THE AFRICAN UNION PHARMACEUTICAL MANUFACTURING PLAN FOR AFRICA – PIPE DREAM OR PANACEA?

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Public Launch of Southern African Generic Medicines Association (SAGMA)

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SPEECH

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The African Union Pharmaceutical Manufacturing Plan for Africa – Pipe dream or Panacea?

Acknowledgements and thanks

I am pleased to be with you today for the launch of the Southern African Generic Medicines Association (SAGMA). I send you greetings from Michel Sidibé, the Executive Director of UNAIDS, and although my talk will be from an AIDS perspective the issues discussed here are relevant to not just a successful HIV response but also to a broader health delivery agenda. I therefore want thank the Board of SAGMA and UNIDO for giving me the opportunity to join this important event.

I want to commend the countries of the SADC region for establishing SAGMA.

SAGMA will, without any doubt, make a unique contribution in bringing the commitments of the African leaders in harmony with one of the major aspirations of the African peoples: access for all to quality essential drugs, including ARVs, at affordable prices.

The theme of today's event is "the African Union Pharmaceutical Manufacturing Plan for Africa – Pipe Dream or Panacea?" I will argue that it is neither a pipe dream nor a panacea. The AU Pharmaceutical Manufacturing plan is a necessity. I believe that SAGMA can play a major role in its implementation.

In my talk today I will want to cover three areas:

1) HIV prevention;

2) HIV Treatment and treatment as prevention;

3) Broader set of issues for health delivery.

I don't have to remind this audience that today we are thirty years into the epidemic, ten years since the first General Assembly Special Session on AIDS, and five years since the adoption of the Universal Access goals.

First of all in terms of Prevention, we do have some good news, the number of people newly infected with HIV has fallen by 20% in the last 10 years and in 33 countries, of which 22 are in sub-Saharan Africa, incidence fell by at least 25% between 2001 and 2009.

Prevention messages are getting through as we see people starting to adopt safer behaviours. In 59 countries, less than 25% of men reported having sex with more than one partner in the last 12 months and condom use has increased dramatically.

Investments in AIDS are clearly paying off, but gains are fragile. For the first time, resources available from international sources in 2009 were less than in previous years: US$7.6 billion in 2009 compared to US$7.7 billion in 2008.

In terms of Treatment, at the end of 2010, six million people were on life-saving antiretroviral treatment—more than ever before and resulting in a 20% decline in AIDS mortality over the past five years. However, another 8 million still need treatment as of today, making a total of 15 million people in need. Furthermore for every one person being put on ART, two persons will have become infected with HIV.

For the first time in 2009, global coverage of services to prevent mother-to-child transmission of HIV exceeded 50%.

In terms of treatment as prevention, there are a number of new biomedical prevention methods coming on stream based on antiretroviral drugs, including microbicidal gels, pre-exposure prophylaxis. While the whole area of treatment as prevention still needs to be carefully evaluated and guidelines distributed, it is clear that ARVS will increasingly play a role on the prevention side of the equation.

It's interesting to compare the difference in attitude towards treatment in the past 10 years. In 2001, when the Declaration of Commitment was endorsed at the General Assembly, naysayers were declaring that AIDS treatment was impossible in low resource setting. We have proven them wrong. However, now the naysayers are saying that treatment is not sustainable.

Sustainability of access to treatment remains a real challenge as more patients will fail first-line antiretroviral therapy through either adverse effects or developing drug resistance and need more expensive and more patent-protected second- and third-line ARVs. Some projections see ART treatment costs escalating as much as twenty-fold.

The current world economic situation, characterized by scarcity and austerity, means that less resources will be available from multilateral, bilateral and domestic sources for funding global health. These sources have greatly contributed to supporting and expanding access to medicines in middle- and low-income countries but are now likely to decrease. We therefore will have to sustain our gains in the HIV response with fewer resources, including for treatment. This can only be achieved by reducing the price of HIV treatment, especially for second and third line treatment.

It's also important to note that the need for access to treatment is expected to grow for a number of reasons including:

- people living with HIV are now recommended to be started earlier on treatment (WHO 2010 treatment guidelines);
- more people worldwide will need to be started on second and third-line treatment as resistance to first-line treatment regimes develops and builds up.

Access to cheap and effective HIV treatment is a human rights and a public health issue. It is central to realizing our common vision stated in our new UNAIDS Strategy of Zero New infections – Zero AIDS-related Deaths – Zero Discrimination

Access to treatment therefore also is a development issue, which—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.

UNAIDS and its partners now have a new treatment paradigm, which we call Treatment 2.0

It was for these reasons that Michel Sidibé in 2010 launched the Treatment 2.0 Strategy – currently a joint initiative led by UNAIDS and WHO with many partners (UNITAID, CHAI, PEPFAR/NIH, Medicine Patent Pool, GF, MSF, Gates, Pangaea, ITPC…)

The long-term chronic management of HIV infection will be improved with radical simplification of treatment to achieve sustained universal access

- high quality treatment,
- easier to take,
- easier to monitor,
- more affordable for all.

As well as maximizing the prevention benefits of treatment

Treatment 2.0 is based on the following five pillars:

- optimize drug regimens,
- promote diagnostics using point of care and other simplified technologies,
- reduce costs,
- adapt delivery systems and
- mobilize communities around treatment.

It is a strategy for the next ten years and beyond and has

- Short-term goals (2015) which includes some “Quick Wins”
- Medium-term goals (2015-2020) “Better regimens” and
- Long-term goals (Beyond 2020) “New products”

I would like to talk a bit more about these three phases

2011 – 2015: focuses on optimizing existing treatment.

At this point it is crucial to identify and promote innovative incentives for public-private partnerships in HIV R&D needed for long term improvements in HIV treatment

“Some immediate quick wins” by 2012 would be increasing use of FDC and phasing out d4T, for example.

2015 – 2020: implementing emerging new technologies:

i) In terms of clinical monitoring –point of care Viral Load (VL) test could increase dramatically the capacity of health providers to assess the effectiveness of treatment in individual patients

ii) next-generation low cost, highly effective second line treatments

iii) first generation of long lasting injectables?

Beyond 2020: implementing a new paradigm of treatment management that makes HIV an easily managed chronic disease, resulting from the previous decade's renewed investment in HIV R&D, treatment scale-up experience, community mobilization and systems strengthening. It is during this third phase that we may see the possibility of curative interventions.

The primary emphasis of Treatment 2.0 is on treatment optimization with the ultimate aim of making HIV infection as a global manageable chronic condition.

Generic drugs have been the game changer for treatment - today Universal Access to Treatment is no longer a pipe-dream

The cost of the least-expensive first-line ART regimen is now less than $116 per patient, per year, thanks to generic production and changes in the laws for patent protection for low-income countries.

Today, 80% of people living with HIV on treatment in Low and Middle Income Countries are using Indian generic drugs. The decrease in price of ARVs can be largely attributed to generic competition, partly stimulated by the use of the flexibilities under the TRIPS Agreement. There are also several examples where the use of TRIPS flexibilities such as compulsory licensing has decreased ARV prices. E.g. Malaysia, Ecuador, Brazil, Thailand.

One of the reasons we have not seen more countries using TRIPS flexibilities is that, at present, more than 95% of patients on anti-retroviral therapy are still on first generation ARVs, most of which are off patent. As patients move on to more efficacious forms of patented first-generation treatment, or second and third generation treatment, most of which is still under patent, we anticipate there will be more need to use TRIPS flexibilities.

TRIPS flexibilities have helped reduce price of medicines, but their use remains limited

It is estimated that the Brazilian Government's policies, including the use of TRIPS flexibilities, saved approximately US $ 1.2 billion on antiretroviral drug purchasing costs between 2001 and 2005.

This clearly shows that effective use of TRIPS flexibilities can drive costs down and expand access to treatment. Unfortunately, the numbers of countries (esp. low- and middle- income countries) that have so far successfully use TRIPS flexibilities to ensure access to cheap and effective HIV treatment remains limited. This is mainly due to inadequate legislative framework, limited capacity for national production of drugs combined with limited use of existing mechanisms for import and export (e.g., the WTO paragraph 6 system), and finally insufficient technical capacity on intellectual property issues including within national regulatory authorities, and insufficient global cooperation.

These challenges have been compounded over the past few years by the adoption of so called "TRIPS plus" provisions, including Free Trade Agreements which have included more extensive intellectual property restrictions than are required by the TRIPS Agreement (such as data exclusivity) and which may compromise the ability of middle- and low-income countries to effectively use the TRIPS flexibilities.

It is therefore increasingly essential that countries incorporate TRIPS flexibilities into national law as they almost certainly will be needed to sustain and scale up treatment in the future.

SAGMA has an essential role to play in supporting the development of a Pharmaceutical regulatory plan for Africa that will support Universal Access to treatment

The Southern African Generic Medicines Association has a key role to play, in supporting countries with implementation of TRIPS, innovative licensing schemes and the Medicines Patent Pool to keep prices going down and ensure that new generations of good quality drugs become available.

However, none of us, the SAGMA or UNAIDS can make progress in this area alone. The issues I have outlined today are issues of regulation, good governance and institutional capacity development. Currently there are over 50 different National Medicines Regulatory Authorities (NMRAs) working independently using different administrative and technical requirements, without clear timelines. If a pan-African vision and regulatory system in this area can emerge this can allow for fewer delays in authorisation of medicines, better quality control, stronger support to innovation and a more sustainable response to HIV.

In this context, I would like to recognize the work that is being done by the NEPAD Agency, the African Union Commission and a consortium of partners, including WHO, the World Bank, Gates Foundation to harmonize medicines registration at regional level (African Medicines Regional Harmonization initiative).

All stakeholders, including organizations such as SAGMA, are critical to maintaining the world's attention to access to affordable medicines. The June 2011 High Level Summit on HIV will provide a unique opportunity for this much needed mobilization and re-commitment to increasing access to treatment, including for HIV.

There are many opportunities today, and many challenges as well which involve all of us who are here today. That is why it is so important that we have an opportunity to hear from the African pharmaceutical manufacturers about their thoughts on how we can advance an African Medical regulation authority.

We look forward to hearing the panels about the work of the African Pharmaceutical industry, and to working with SAGMA long into the future.

Thank you

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UNAIDS, the Joint United Nations Programme on HIV/AIDS, is an innovative United Nations partnership that leads and inspires the world in achieving universal access to HIV prevention, treatment, care and support. Learn more at unaids.org.