing Practices while building economic viability, including generating robust regional markets and financing sustained demand through health insurance.

This will require strong political commitment and leadership, and I call on the African Union to step up and urge its member states to establish regulatory and financial environments that are conducive to the long-term engagement of investors.

Fifth, we must invest in knowledge and technology transfer for pharmaceutical innovation and R&D in Africa. The point at which ARV treatment progressed from 10 pills a day to one pill three times a day, we turned an important corner in Universal Access to treatment. It is essential right now to continue developing fixed-dose combinations, especially for second-line treatments.

Let us give our full support to the HIV Patent Pool initiative, championed by UNITAID. It aims to diversify supply sources and reduce prices of medicines by making intellectual property more widely available, facilitate and accelerate the development of improved formulations. The focus of the pool is initially on ARVs—but it can serve as a model for other diseases or incorporate them in due course. Apart from patents, processes and organizations have to operate to synchronized standards, applicable across all new plants. The transfer of technology is essential to speeding access to newer, quality assured essential drugs—including ARVs.

I want to take this opportunity to commend the NEPAD Secretariat and the Council on Health Research for Development (CORHED) for their collaborative effort to produce the important study on “Strengthening Pharmaceutical Innovation in Africa”, with support of the Dutch Government.

Now we need to strengthen partnerships to make sure we are all playing our chosen instruments to the same tune. Given the complexity of the challenges in advancing innovation and quality local production on the Continent we need to leverage the resources of the Africa Union, NEPAD, Regional Economic Communities, the UN—specifically WHO, WTO, UNDP, WIPO and UNICEF—and other key stakeholders. Our challenge is to orchestrate action—something in which an African Drugs Agency could play a central role.

Prevention Revolution

My final point is on prevention. For every two people newly put on treatment, no fewer than five people are becoming infected. These are our daughters and sons, our brothers and sisters; they are close to our hearts.

The personal dramas playing out privately have much broader implications—for the financial stability of families, for access to children’s education and for the social fabric of our communities.

I have therefore called for a Prevention Revolution: I use the word “revolution” deliberately, as I believe that at this point in the epidemic, as we are coming up against stated targets for Universal Access, we need to stage a tremendous push for combination prevention. By understanding and disabling the drivers of the disease’s spread, stopping transmission of the virus, we can save many millions of lives and livelihoods without the need for costly drugs.

Yet drugs are also essential to prevention. Already we are firmly on the path to virtually eliminating mother-to-child transmission. Imagine: within the next few years we could essentially end one of the three major forms of transmission. But again, this comes down to having the right drugs at the right time at the right price.

The music we are writing together is complicated, and time races on, threatening to leave us many beats behind. We will be held accountable by future generations for the steps we took, or failed to take today, to ensure a more fair distribution of life-saving drugs. The strands of the melody are with each of you; let us now bring them together in perfect concert.

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UNAIDS is an innovative joint venture of the United Nations, bringing together the efforts and resources of the UNAIDS Secretariat and ten UN system organizations in the AIDS response. The Secretariat headquarters is in Geneva, Switzerland—with staff on the ground in more than 80 countries. The Cosponsors include UNHCR, UNICEF, WFP, UNDP, UNFPA, UNODC, ILO, UNESCO, WHO and the World Bank. Contributing to achieving global commitments to universal access to comprehensive interventions for HIV prevention, treatment, care and support is the number one priority for UNAIDS. Visit the UNAIDS web site at www.unaids.org

[1] UNAIDS, WHO (2009). *AIDS epidemic update*. Geneva, UNAIDS
[2] www.who.int/hiv/pub/arv/advice/en/index.html
[3] www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2009/20090702_Made_in_Africa.asp
[4] www.un.org/apps/news/infocus/sgspeeches/search_full.asp?statID=346