AIDS, Africa, and ARVs

Domestic Production as the Solution to the Treatment Gap

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Abstract

Part I gives an overview of key terms, including ARVs, TRIPS, Global Fund and CHAI, which are necessary to understand before delving into the more complex issues within the treatment of HIV/AIDS. Part II investigates the weaknesses of the current system of ARV supply. The first section discusses the problems with brand-name production, while the second looks at challenges that current generic manufacturers face, which could restrain Africa’s access to their imported drugs- such as changes in patent laws and WHO recommendations, or decreased Global Fund budgets. Part III provides the solution of domestic production and then goes into the details of what has worked, what hasn’t worked in the past, and also what could work in the future, using five specific case studies of current generic pharmaceuticals in Africa as examples. Part IV addresses the main criticisms of the model of domestic production: comparative advantage, the infant industry argument, and opportunity cost, and then provides counterarguments for each of these points. Part V is a policy proposal to the World Bank suggesting that they grant a loan of $2 million to domestic manufacturers seeking WHO approval who apply and qualify. The paper also includes a mock press release that could be used by the World Bank to introduce the nature of the loan.
Introduction

“Most global health issues can truly be understood only within the larger context of the HIV/AIDS pandemic.”¹ This statement may seem exaggerated considering only 33 million out of six billion people in the world are infected with HIV/AIDS. However, when left out of control, AIDS weakens individuals and makes them more susceptible to other infectious diseases, such as TB.² In addition, the economic burden of AIDS consumes entire public health systems in developing countries.³ Considering these factors, focusing on the AIDS epidemic can help to reduce the threat of global pandemics, and free up funding and space for other diseases to receive the attention and support they need.

Though investment in prevention is also important to mitigate the epidemic, without treatment, the current 33 million people infected with AIDS will be left to die. Anti-retrovirals have been proven to increase life expectancy of someone living on AIDs, and with generic manufacturing, they are now affordable to people in developing countries. Many organizations, such as Global Fund, PEPFAR, and the Clinton HIV/AIDS Initiative have donated significant money towards achieving their 2010 goal of universal access of ARVs. Despite these efforts, they expect to fall short of the 2010 goal, leaving many people without treatment⁴.

Sub-Saharan Africa has been the hardest hit by the epidemic. In 1993, 9 million (out of a worldwide 14 million infections) were in Sub-Saharan Africa. Today, 22.5 million (out of a global 33 million infections) are from Sub-Saharan Africa. To put things in perspective, Haiti is the country with the highest prevalence rate outside of Sub-Saharan Africa, with a prevalence rate of only 2.2%.⁵

In terms of treatment, Sub-Saharan Africa uses almost four times the ARVs of the rest of the world combined. However, the current system of treatment for HIV/AIDs is still insufficient. According to the WHO/UNAID/UNICEF 2009 progress report “Towards Universal Access,”

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² Ibid.
³ Ibid. p. 45
⁵ HIV InSight. 2009. HIV/AIDS in Haiti. HIV InSight. University of California, San Francisco
66% of people who ARVs in Sub-Saharan Africa (around 6,700,000 people), are still not receiving treatment. Not to mention the 2,925,000 people who have already begun treatment, will need to continue receiving ARVs for the rest of their lives. There is still a gap between what Donor organizations are able to provide and what is needed on the ground. The burden continues to expand as new people need treatment and old patients need to switch to even more expensive second-line drugs. Moreover, international donor funds have recently been more constrained, leaving African countries to find new resources to solve the demand for ARVs.

Domestic Production of ARVs can help to reduce the cost of ARVs while lifting the entitlement burden off the shoulders of the United States and international donors. Many big pharmaceuticals have already begun to partner or invest in African generic pharmaceutical companies, in countries such as Ghana, Uganda, South Africa, and Mozambique. While each of them has applied for domestic or voluntary licensing to produce generic ARVs, this paper

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suggests that they consider working under the never-before invoked Article 6(i) of the Doha Declaration, which allows developing countries to bypass patent laws and produce and export to countries within their respective trade agreement regions, as long as more than half of them are least developed countries. In addition, the paper asks the World Bank to help secure a non-interest loan of $2 million dollars to allow African Pharmaceuticals to get WHO bioequivalency testing, and to be able to access wider markets for their drugs.

Part I. Terms

**Anti-retroviral Treatment**

Anti-retrovirals (ARVs) are not a cure for HIV/AIDS, but they can keep people from becoming ill if they take them everyday for the rest of their lives. Patients have to take a combination of drugs (drug cocktails) so that they do not develop resistance to the treatment. There are over 20 WHO approved drugs, but they vary in price, availability, and side effects. After as short as 4-5 years of “first-line” drug therapy, doctors have to shift HIV-infected patients to “second-line” treatment. Most treatments consist of two NRTIs and one NNRTI. The most common anti-retroviral therapy (ART) was triamune, or triple combination therapy which consisted of stavudine, lamivudine and nevirapine (trioptune) but a recommendation by the WHO on December 1 of this year, suggests the discontinued use of stavudine because of its negative side effects. Some improved first line combinations have been combined within a daily pill called a ‘fix dose combination.’ Also, in recent years, first-line drugs have ranged around $99 pp/year in least developed countries (LDCs), whereas second-line drugs start at around $700 pp/year in LDCs. Second-line drugs are more complicated to manufacture, as well as have newer patents, therefore few generic producers have attempted to manufacture them. The focus of this paper will be on the domestic production of first-line ARVs.

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9 Médecins Sans Frontières. 2007.
TRIPS and Licensing

One of the greatest obstacles to keeping ARV prices low, is intellectual property rights also known as TRIPS (Trade Related Aspects of Intellectual Property Rights). TRIPS was introduced in 1995 to give pharmaceutical industries the right to patent their drugs for twenty years. This prohibits the production of generic drugs (i.e., identical copies or bio-equivalents of the patented brand-name drug). Therefore, no company can make, use, sell, offer to sell, or import the patented drug. The patents do not always benefit research and development, however, since Universities who create patented drugs often spend billions on R&D and are lucky to make only a few million on royalties. In any case, the majority of developing nations with high manufacturing capacity, were given a ten year transition period to bring their legislation in line with TRIPS; developing countries such as India were given until 2005, while least developed countries are allowed to disregard patents until 2016.

One way that a generic drug manufacturer can avoid patents is through applying for a voluntary or a compulsory license. Patent holders grant companies voluntary licenses, if they want to produce or import a generic version of the drug during a public health emergency. Governments grant compulsory licenses to companies who make a case that patent holders are abusing their rights and keeping prices unfairly high for potential consumers. Since 2001, compulsory licenses can be issued during a severe health emergency without having to pay royalties to the patent holder. Thankfully, the production of generic ARVs have provided affordable drugs on the market. To meet their new competition, many brand name producers dropped their prices right above generic prices. “The graph below illustrates the effect of generic competition on proprietary drug prices between 2000 and 2001.”

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11 Avert. 2009. AIDS, drug prices and generic drugs
Another way that a producer could avoid patent restrictions is specified in Article 6(i) of the Doha Declaration on the TRIPS Agreement and Public Health Decision of the General Council of 30 August 2003. This clause legally provides an opening for import or production of patented drugs. It allows the company to export to a group of countries party to a regional trade agreement, consisting of more than half Least Developed Countries, and sharing a similar health concern.\(^\text{12}\)

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;\(^\text{13}\)


[http://www.wto.org/English/tratop_e/trips_e/implem_para6_e.htm](http://www.wto.org/English/tratop_e/trips_e/implem_para6_e.htm)
ARV Provision Programs- Global Fund and Clinton HIV/AIDS Initiative (CHAI)

To acquire ARVs in Sub-Saharan Africa, a community can ask their Country Coordinating Mechanisms to send a grant proposal to the Global Fund. The Global Fund is a financing mechanism, which receives money from governments and private donors and then awards it to Principal Recipients, based on the technical quality of their applications. On average, the US is the biggest single donor to the Fund, making up about 33% of the total funds every year. Sixty-one percent of the Funds' budget goes towards HIV/AIDS. More than half of its funds are allocated to Sub-Saharan Africa alone. Forty-five percent of its total expenditures go towards the procurement of drugs, commodities and products. By November 30, 2009, the Global Fund supplied 2.5 million people worldwide with ARVs.

In 2007, The Global Fund established the Voluntary Pooled Procurement (VPP) service so that countries with low procurement volumes of ARVs could pool their drug orders and benefit from more competitive pricing. The Fund also contracted The Clinton HIV/AIDS Initiative (CHAI) to provide technical support, help them to negotiate prices, and select suppliers for ARVs. The VPP also ensures that all ARVs comply with the Global Fund’s Quality Assurance Policy for Pharmaceutical Products. The Global Fund will only purchase from manufacturers who are pre-qualified by the WHO. Especially with ARVs, it is important that standards of quality are ensured so that the chance of resistance to the treatment is minimized.

Founded in 2002, The Clinton HIV/AIDS Initiative (CHAI) was designed to negotiate lower prices for ARVs. Since then it has “transformed the marketplace for HIV commodities from a low-volume, high-margin market to a high-volume, low margin market through

simultaneous and intensive engagement on both the supply and demand sides of the market.” 19 Since CHAI combined their negotiating power with the purchasing power of UNITAID in 2006, the price of first line treatment has decreased by 50% and second line treatment by a cumulative 30% in low income countries. 20 More specifically, CHAI currently works with 8 suppliers, who offer some of the lowest prices on 40 formulations, simply by being able to sell and deliver in bulk. CHAI sends out a bid for new suppliers every year and selects based on three criteria: price, registration coverage in countries where UNITAID-CHAI have programs, and historical supply performance including adherence to delivery dates.21

Unlike Global Fund, The Presidents Emergency Plan for AIDS Relief focuses on direct funding from the US Government. A Global AIDS Coordinator, supplies money to government agencies who then supply the funds to prime partners in different countries. PEPFAR also uses a one-stop-shop for procurement of their ARVs. Since September 2008, they have supplied 2.1 million people with ARVs. PEPFAR also uses a “one-stop-shop” for procurement of their ARVs. In 2005, they contracted Partnership for Supply Chain Management (SCMS). In 2008, PEPFAR gave more money to SCMS ($84 million) than any of their other partners.22 Another criticism of PEPFAR is of particular concern; the Statement of the Ecumenical Pharmaceutical Network from Moshi, Tanzania argues that “PEPFAR disregards national drug regulations and local supply chain management systems, which could damage national health systems, especially the pharmaceutical sector.”23 According to the Institute of Medicine, the SCMS should support local and regional systems rather than simply support a “US-controlled system.”24

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Part II. Problems with the current system of ARV supply

The current system of treatment of AIDS is insufficient because costs of ARVs are out of reach for many people in developing countries, where treatment is needed most. Donor organizations, like the Global Fund and PEPFAR, have a limited budget and can only afford to treat a small percentage of the people who are in need. To improve the current system, it is necessary to find ways to lower costs of treatment.

Known as Big Pharmaceuticals, Originators, Innovators or Brand name manufacturers, these firms have been notorious for keeping their drug prices high. One quarter of ARV drugs developed between 1988 and 2005 were patented by Universities and then eventually licensed to big pharmaceutical companies. In many cases, the Universities neglect to specify global access provisions. For example, Harvard “only included global access provisions in 5 out of 62 licenses over the past two years (2007-2009).” Global Access provisions include tiered pricing, financial incentives, mandatory sub-licenses to generic manufacturers and non-patenting policies; these provisions are an attempt to enable poorer countries to have more access to the drugs they need.

In 2001, “a group of Yale students learned that d4T (stavudine), an HIV antiretroviral drug patented by Yale and licensed to Bristol-Myers Squibb, was being sold at outrageous prices overseas, blocking off access for HIV patients living in South Africa and other developing countries.” Without the provisions in place, big pharmaceutical companies often choose to sell their brand name drugs primarily to developed countries. “PhRMA [...] concedes that Africa comprised only 0.5% of sales in 2007” while “the U.S. represented 67.7% of 2007 world sales.”

However, global access provisions are not necessarily the best solution for creating more access for ARVs. First, provisions can remain secret or hidden within the patents; “the nature of the access provisions, the number of medical licenses, and even the identity of the drugs covered,

26 Ibid.
27 Ibid.
Secondly, the provisions themselves can be incredibly hard to monitor. One provision, tiered pricing, which allows pharmaceuticals to change the prices of their ARVs for different countries, makes it incredibly hard for countries to compare prices or find the lowest cost supplier. In an article by the African Press International titled “Countries pay widely varying prices for ARVs” it states, “some nations are paying up to three times more for the life-prolonging medicines than others with similar HIV prevalence and income levels. In 2007 Nigeria paid US$334 per patient per year for a combination of first-line ARVs that cost Congo only US$95. Both are low-income countries, but Nigeria has a higher HIV prevalence of 3.1 percent, compared to Congo’s 1.2 percent.” This discrepancy in pricing is due to global access provisions because “when originator companies apply discounted prices on ARVs, each has different eligibility criteria, which is a considerable source of confusion for purchasers” For example, according to Médecins Sans Frontières, Merck gives discounts to countries which are lowest on the Human Development Index and have >1% HIV prevalence rates, GlaxoSmithKline offers its lowest prices to Global Fund Grantees and Gilead has an entirely different list of eligible countries. Therefore, access to ARVs is not fair and those countries who need them most may have to pay more for them if they depend on the big pharmaceuticals to decide.

As a result many governments and donors have neglected to buy from brand producers and substituted their ARV supply with generic drugs instead. According to PEPFAR's 2009 annual report to Congress, "In FY2007, 73 percent of antiretroviral drugs delivered through PEPFAR, and 93 percent delivered through SCMS, were generic formulations. By using generics, PEPFAR partners were able to save an estimated $64 million — a 46 percent reduction in cost if they had purchased only innovator drugs." Generic production has indisputably
contributed to lower costs of ARVs, and consequently increased access to AIDS treatment in poorer countries. Generic producers (specifically an Indian Pharmaceutical company) created a triple combination therapy in 2001 that was available for $295 per person bringing the price of treatment down from a whopping US $10,000-15000 in 1996. Today the most widely used drug treatment (d4T+3TC+NVP) is available for US $88 per person per year.\textsuperscript{33}

Generic Production may not be able to continue in the way it has in the past because of approaching patent blocks. Indian Pharmaceuticals skirted their 2005 WTO compliance deadline using the Indian Patents Act 2005, which, overrides the WTO patent regulations using an “automatic licensing system.” This automatic licensing allows the manufacturers to continue producing generic drugs that they were already producing, as long as the pay a reasonable royalty to the patent holder. Whether India or China will be able to apply for voluntary or compulsory licenses to produce new drugs (such as second-line ARVs) that will come out in the future is still in question. Since these companies often supply over 40% of the API to many countries, if they are blocked by new patents, ARV prices will again spike up creating a new price crisis. (Graph 4 and explanation\textsuperscript{34})

\begin{figure}
\centering
\includegraphics[width=\textwidth]{graph4.png}
\caption{This chart shows real transaction prices as reported by the GPRM from January 2006 to June 2007. It shows that for more recent ARVs, competition is very limited. As a result, the lowest price offered by the originator remains high, as do generic prices. Moreover, there are still no generic versions prequalified by WHO for some of the newest ARVs, limiting demand. In the case of older ARVs for which generic competition is much less restricted, prices have dropped much lower and price offers by originators more or less match generic prices. LPV/r sgC: old formulation that requires refrigeration. LPV/r tab: new tablet form that does not require refrigeration.}
\end{figure}

\textsuperscript{33} Avert, 2009. AIDS, drug prices and generic drugs.
\textsuperscript{34} Médecins Sans Frontières. 2007.
Generic producers also depend on WHO regulations and guidelines to determine what drugs are in demand and which drugs should be created. First, if the WHO recommends a drug to be included in the first line therapy, that is still under patent, the cost of treatment could significantly rise. On December 1, 2009 the WHO recommended “that countries phase out the use of Stavudine, or d4T, because of its long-term, irreversible side-effects. Stavudine is still widely used in first-line therapy in developing countries due to its low cost and widespread availability. Zidovudine (AZT) or Tenofovir (TDF) are recommended as less toxic and equally effective alternatives.” 35 Fortunately, the Clinton Foundation (CHAI) and UNITAID have been able to keep prices low by buying drugs in bulk. “These price reductions were made possible by the UNITAID Second-Line Project, which has increased and aggregated demand for tenofovir by supplying other tenofovir-based products for use in second-line treatment and also on an exceptional basis for first-line use in three countries. While the focus of this UNITAID project is on second-line price reductions, the increased tenofovir volumes have translated into a cumulative price reduction since 2007 of 62 percent for once-daily first-line HIV/AIDS treatment in low-income countries, further broadening the market impact of UNITAID support.” 36

In the same recommendation, the WHO pushed back their recommendation for when to begin treatment with ARVS. Whereas in 2006, the WHO had people begin treatment when they were typically showing symptoms, the “WHO is now recommending that ART be initiated at a higher CD4 threshold of 350 cells/mm3 for all HIV-positive patients, including pregnant women, regardless of symptoms.” 37 Now that AIDS treatment is recommended for patients at an earlier stage, there will be more of a demand for ARVs in the near future.

As the WHO changes their recommendations to include newer drugs and start treatment at an earlier stage, organizations like the Global Fund, are struggling to meet the increase in demand. “The Fund’s 8th funding round, which closed in the Fall of 2008, was three times the

http://thepage.time.com/release-from-clinton-foundation/  
37 Ibid.
size of Round 7. This was due to an increased number of higher quality and larger applications than in the past [...] If Round 8 is funded at the recommended levels, very little money would be left for future rounds.”

To save money, grants Approved Grants have to take 10% efficiency cuts, phase II of existing and future grants will be cut by 25%, the number of rounds per year is reduced to 1 again and round 9 postponed 6 months and second round grants are capped at 140%. Uganda has been hard hit by cuts in the budget since 95% of their ART program is funded by PEPFAR or Global Fund.

Milly Katana, an HIV activist, attributes ARV shortages in the country to lack of donor funds: “many donors like PEPFAR, the Global Fund and others, who had been providing ARVs, are reducing the assistance because of the current credit crunch.”

Dr. Michael Strong, the PEPFAR coordinator, announced “a blanket freeze on new patient enrollment” and asked partner organizations to try to postpone treatment and refocus on care.

All this to say, people who depend on ARVs and the goodwill of donor foundations such as the Global Fund may be at risk if budgets are constrained as demands and recommendations for treatment continue to expand. Domestic Production is a viable option for those countries who want to maintain their sovereignty and avoid being affected by the decisions of other countries.

Part III. The Solution is Domestic Production

What has worked

There have been several attempts at domestic production in Africa: Zimbabwe (Varichem), Kenya (Cosmos), Ghana (Danadams), South Africa (Aspen), Uganda (Quality Chemicals Ind.), and most recently Mozambique. This section will look at what has worked for these case studies and then what hasn’t worked. As a preface to this section, domestic production

http://www.healthgap.org/globalfundshortfallfacts.htm
http://healthdev.net/site/post.php?n=5757
http://allafrica.com/stories/200907270244.html
41 Basudde. 2009.
42 Personal correspondence with Dr. Rudolf V. Van Puymbroek, Senior Scholar at the O’Neill Institute for National & Global Health Law of the Department of International Health at Georgetown University December 11, 2009.
can only be a solution to fill the gap of supply for ARVs in countries where the environment will not prove to be a barrier to production. For example, some countries, such as Zimbabwe experienced more challenges than others, such as South Africa because of their external environments. The economy and political system must be sufficiently stable to support this enterprise.

Four out of the five domestic producers offer prices that are competitive with the market. Improving access to HIV/AIDS medicines in Africa Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities utilization, a book published by the world bank in 2008 argues explicitly that Zimbabwe, Kenya and South Africa were able to offer prices below the current domestic prices. Before the expansion of Varichem to include ARVs, costs of treatment per person in Zimbabwe ranged from $30-$50 per month. However, Varichem’s generic versions of lamivudine-zidovudine would only cost about $15 per person. Kenya’s domestic producer Cosmos, was granted a voluntary license from pharmaceutical giants GSK and Boehringer Ingelheim (BI) for the production of lamivudine, nevirapine, and ziduvudine. Although Cosmos offered lower prices for their generic versions, GSK and BI cut their prices for these drugs in order to compete with the domestic producer. Although Cosmos did not retain the lowest cost for ARV supply, their entry into the market was significant because it cut the cost of brand name drugs and thus benefitted the population in need of ARVs. Lastly, Aspen commands a high portion of the local South African ARV market and its public sector prices, at R100 (US$10) per month per person, are highly competitive. These are partially offset through government purchase of production materials in a tradeoff for lower prices. In another article, The African private sector steps in to fill the drug gap, Danadams prices are reported as extremely competitive. According to Sarah Perkins, Faculty of Law at the University of Toronto, "If Danadams could afford the bioequivalence tests to obtain WHO approval, it could be supplying

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44 Osewe et al. 2008, p. 33-34
45 Osewe et al. 2008. p. 37
even more of the country’s drug needs at prices on a par with or lower than those from India.” 46  
Lastly, according to the WHO, Uganda imports most of its drugs, but that may be about to change: “The first batch of locally produced generic ARVs and antimalarial drugs are expected to be delivered to the health ministry this year in a move that will see the cost of these life-saving remedies dropping from between US$ 15 and US$ 9 to between US$ 9 and US$ 2 per patient per month, Ugandan officials say.” 47  In sum, Zimbabwe, Kenya, South Africa, Ghana, and Uganda have all quoted prices that compete with the current generic ARV prices.

Domestic Producers have sometimes functioned as key suppliers in moments of drug shortage. For example, During a 2004 shortage of ARVs in Ghana caused by a change in patent laws and the issuance of a compulsory license to Danadams, Ghana was forced to find new sources of ARVs. From this situation Danadams received a one-time contract worth over $250,000, or a little over 5% of the ARV market in Ghana. The other 95% came largely from Indian generics manufacturers. 48  An article entitled “Crisis of lack of antivirals in Uganda” reports that in the summer of 2009, “Ministry of Health facilities across the country have reported stock outs of ARVs which means people living with HIV stop taking the drugs or have their drug regimens (combinations) changed.” 49  According to Dr. Michael Strong, the PEPFAR coordinator, "We expect that PEPFAR funding for Uganda will continue at its current level of around $280m annually through 2013. But this will still leave a gap between national treatment needs and the funds available. Uganda needs to identify other resources to fill this gap.” 50  Since Uganda used to be 95% funded by PEPFAR and Global Fund, Uganda’s new domestic pharmaceuticals factory, which opened in October 2007 to manufacture ARVs and antimalarial drugs hopes to step in to fill the new gap with targets of 240,000 people on treatment by 2012 and 342,200 by 2020. 51  South Africa is the domestic production success story. Originally

http://www.who.int/bulletin/volumes/86/6/08-020608/en/print.html  
48 Osewe et al. 2008. pp. 40  
49 Kintu. 2009.  
50 Basudde. 2009.  
http://www.avert.org/aids-uganda.htm
established in Steven Saad’s suburban home in 1997, today Aspen is one of the top 20 manufacturers of generic medicines globally today, and secured nearly 50% of the local generic market share in 2007.\textsuperscript{52}

\textit{What has not worked}

First, many countries do not even look into domestic production as an option because they are intimidated by the paperwork and legalities. Few countries have tried to exercise the rights of flexibilities in TRIPS laws, “citing a lack of capacity and legal know-how to negotiate the complicated paperwork required, and political pressure from foreign governments.”\textsuperscript{53} The idea of licensing can be daunting, and compulsory licensing can sometimes result in a slap on the wrist from big pharmaceutical companies. For example, Thailand issued a compulsory license in 2007 to import and produce LPV/r, but the patent holder, Abbott retaliated by refusing to register new drugs in Thailand.\textsuperscript{54} Although Abbot has received condemnation in the global eye, their response has created fear within countries who might consider applying for licenses but do not want to risk their ability to access these life-saving drugs. An article from SouthAfrica.info titled \textit{SA’s pharmaceutical success story}, attributes Steven Saad’s ability to make Aspen into South Africa’s leading pharmaceuticals producer, to his “foresight in securing voluntary licenses from multinational pharmaceutical companies for the manufacture of more affordable generic antiretrovirals.”\textsuperscript{55} Without attempting to work within the TRIPS agreement, countries will always depend on foreign producers to make decisions about what drugs and what prices are best for them.

Many domestic manufacturers cite the high cost of bio-equivalency tests and API import costs as barriers to entry into the market.

\textsuperscript{52} Reuters. 2009. “\textit{Update 2-SAfrica’s Aspen wins tender, shares soar.}” Reuters.  \url{http://www.reuters.com/article/idUSL2661471720080626}

\textsuperscript{53} AlertNet. 2009. “\textit{GLOBAL: Countries pay widely varying prices for ARVs.}” Thomas Reuters Foundation: AlertNet.  \url{http://www.alertnet.org/thenews/newsdesk/IRIN/e2eea90174c4149a37c6d0a8f5afdeec.htm}

\textsuperscript{54} Médecins Sans Frontières. 2007.

\textsuperscript{55} Zachariasen, Angela. 2008. “\textit{SA’s pharmaceutical success story.}” SouthAfrica.info.  \url{http://www.southafrica.info/business/success/aspen-290708.htm}
“The prices of locally produced ARVs in Ghana, Kenya, and Zimbabwe do not include the extremely high cost of in vivo bio-equivalence tests. Given that in vivo bio-equivalence is a prerequisite for the attainment of WHO pre-qualification, the current prices will most likely increase sharply should these countries attempt to meet this requirement.”

In an interview, the chief executive of Danadams (Ghana) identified three major challenges:

(a) the high cost of bio-equivalence tests for each product that are required for the acquisition of WHO pre-qualification, (b) the high cost of APIs when purchased in relatively small quantities, and (c) the inadequate market share and lack of economies of scale that result from an inability to supply under the Global Fund arrangements (this in turn the result of the absence of WHO pre-qualification).  

Cosmos cited the same major obstacles quoting bio-equivalency tests at “$50,000 per ARV (and even higher for fixed-dose combinations), as well as the high cost of APIs, which accounted for an estimated 50 percent of the ex-works price of ARVs.”

Costs of bio-equivalency tests are only the tip of the iceberg, while the larger problem of achieving successful domestic production is breaking into the supply chain that is already well-established. Sarah Perkins, Faculty of Law at the University of Toronto, argues that:

Quality assurances are important for antiretrovirals, [and] obtaining WHO approval is expensive and daunting for burgeoning manufacturers. By linking Fund money to WHO approval, a monopoly has been created, ensuring that only well established manufacturers, such as those in the USA, Canada, Europe, and India, will be able to supply most of the world's antiretrovirals. Unless something changes, manufacturers in developing countries will be left out from the potential financial boon in antiretrovirals created by the Fund and WHO.

Dr. Rudolf V. Van Puymbroek, Senior Scholar at the O'Neill Institute for National & Global Health Law, advises any new domestic producers trying to break into the business to avoid producing the same drugs produced by CHAI manufacturers. These contracts for large sums of ARVs keep their prices as low as possible and make it extremely hard for small start-ups to even have a chance at offering competitive prices when CHAI and UNITAID send out their yearly bids for the lowest prices. Kenya experienced a similar scenario when they first began producing ARVs in 2003. “It is pertinent to note that the moment Cosmos started manufacturing ARVs, GSK and BI lowered their prices for those ARVs below the prices offered by Cosmos, further

56 Osewe et al. 2008. p. 43
57 Osewe et al. 2008. p. 41
58 Osewe et al. 2008. p. 34-35
60 Personal correspondence with Dr. Rudolf V. Van Puymbroek, Senior Scholar at the O'Neill Institute for National & Global Health Law of the Department of International Health at Georgetown University December 11, 2009.
endangering the viability of the Kenyan company's ARV production plan.” 61 This case reveals how established firms with a large market share have an advantage of price flexibility over a start-up firms that might depend solely on independent or government contracts.

**What could work**

If a country feels that they want to begin domestic production of ARVs in their pharmaceutical industry, Sarah Perkins, suggests they look at Article 6(i) of the Doha, Declaration on the TRIPS Agreement and Public Health Decision of the General Council of 30 August 2003. 62 Though the clause has never before been invoked, it allows domestic producers to bypass the complicated paperwork of applying for a voluntary license as well as the risks of applying for a compulsory license and accusing a patent-holder of unfair pricing, such as was the case with Thailand. 63

Especially in Africa where 33/47 countries are LDCs, there are several groupings of countries which fit the description of Article 6(i) and belong to a regional trade agreement that consists of more than 50% LDCs. For example, Danadams in Ghana could produce and export to ECOWAS (the Economic Community of West African States) which consists of 9/13 LDCs. Cosmos in Kenya or Quality Chemical Industries in Uganda (a LDC) could export to the EAC (East African Community) which consists of 4/5 LDCs. Mozambique could export to the SADC (Southern African Development Community) which consists of 7/14 countries (with Madagascar’s recent suspension). Firstly, exportation to a regional grouping allows local producers to focus specifically on the gap between what donor countries are offering, and who still needs treatment in that region. If transportation is feasible between the countries in the region, they could benefit from lower transportation costs by importing the drug from a regional producer rather than importing it from a foreign one. Secondly, countries grouping together around a shared health concern would be positive for general regional integration purposes, as

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61 Osewe et al. 2008. p. 34-35  
63 Médecins Sans Frontières. 2007.
well as for African countries taking on the responsibility of solving the ballooning HIV/AIDS burden themselves.

Countries hoping to begin domestic production should select the drug cocktail they choose to produce very wisely. CHAI has done extensive research on how to get the lowest prices from its 8 generic manufacturers. These manufacturers already produce every drug product on the WHO list of recommended drugs. At the same time, these suppliers will not always have the upper-hand on incoming producers, because the list of recommended drugs keep changing. For domestic production, Dr. Rudolf V. Van Puymbroek suggests that producers avoid producing what CHAI does best (the standard first-line cocktail). Uganda made the mistake of getting into production of the wrong drug, Stavudine, which the WHO recently removed from its list of recommended drugs. “This has shuttered the hopes of PLHIV [People Living with HIV] who had hoped that now that the drugs being home-made, they will be more affordable and readily available to the Ugandan population.” 64

It is important that domestic producers are very strategic. If they choose to produce a drug that is already being manufactured by a CHAI producer, it might be advised that they look at drugs that are being produced by only 1/8 manufacturers and are still only offered at a high cost.

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64 Kintu. 2009.
For example, countries might want to focus on improved first line drugs, such as a daily pill that combines the drugs tenofovir, lamivudine and efavirenz (EFV) and abides by the new WHO recommendations. CHAI has negotiated pricing for this treatment to $210 pp/year down 37% from the average market price for low income countries, but only one generic drug company, Matrix, is producing it.

Part IV. Counter arguments of domestic production

The most basic economics argument against domestic production is that Africa does not have comparative advantage in the pharmaceuticals industry. Few may believe that anyone could produce generics more cheaply than China or India. Dr. William McGreevey, Associate
Professor in the Department of International Health at Georgetown University advises Africa to take China’s advice and find out what it can sell to developed countries, whether that be textiles or handicrafts. Economists fear that if Africa tries to take on an industry in which it does not have comparative advantage, it will fail miserably. In a personal correspondence, Dr. McGreevey cited the import substitution model - every country who adopted it in the 50s and 60s failed to grow because they were trying to make domestically what could be more easily and more cheaply bought abroad. McGreevey argues that, by allowing the market to do the work, countries can enjoy unexpected consequences. For example, skilled health professionals might board on a plane to the United States on the day of their graduation from medical school in Africa, but they will send money home, which will help their families and which could encourage their children and grandchildren pursue their education.

The comparative advantage argument is sound in a perfect world, but it disregards countries’ desires for self-sovereignty. ARVs seem to be different than any other average commodity because of their emotional tug on the people. Countries may want the assurance that the lives of their own populations are somewhat in their control. Ghana-born Managing Director of Danadams Pharmaceuticals Limited, Dr. Yaw Adu Gyamfi states:

The reason why we specifically focused on HIV and anti-malaria medication is that five years ago we identified these diseases as the ones that are having the greater impact upon the public as a whole...rather than producing over the counter medication, like pain killers, we decided to become focused in an area where we knew there was a market, while at the same time the social dimensions of our a work would have a greater impact on society. Gyamfi argues that Ghana should take responsibility. “Each country must solve its own problems,” he says. “For Ghana or Africa to make it, we have to make things happen ourselves.” If international donors or the US suddenly dropped the ball, people who could not

67 Personal correspondence with Dr. William McGreevey, Associate Professor in the Department of International Health at Georgetown University. December 2009.
68 Ibid.
69 Ibid.
70 Personal correspondence with Dr. Mead Over Senior Fellow at the Center for Global Development (CGD), and former Lead Health Economist in the Development Research Group at the World Bank. December 2009.
72 Ibid.
afford drugs would die. Uganda has already experienced this crisis when the drugs stopped coming. Within 2 months of not receiving drugs, “Denis Mock, from ADFPHA Apac District forum of People living with HIV/AIDS, said 17 people [in Uganda] have died.” Domestic Production answers the call by PEPFAR to “identify other resources to fill [the] gap” between available funds and the needs of the people.

The other evidence against the comparative advantage argument is that many big pharmaceuticals have chosen to partner with African local pharmaceuticals. In 2008, Chinese pharmaceutical company, Adams Pharmaceutical (Anhui) Co. Ltd agreed to a joint venture with Danpong Pharmaceuticals Ghana Ltd in the creation of Danadams; Indian Generic Pharmaceutical, Cipla works directly with Ugandan pharmaceutical importer Quality Chemical Industries Ind who manufactures an ARV combination therapy; Brazil, a model in the fight against HIV/AIDS, is investing $23 million to build a factory in Mozambique in 2009; China, India, London, and Brazil have been the leading pharmaceutical manufacturers in the world, yet they see openings in Africa.

Many fear that domestic production in Africa is an attempt at the infant industry model which always fails. Economics has revealed that protection of a domestic industry using tariffs and trade barriers never benefits the consumers and decreases the net welfare of the country. If countries choose to protect a domestic industry by taxing imports of the same product to create a level playing field, the government and the producers will be pocketing the tax-payers money and the profits from an inefficient industry. People fear that this kind of protection will give

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corrupt officials more money, and therefore more leverage, hurting the economy and the growth of the country more than it would give it support. The market does a better job than the people. Domestic producers should have to bid for the lowest prices like any other company so that they are forced to be efficient.

This paper’s model for domestic production is not the infant industry argument model. First, domestic production under article 6(i) is legally written into the Doha Declaration as of 2003 and provides an opening for LDCs to ask for forgiveness of patent laws. Producing under this clause does not ask for any government tariffs against imported ARVs, which could cause complications or lead to corruption. Second, the infant industry model was designed for the sole purpose of benefitting the domestic economy, disregarding the current level of supply. However, in the case of domestic production of ARVs in Africa, gaps in the supply have been recognized and could be filled by the new manufacturers (which may in turn have positive consequences on the domestic economy).

Finally, opportunity cost is important to take into consideration. Some may argue that within the constrained budgets caused by the recent financial crisis, money should be used to find the cheapest drugs, and not reallocated to a risky venture of creating domestic industry. But, to view the world in terms of its current crises negates forward-looking attempts at preventing crises before they happen. Opportunity cost can also be thought of in a different way- what donors could fund now, versus what they would have to fund later. According to Dr. Mead Over, Senior Fellow at the Center for Global Development and former Lead Health Economist in the Development Research Group at the World Bank:

> Escalating treatment costs coupled with neglected prevention measures threaten to squeeze out U.S. spending on other global health needs, even to the point of consuming half of the entire U.S. foreign assistance budget by 2016 [...] The United States has unwittingly created a new global ‘entitlement’ to U.S.-funded AIDS treatment that currently costs about $2 billion per year and could grow to as much as $12 billion a year by 2016- more than half of what the United States spent on total overseas development assistance in 2006. And the AIDS treatment entitlement would continue to grow, squeezing out spending on HIV prevention measures or on
other critical development needs, all of which would be considered ‘discretionary’ by comparison.\textsuperscript{79}

Domestic Production is the sustainable solution to the entitlement burden because by funding domestic production, investors will also be benefitting Africa’s healthcare system, and the health of Africans infected with other diseases. In countries such as Ghana, Nigeria, and Uganda, domestic production of anti-retrovirals significantly improves the procurement and distribution of drugs for other diseases such as tuberculosis and malaria\textsuperscript{80}. In an October 2009 article, the chief financial officer of Uganda’s QCIL, Frederick Mutebi Kizito, confirmed that international investment in the distribution and production of ARVs contributes to a more efficient disease control mechanism and a substantial price reduction in ARVs and anti-malarial drugs. His facility, produces both anti-retrovirals and anti-malarial drugs\textsuperscript{81}.

Studies also show that domestic production improves the skills of pharmacists and healthcare workers. Particularly, it has improved the skills of pharmacists to provide adherence counseling\textsuperscript{82}. More and more pharmacy assistants and nurses have been trained to dispense anti-retrovirals as well as drugs for other chronic diseases\textsuperscript{83}. According to a \textit{Lancet} publication one reason for this is that:

The managerial skills needed to keep antiretroviral drugs in stock, to minimize diversion, to confirm that they are administered to those who can use them, and to monitor adherence and side-effects are the same types of skills needed to assure that other important programmes such as safe motherhood packages, malaria, tuberculosis, and sexually-transmitted disease control and diarrheal disease treatment are delivered effectively and consistently\textsuperscript{84}.

Therefore, investing in the infrastructure needed to deliver ARVs will spill over into other collateral health benefits.

More specifically, in Mozambique, investment in domestic production has forced its pharmaceutical company and ARV national programs to adopt task shifting in which mid-level
health care workers are trained with the skills of medical doctors to administer ARVs to HIV patients. Such an approach has been highly effective in a nation that once had merely eighty physicians for 10.6 million peoples. Even patients from rural and disadvantaged areas now have access to quality ART services. This method tripled the number of facilities providing medication within six months.\(^8^5\)

Part V. **Policy Proposal**

**Challenges**

In order to fund the development necessary to achieve large scale domestic production of ARVs in Africa, several possible negative effects must be screened for and avoided. Some of these problems, such as corruption and rent seeking behaviors, are major political issues in several Sub-Saharan African nations. Others, such as heavy subsidies, are economic issues that can decrease the positive effects of development.

First of all, corruption is a considerable issue in many African governments. In 2006, it was estimated by those inside of African governments, that corruption cost African nations about 25\% of government income each year\(^8^6\). Money and goods are stolen largely through bribes, political favoritism, and informal connections between politicians and the private sector\(^8^7\). This often makes investment in African countries and companies a risky venture, as it is possible that large amounts of the money may be skimmed off of the top or the project could become mired in political deal-making. Political nepotism may also cause governments to channel aid money and other funds to companies run by close relatives\(^8^8\). Should this happen, the best case is that the money may be given to a relatively inefficient company or industry. In the worst case, much of the aid money could simply be embezzled.

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\(^8^7\) BBC News. 2009. "**Corruption ’Stifling Economies’.**" BBC.co.uk. [http://news.bbc.co.uk/2/hi/business/8271547.stm](http://news.bbc.co.uk/2/hi/business/8271547.stm)

\(^8^8\) Ibid
Widespread corruption may then lead to the even larger issue of rent seeking. This occurs when the political group in power has unprecedented access to further power and wealth and everyone outside of that limited group is left with almost nothing. Because all of the power is concentrated in the ruling group and opposition groups are left with no possible avenues, all of the groups in the system will seek to become in power. And, once in power, these groups will use their considerable benefits to stay in power rather than develop the country as a whole, simply because the greatest benefits are derived from staying in power\(^89\). Not only could this be caused through aid donations being dispersed amongst the leading class, but also the through development of an inefficient industry that is run by government officials or their relatives.

In order to effectively develop domestic production of ARVs in Africa these situations must be avoided. Corruption, of course, would be against the interests of such a development program. Bribes could increase operating costs and embezzlement would decrease the total amount of aid funds available for use. Funding a rent seeking class will only serve to add to the already numerous adversities facing certain countries.

Heavy subsidies given to the pharmaceutical industry are red flags that must be screened for by effective policy. Subsidies indicate that the industry is unable to be competitive without help from the government. While this may be economically viable if limited subsidies are needed, the costs of heavy subsidies often far outweigh the benefits that the industry can produce. This is especially true in Africa where heavy subsidies often mean that taxpayer money that could have gone to basic development (greater access to drinking water or primary education for example) is instead being spent to help prop up an inefficient industry\(^90\). This puts a heavy burden on the state and, as a result, the taxpayers.

There have been a couple of examples of African ARV producers requiring subsidies in order to continue production; most notably in Zimbabwe where the state played a large role in both the development of the pharmaceutical industry and its maintenance\(^91\). While providing


\(^{90}\) Personal Correspondence with Mead Over. Senior Fellow, Center for Global Development. December 3, 2009.

\(^{91}\) Osewe et al. 2008. p. 30
funding to such an industry may lead to a decrease in the subsidies down the road as the industry develops, there has been little historical evidence that this will happen. Instead, these industries will often remain inefficient, as the protective subsidies and aid funding provide little incentive for the industry to streamline and become competitive\textsuperscript{92}.

\textit{Policy}

With these challenges in mind, we believe the most effective policy route to take in order to help develop domestic production of ARVs in Africa is through the creation of a loan. Such a loan would be provided through the World Bank International Development Agency (IDA), which gives low to no interest loans to developing nations, and given to the best proposal depending on a number of specific criteria.

First of all, the company must satisfy the requirements outlined under Article 6(i) of the 2003 Doha Declaration. At least 50\% of the ARVs produced in the company must be designated for export only throughout the economic region. At least 50\% of the region must be composed of Least Developed Countries, yet considering both ECOWAS and the East African Community are largely composed of LDCs, this will not be an issue for companies in these economic communities. In order for the World Bank to approve a loan for the production of goods involving intellectual property, patent rights must be agreed upon beforehand\textsuperscript{93}. Through satisfying the Doha Agreements, however, these companies will be able to produce without patents and still be in accordance of World Bank policy\textsuperscript{94}.

Secondly, the company must be compliant with international good manufacturing practices (GMP). These are international guidelines for management control and quality control in pharmaceutical production\textsuperscript{95}. In order to acquire WHO qualification and the subsequent international recognition of quality, companies must be compliant with GMP guidelines\textsuperscript{96}.

\textsuperscript{92} Personal Correspondence with Mead Over.
\textsuperscript{93} Personal Correspondence with Professor Callisto Madavo. Former Vice President for Africa at the World Bank. November 22, 2009
\textsuperscript{94} Perkins. 2007. p. 722
\textsuperscript{96} Osewe et al. 2008. p. 34.
Auditors who specialize in GMPs may be brought in to assess the company’s facilities and systems to determine if they are in compliance.97

Companies must also be able to display the capacity to produce ARVs at a large scale in order to provide treatment, through aid agencies, to at least 25% of those who need it in their region. Considering that 25% of people requiring ARVs ranges from 225,000 in West Africa to 500,000 people in East Africa, these numbers are certainly within the capacity of current domestic producers.98 Connected to this, the company must also have a plan to eventually increase their capacity to reach all of the people who need ARVs in their region. This means that these companies will be able to start producing and providing ARVs to large portions of the region as soon as they upgrade facilities and pass quality tests. This ability, coupled with a detailed plan for future increases, would immediately help scale up current ARV provision programs.

The drugs being produced must be competitive on an international scale. This also includes a lack of heavy government subsidies, as the drugs must be competitive with limited government help. This, above all else, is one of the most important criteria. If these drugs are not competitive the money being spent on the development of the industry, subsidizing its costs, and purchasing its drugs could all be spent on a far more effective project.

Finally, both the rule of law and corruption ratings, measured annually by the World Bank through Worldwide Governance Indicators, are important indications of the strength, freedom, fairness, lack of violence, and corruption of governments in individual nations.99 This is especially important for aid projects as political instability or corruption could easily destroy projects and wipe out any gains made. Yet, the outlook for Africa is not entirely negative. In the 2008 ratings for control of corruption, West African nation Ghana scored better than both India

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97 Ibid, p. 35
98 Osewe et al. 2008. p. 34, 38
and China and on a similar level to Italy\(^{100}\). Hopefully, these ratings can provide a way to predict and avoid countries where upheaval and corruption are likely.

Using these different methods of screening, the loan seeks to reward companies that have the greatest chance of succeeding in producing cost-effective ARVs to a large international market. By avoiding countries that are likely suspects of corruption and political violence or companies that require heavy government support, the loan also will avoid the challenges that were stated earlier. Instead, this proposed policy would simply provide enough start up capital, $2 million, for specific companies to reach economies of scale so that production can be streamlined and input costs reduced.

This $2 million figure comes from a combination of bio-equivalence costs and facility upgrades needed to reach higher capacity production. Considering that WHO bio-equivalency tests can run to $60,000 per drug produced and that production companies often try to produce between five and seven drugs in order to produce the necessary drug cocktails, costs can run upwards of $420,000 for these tests.\(^{101}\) Current domestic producers have also cited facility upgrade costs of $1 million-$2.5 million in order to reach higher capacity production\(^{102}\). Therefore, the loan would provide anywhere up to $1.5 million to upgrade facilities to increase capacity and efficiency and $500,000 in order to pass bioequivalency tests. This loan would not be too difficult for most companies to pay back, especially at a low or no interest rate. Ghana’s Danadams company, for example, had a turnover of $4.5 million in 2009 and has seen a steady increase profits since 2005.\(^{103}\) Also, considering the World Bank gave $297.2 million solely for Sub-Saharan African private sector development in 2009, this loan would be well within the means and the goals of the IDA\(^{104}\).

Should several proposals score well on the screening, it is important that the funding go to the best prospects in each region. Given the Doha Agreement’s clause, a producer in an

\(^{100}\) Ibid.

\(^{101}\) Osewe et al. 2008. p. 37

\(^{102}\) Osewe et al. 2008. p. 32

\(^{103}\) Denby and Frempong. 2009.

economic community composed of more than 50% least developed countries can produce without patents as long as more than 50% of the products are exported, the loan would be specifically looking for companies in West Africa and East Africa to satisfy the requirements. The top prospect from ECOWAS and the East African Community, should they satisfy all the requirements, would be awarded the loan. Should no company satisfy the requirements in either region, no money will be awarded and the companies can resubmit proposals each year until one company can satisfy all of the requirements.

Conclusion

Using the legal framework provided by Article 6(i) of the Doha Declaration on the TRIPS Agreement in 2003 coupled with a financial boost provided through the World Bank, African production of ARVs could increase dramatically in a very short period of time. Given the benefits of this possibility: decreased cost of the drugs produced domestically, sovereign control over a necessary product, increased regional integration and increased healthcare capacity, domestic production is something that is of great interest to countries currently crippled by the AIDS epidemic and those scrambling to meet the needs of treatment. And, while there are strong economic objections to the development of this industry, issues of dynamic comparative advantage and important social costs change the structure of this issue beyond a strictly classical economic interpretation.

The development of African domestic production could prove to be the force that changes the current issues with the inaccessibility of ARVs by reducing costs, providing a trusted source of the drugs, and increasing the confidence of people in the ability of their governments to be able to handle the challenges of HIV/AIDS. Only with a reliable plan set in place for the treatment of those with HIV/AIDS, can focus then be turned toward the necessary issue of prevention to finally bring the epidemic under control.
Sub-Saharan Africa: World Bank Announces $2 Million Loans for Development of Antiretroviral Production

WASHINGTON, December 14, 2009– The World Bank’s Board of Executive Directors today approved up to two US$2 million loans to Sub-Saharan Africa. These loans comprise the African Antiretroviral Production Development Loan.

The African Antiretroviral Production Development Loan is one of the newest parts of the World Bank’s action against the African HIV/AIDS pandemic. The program is designed to help immediately increase the capacity of African domestic production of ARVs needed to prolong the lives of those living with AIDS. The loan will be awarded to projects currently producing ARVs. It focuses on two main areas: funding for international quality recognition through WHO certification and increase of production capacity to meet the needs of the economic communities the companies are in.

Loan applicants will be screened to determine licensing, good manufacturing practices, subsidies, current capacity, and possibilities of corruption. It is targeted towards projects in the Economic Community of West African States (ECOWAS) and the East African Community (EAC). If multiple companies satisfy the loan requirements, then the loan will be awarded to the best company in each region.

The US$2 million, no interest loan is repayable in 5 years.
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