ARV Market Report

The State of the Antiretroviral Drug Market in Low- and Middle-Income Countries

ISSUE 5, December 2014

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Market Overview

Market Size and Funding Outlook

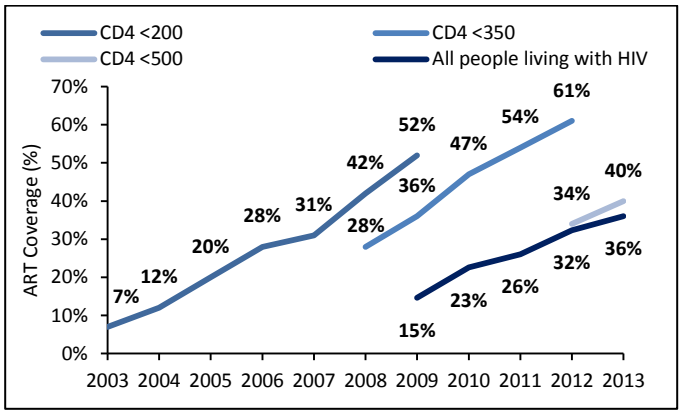
Market Size

Number of patients on ART increased by 21 percent in 2013

By the end of 2013, 11.7 million people in low- and middle-income countries (LMICs) were on antiretroviral therapy (ART).[i] This increase of 2 million from the previous year represents the largest single-year increase to date and is almost triple the number on ART just five years ago. At this pace, the target of 15 million people on ART by 2015, set in the United Nations 2011 Political Declaration on HIV/AIDS, will be reached.

An estimated 40 percent of the 29 million people eligible for ART in LMICs were on treatment in 2013,[ii] compared to 34 percent in 2012.[iii] Exhibit 1.1 shows the coverage rates since 2003 under periodically expanding eligibility criteria, as well as rates based on all people living with HIV.

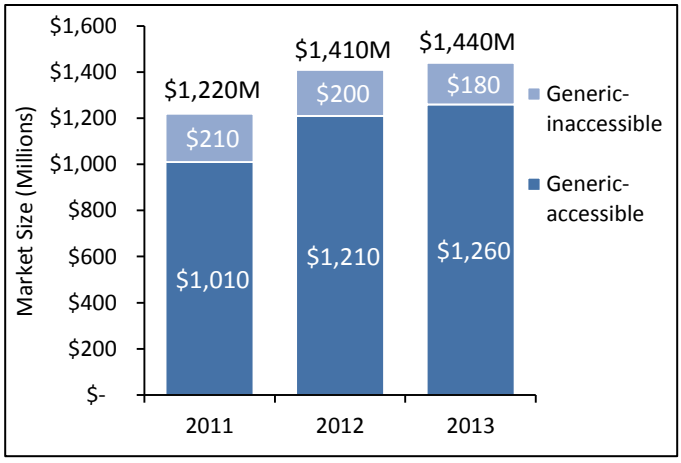
EXHIBIT 1.1: ART COVERAGE IN LMICs BASED ON EVOLVING CD4 THRESHOLDS[1]



ARV market size in LMICs was US$1.4 billion in 2013[2]

In 2013, the size of the total market for antiretroviral medicines (ARVs) in LMICs remained relatively steady at US$1.4 billion, with increased volumes offset by a reduction in prices across lines of therapy for both adults and children. Though market size remained relatively steady in 2013, additional growth is expected in future years, as patient numbers increase and some well-established drugs approach the minimum prices at which they can be produced. The market size is expected to grow to US$2 billion by 2018, even with decreased prices for certain ARVs.

EXHIBIT 1.2: ARV MARKET SIZE (USD) IN GENERIC-ACCESSIBLE VS. GENERIC-INACCESSIBLE COUNTRIES[3]



In the generic-accessible ARV market, which represents 95 percent of patients in LMICs, the total market size was US$1.3 billion in 2013. Adult first-line ARVs

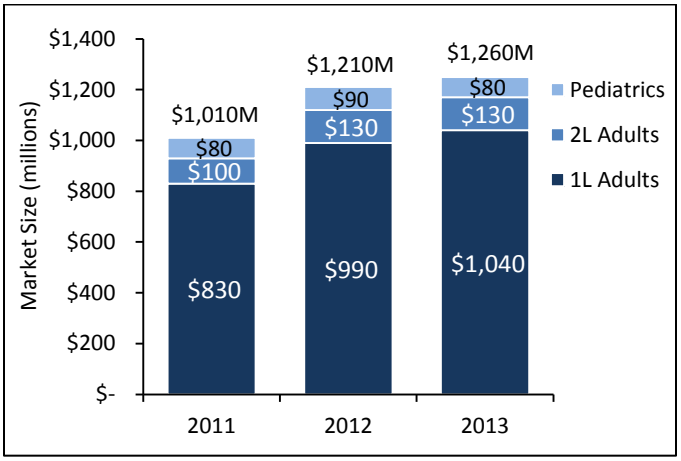
[1] Coverage rates calculated using UNAIDS treatment and population data for adults and children living with HIV with exception of 2013 LMIC coverage as reported in 2014 WHO Global Update and UNAIDS Gap Report. LMICs were classified based on World Bank income definition. Data was not available for all countries.

[2] Due to a minor change in methodology, some 2012 figures in this section may not match those cited in the 2013 ARV Market Report.

[3] 'Generic-accessibility' is a term used to denote countries in which global generic manufacturers are able to register and sell generic ARV products at considerable volumes as a percentage of the total ARV volume required by that country. The largest 'generic-inaccessible' countries are: Argentina, Brazil, China, and Mexico.

accounted for 83 percent of the total dollar value of the market, totaling US$1,040 million. Adult second-line ARVs accounted for 10 percent and pediatric ARVs accounted for 6 percent of the total dollar value. The market share distribution across first-line adults, second-line adults, and pediatrics has remained relatively steady over the past few years.[iv]

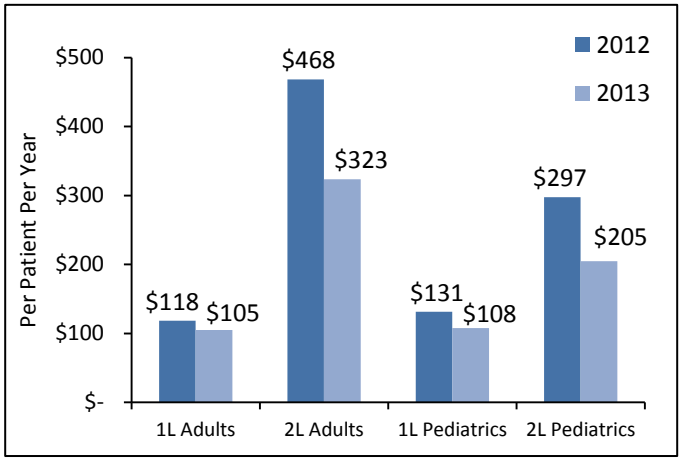
EXHIBIT 1.3: ARV MARKET SIZE (USD) IN GENERIC-ACCESSIBLE COUNTRIES[4]



The average market price in generic-accessible countries for adult first-line treatment decreased from US$118 per patient per year (pppy) to US$105 pppy, or by 11 percent.[v] This decrease was largely driven by significant price reductions for specific products, including fixed-dose combination (FDC) products containing zidovudine (AZT) or tenofovir (TDF). The average price for adult second-line treatment decreased more significantly, from US$468 pppy to US$323 pppy[vi] or by 31 percent, due mainly to price decreases for lopinavir-ritonavir (LPV/r). The average market price of LPV/r dropped 31 percent between 2012 and 2013, and is largely attributed to price competition from atazanavir-ritonavir (ATV/r). For pediatric treatment, the average price in 2013 was US$108 pppy for first-line treatment and US$205 pppy for second-line treatment. These prices represent an 18 percent and 31 percent decrease, respectively, from 2012.[vii]

Public data on ARV pricing in generic-inaccessible markets continues to be limited. As a result, the market size is estimated based on standardized pricing provided in a 2013 report published by the Pan American Health

EXHIBIT 1.4: AVERAGE MARKET PRICE (USD) FOR ARVs IN GENERIC-ACCESSIBLE COUNTRIES



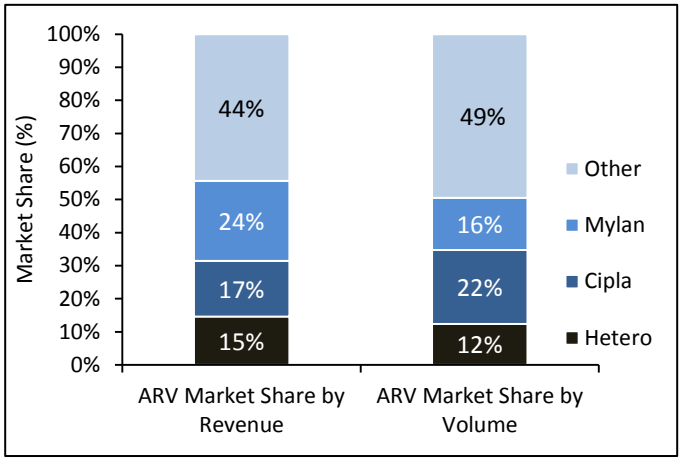
Organization (PAHO). Using those prices, CHAI estimates the generic-inaccessible market in 2013 was US$180 million, or 13 percent of the global market by revenue.[viii] A notable change in the generic-inaccessible market is that Brazil, which has historically procured ARVs almost exclusively from local manufacturers, has begun to procure an increasing share of ARVs from international generic manufacturers. In 2013, Brazil updated their ART guidelines and mandated the use of TDF, lamivudine (3TC) and efavirenz (EFV) in first-line treatment for new and existing adult patients. Since local manufacturers do not produce the FDC, the National AIDS Program initiated procurement from two international generic manufacturers. Brazil is still considered generic-inaccessible for the purposes of this report, but the classification may change in the near future depending on the portion of ARVs that Brazil procures from international generic manufacturers.

Three manufacturers garnered 56 percent of ARV revenues in LMICs

Three manufacturers (Mylan, Cipla, and Hetero) accounted for 56 percent of ARV revenues and 51 percent of ARV volume in LMICs in 2013. Mylan had the highest revenue share at 24 percent, followed by Cipla at 17 percent and Hetero at 15 percent.[ix] Exhibit 1.5 outlines the relative share of the top three manufacturers by revenue and volume. Indian generic manufacturers dominated the ARV market in 2013, capturing 70 percent of the revenue and 65 percent of

[4] Totals may not add up exactly due to rounding

EXHIBIT 1.5: ARV MARKET SHARE IN LMICs BY TOP MANUFACTURERS



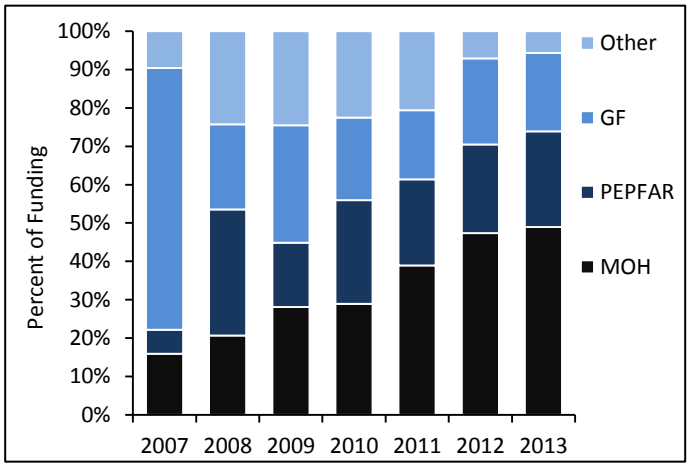
the volume in LMICs.[x] This is an increase from 2012, when they captured 66 percent of the revenue and 64 percent of the volume.[xi] Other generic manufacturers, largely from South Africa, captured 25 percent of the revenue and 33 percent of the volume in 2013, leaving just 4 percent of revenue and 1 percent of volume with innovators.[xii]

Funding Outlook

The global health community, led by UNAIDS and WHO, recently announced relevant and ambitious treatment targets to be reached by 2020: 1) 90 percent of people infected with HIV will know their status, 2) 90 percent of people diagnosed with HIV will receive effective treatment, and 3) 90 percent of people on treatment will be virally suppressed.[xiii] The 90-90-90 targets aim to mobilize governments and partners to end the AIDS epidemic as a public health threat by 2030. In sub-Saharan Africa, which represents 71 percent of all adults and children living with HIV, progress towards the targets was at 45-39-29 in 2013, far short of the ultimate goal.[xiv] A strong commitment from the global community along with more efficient financial investment is required to achieve these targets.

Spending for HIV in LMICs totaled US$19.1 billion in 2013, with domestic spending accounting for US$9.6 billion.[xv] This continues a trend, started in 2011, where domestic HIV investment exceeds international donor spending. The trend is also reflected in spending on ARVs specifically (see Exhibit 1.6). Countries like Kenya, South Africa, and Zambia have dramatically increased domestic spending in recent years.[xvi] However, while many LMICs have committed more domestic funds to HIV, several still rely on substantial support from international donors. With international donor funding projected to flat-line in the coming years,[xvii] making the most efficient use of limited financial resources is paramount.

EXHIBIT 1.6: SOURCE OF ARV FUNDING IN GENERIC-ACCESSIBLE LMICs[5]



The direct commodity costs for treating patients account for only a small proportion of available funding. For example, CHAI estimates that ARVs amounted to approximately US$1.4 billion in 2013, or 7 percent of total HIV spending. Lab commodity spending has historically been significantly less than that for ARVs; CHAI estimates that approximately US$140 million was spent on lab commodities in 2013 (not including rapid diagnostic tests). Looking forward, if the 2013 weighted average cost of ARVs across lines of therapy (approximately US$123 pppy) in LMICs[xviii] remains steady, treating all of the 29 million patients currently eligible for ART for one year would require less than US$4 billion, well within the 2013 HIV funding envelope. This suggests that scaling up treatment and diagnostics capabilities to meet the 2013 WHO guidelines and the 90-90-90 targets may not be as cost-prohibitive as is often believed. It also suggests that efficiency and optimization efforts must extend to non-commodity areas such as service delivery, health systems, technical assistance, and management and overhead costs, given the relatively small portion of overall HIV spending allocated to commodities.

[5] Global aggregate data from CHAI procurement database. 'Other' category includes UNDP and UNICEF.

Adult Market Trends

Patient Numbers, Regimen Mix, Formulation Mix, and Looking Ahead

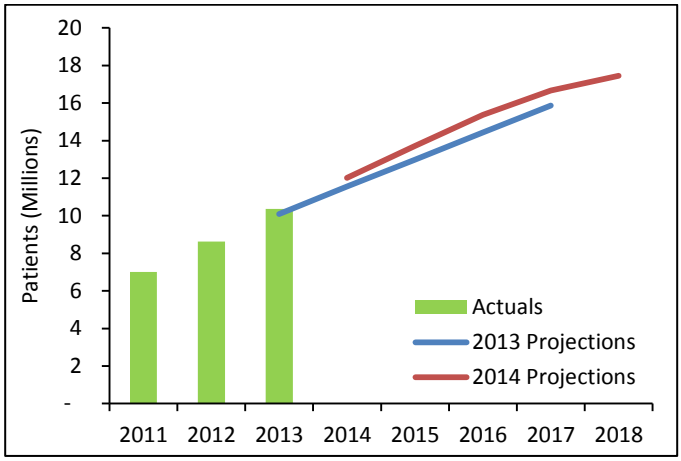
Adult Patient Numbers

In July 2013, the WHO released updated guidelines on the diagnosis, care and treatment of HIV that increased the number of adults eligible for treatment. The two key changes that affected treatment eligibility for adults were an increase in the CD4 threshold level for initiation to 500 cells/mm^3 and lifelong ART for all pregnant and breastfeeding women regardless of WHO clinical stage or CD4 cell count (Option B+). The WHO estimated that an additional 9.2 million adults became eligible for treatment in 2013 due to these changes.[xix]

As of July 2014, many high-burden countries had updated their guidelines to initiate treatment at the new CD4 threshold, including Ethiopia, Kenya, Malawi, South Africa, Swaziland, Uganda, Zambia, and Zimbabwe. The previous WHO guidelines recommended starting patients at 350 cells/mm^3 and several high-burden countries, such as Mozambique and Tanzania, are still initiating patients under that criteria. As of June 2014, 15 of the 22 Global Plan priority countries had adopted Option B+.[xx]

As countries started to adopt these new guidelines, a modest increase in adult patient scale up was observed by the end of 2013, relative to prior projections. Exhibit 2.1 shows the number of adult patients on ART through 2013, as well as patient projections developed by CHAI in 2013 and 2014. The 2013 projections were finalized shortly before the release of the WHO guidelines, and actual patient numbers in 2013 were 3 percent above the CHAI forecast. Though the difference is small, it may reflect the early impact of the expanded eligibility criteria. The 2014 projections account for this trend and reflect a 5-7 percent increase above the 2013 projections.

EXHIBIT 2.1: NUMBER OF ADULT PATIENTS ON ART, ACTUALS AND CHAI PROJECTIONS



Viral load implementation could alter second-line patient scale-up

In the 2013 guidelines, the WHO made a strong recommendation for using viral load testing to monitor the effectiveness of ART treatment in patients.[xxi] Viral load testing measures the quantity of virus in a patient's blood, and results are used by clinicians to identify potential adherence issues and to detect cases of treatment failure. In high-income countries, viral load is the standard of care for monitoring patients' response to ARVs.

Historically, the high price of viral load—ranging from US$10.50 per test to as high as US$25 dollars or more in some low-income countries—posed a significant barrier to scale up. However, this barrier was alleviated in September 2014, when Roche Diagnostics announced a global access price of US$9.40 per test, which was negotiated by South Africa in partnership with CHAI, UNAIDS, Global Fund and PEPFAR. This reduced price will make viral load testing much more affordable for countries.[xxii]

Several countries in sub-Saharan Africa, including South Africa, Namibia, and Botswana, already have strong public sector viral load programs. More recently, Rwanda, Malawi, and Kenya have begun scaling up national testing programs. A number of others have begun pilot programs or are in the process of approving national guidelines and developing a scale-up plan, propelled by the recent price reductions.

There is little data on the net impact of viral load testing on the number of patients on second-line ART, particularly at a national program level. To some extent, viral load will enable earlier detection of true treatment failure and thus result in more transitions to second-line. At the same time, viral load testing is also expected to help avoid unnecessary switching. A meta-analysis of eight studies showed that with adherence support, 70 percent of patients with detectable viral load were able to achieve re-suppression.[xxiii] Further, a study in India found that 24 percent of patients who met the WHO criteria for clinical and immunological failure were, in fact, virologically suppressed;[xxiv] without viral load testing, these patients would likely be unnecessarily switched to second line.

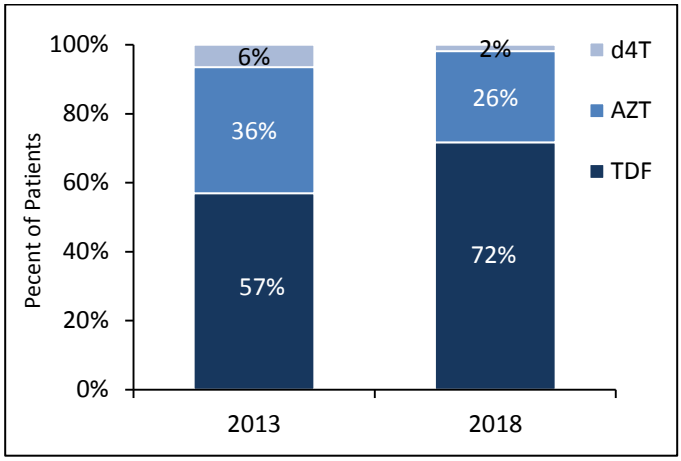
Over time, the implementation of viral load testing will likely yield a net increase in the number of patients on second-line treatment. However, given the paucity of data that currently exists at a national program level, it is difficult to robustly quantify the projected impact of viral load scale up on second-line patient numbers. CHAI will continue to monitor emerging data that could help inform this estimate.

Adult Regimen Mix

TDF share of NRTIs increased to 57 percent

For the first time, the WHO guidelines recommend TDF as the single preferred first-line nucleoside reverse transcriptase inhibitor (NRTI). Several high-burden countries made the shift to TDF as the preferred first-line in 2013, including Mozambique, Nigeria, and Tanzania. Almost all high-burden countries have now adopted TDF-based regimens as their preferred first-line regimen; exceptions include India, where AZT is used. Exhibit 2.2 shows the split between NRTIs in generic-accessible countries.

EXHIBIT 2.2: SHARE OF TOTAL ADULT NRTI MARKET IN GENERIC-ACCESSIBLE COUNTRIES



An estimated 57 percent of adult patients were on TDF in 2013, up from 46 percent in 2012. In total, across lines of therapy, almost 5.9 million patients were on a TDF-based regimen at the end of 2013 in generic-accessible countries. Compared to 3.9 million patients in 2012, this represents a 51 percent increase in the number of patients in just one year. CHAI expects this trend to continue, estimating that 12.5 million patients, or 72 percent of all adults, will be on a TDF-based regimen by 2018.

While many countries have made the transition to TDF in first line, AZT-based regimens are gaining share in second-line. Looking exclusively at second-line patients, AZT is expected to increase from 28 percent in 2013 to 59 percent in 2018. Across lines of therapy, 3.8 million patients, or 36 percent of all adults, were on AZT in 2013. CHAI estimates that by 2018, the number of adult patients on AZT across lines of therapy will increase to 4.6 million, though the share will fall to 26 percent.

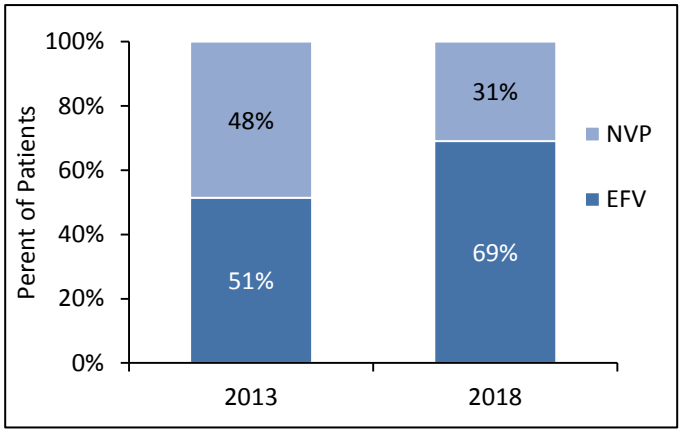
As in previous years, all high-burden generic-accessible countries have phased out stavudine (d4T) or are in the process of phasing out, with less than 700,000 patients still on d4T-based regimens in 2013. By 2018, d4T will represent only 2 percent of the NRTI market.

EFV continued to gain market share from NVP

Since the WHO updated the guidelines to recommend EFV as the preferred first-line non-nucleoside reverse transcriptase inhibitor (NNRTI) for all patients, including pregnant and breastfeeding women and women of childbearing age, there has been an increase in patients on EFV over nevirapine (NVP). In 2012, 45 percent of

adult patients in first-line were on EFV, compared to 51 percent in 2013 and a forecasted 69 percent in 2018. In total, 5.1 million patients were on EFV at the end of 2013; this is approximately 7 percent higher than CHAI's 2013 projections, which were published prior to the release of the updated guidelines. Several high-burden countries will have over 75 percent of patients on EFV by the end of 2014, including Malawi, South Africa, and Zambia.

EXHIBIT 2.3: SHARE OF FIRST-LINE ADULT NNRTI MARKET IN GENERIC-ACCESSIBLE COUNTRIES



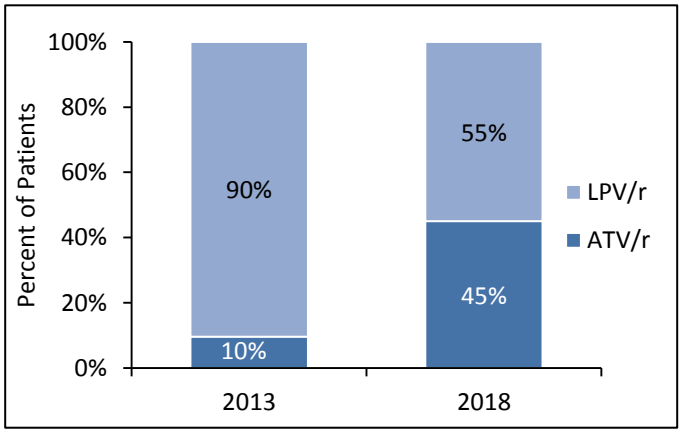
Future split between 3TC and FTC will largely depend on South Africa

Use of emtricitabine (FTC) has become very limited outside of South Africa, particularly with Zambia transitioning from FTC to 3TC in 2014. Only 13 percent of patients outside of South Africa were on FTC at the end of 2013, and that figure is expected to drop to 8 percent by the end of 2014 as Zambia continues their transition to 3TC. In South Africa, the government achieved very competitive prices for TDF-based FDC products containing FTC in their ARV contracts covering 2013-2014. As of the end of 2013, 22 percent of patients in generic-accessible countries were on FTC, with 54 percent of patient volumes coming from South Africa. However, as South Africa prepares for their next tender and advertises for both 3TC and FTC, there is some question about the extent of FTC utilization beyond 2014.

ATV/r use in second line continues to grow

Although LPV/r remains the dominant protease inhibitor (PI) in second line, use of ATV/r continues to grow and is expected to show significant uptake in the coming years as more countries procure and initiate second-line patients on ATV/r. At the end of 2013, 10 percent of second-line patients were on ATV/r, up from 6 percent in 2012. By 2018, ATV/r use is expected to increase to 45 percent of all second-line patients. Several early adopters such as India and Zimbabwe already have over 80 percent of second-line patients on ATV/r, while Malawi has transitioned nearly 95 percent of patients. In addition, several high-burden countries began to initiate patients on ATV/r in 2013, including Ethiopia, Lesotho, and Tanzania. By 2018, CHAI expects approximately 390,000 patients to be on ATV/r in generic-accessible countries. South Africa has also advertised for ATV/r along with LPV/r in their latest tender, which could potentially alter the second-line market dramatically.

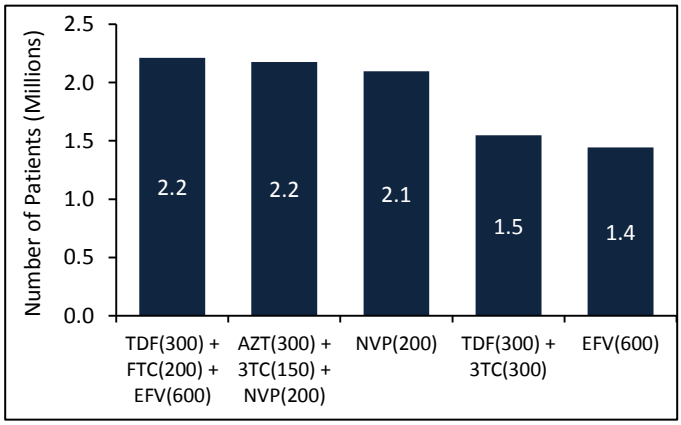
EXHIBIT 2.4: SHARE OF SECOND-LINE ADULT PI MARKET IN GENERIC-ACCESSIBLE COUNTRIES



Adult Formulation Mix

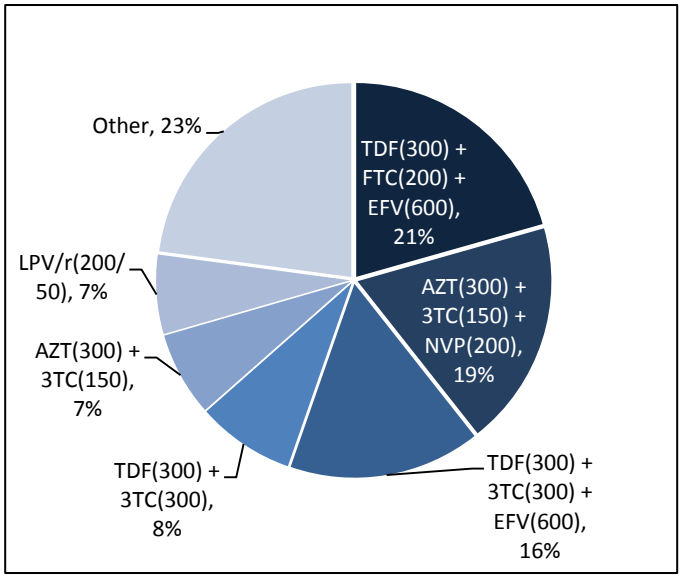
In 2013, the top five adult formulations by volume were the TDF+FTC+EFV triple FDC, AZT+3TC+NVP triple FDC, NVP singles, TDF+3TC dual FDC, and EFV singles (Exhibit 2.5). Approximately 77 percent of all adults were on at least one of these formulations at the end of 2013.

EXHIBIT 2.5: TOP FIVE ADULT FORMULATIONS BY PATIENT VOLUME IN GENERIC-ACCESSIBLE COUNTRIES



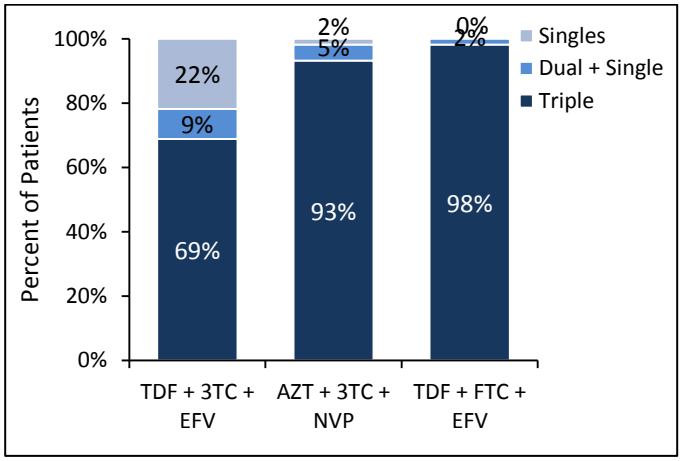
The TDF+FTC+EFV triple FDC represents the largest share of the market by revenue (Exhibit 2.6). This is largely driven by the high patient volumes in South Africa, which represents 24 percent of adult patients on treatment, though market share for the triple may decrease significantly if South Africa shifts to FDCs containing 3TC as a result of their tender. The other top formulations by revenue are also FDCs. Although NVP and EFV singles are part of the top five formulations by patient volume, they are procured at lower prices and thus represent lower revenue as single formulations.

EXHIBIT 2.6: 2013 TOP ADULT FORMULATIONS BY REVENUE



There are three main adult regimens where a triple FDC is available for use in generic-accessible countries: TDF+3TC+EFV, TDF+FTC+EFV, and AZT+3TC+NVP. In each of these cases, the majority of patients are on the triple FDC as opposed to the dual or singles (Exhibit 2.7). This is a signal that countries have clearly prioritized reduction of pill burden and convenience in procuring ARVs. That said, there are still a significant portion of patients who are on the dual TDF+3TC FDC as opposed to the triple. This occurrence is potentially explained by the price premium of the triple over the dual plus single formulations; in 2013, the average market price for the triple was US$137 pppy, compared to US$94 pppy for the dual plus single EFV. Furthermore, 22 percent of patients on the TDF+3TC+EFV regimen are on all single formulations. These patients are primarily in South Africa, where the TDF+3TC+EFV triple FDC is not procured.

EXHIBIT 2.7: 2013 ADULT REGIMENS BY FORMULATION



Looking Ahead

Several new products will be considered for the 2015 WHO guidelines, with other promising options not far behind

The global community is coalescing around a short list of products that have shown superior or non-inferior efficacy compared to existing alternatives but also offer improved durability and tolerability, higher bioavailability, lower pill burden, and the potential for lower frequencies of adverse events. These include lower-dose TDF, tenofovir alafenamide fumarate (TAF), lower-dose EFV, dolutegravir (DTG), and darunavir (DRV), as well as the potential to develop FDCs of existing and new products. Market entry and uptake of these products could dramatically alter the landscape for adult HIV treatment in the coming years.

As a potential improvement to TDF, CHAI is developing a dosage form called TDF(xb) that would be significantly more bioavailable than existing formulations. As a result, TDF(xb) would be as efficacious as TDF but less expensive due to a reduction in the amount of active pharmaceutical ingredient (API) required. CHAI estimates that an FDC containing TDF(xb) and 3TC could become available for use in LMICs in late 2017.

TAF is another potential alternative to TDF. TAF is a tenofovir prodrug that offers high antiviral efficacy and an improved renal and bone safety profile at much lower doses than TDF.[xxv] Clinical trials are underway to compare the efficacy and safety of TAF versus TDF when used in combination with FTC; the outcomes may catalyze the development and eventual use of FDCs containing TAF in LMICs. The earliest that a TAF FDC is

expected to be available in generic-accessible markets is 2019 or 2020.

Once TDF(xb) and TAF are available in generic-accessible markets, most if not all patients who would have otherwise been on TDF 300mg are expected to transition to one of these two products. Under this premise, by 2022, there could be almost 13 million adult patients on an alternative tenofovir product. Because of TAF's superior profile and lower expected price, it will eventually represent the highest share of patients.

Lower-dose EFV will play an important role in adult first-line therapy. ENCORE, a Phase III clinical study, showed that EFV 400mg was non-inferior to EFV 600mg, and suggested that adverse events and discontinuations would be reduced. The WHO has indicated that EFV 400mg will be considered for inclusion in the 2015 guidelines for use in first-line treatment. Pharmacokinetic (PK) studies in pregnant women and TB co-infected patients are being planned. If the results show an insignificant change in EFV levels, the WHO should be able to suggest guidelines without restrictions. Several generic companies have initiated development of a product containing EFV 400mg.

DTG is an integrase inhibitor that was approved by the US FDA in 2013. It has shown non-inferiority or superiority, with better tolerability, than EFV and PIs.[xxvi] DTG could be used in second-line therapy and eventually in first-line therapy for LMICs. In April 2014, ViiV Healthcare announced a new agreement with Medicines Patent Pool (MPP) to accelerate access to DTG in developing countries.[xxvii] DTG is currently only available through ViiV as a single tablet or as a FDC with abacavir (ABC) and 3TC, though generic products are now in the early stages of development. The WHO has indicated that DTG is being considered for inclusion in the 2015 guidelines.

Both EFV 400mg and DTG have the potential to completely replace EFV 600mg in first-line treatment for adults. By 2022, this could amount to 11.9 million adults in generic-accessible countries.

Darunavir (DRV) is a PI that can be used in place of LPV or ATV. The combination of darunavir and ritonavir (DRV/r) is being considered for the 2015 WHO guidelines as a second-line treatment option. The 2013 WHO guidelines already recommend DRV/r as an alternative second-line regimen, but it is currently not available as a heat-stable fixed-dose combination. In addition, the high cost of DRV/r remains a barrier to access in LMICs. In terms of safety and efficacy, DRV/r has shown superiority or non-inferiority over other PIs in multiple clinical trials.[xxviii] If an FDC is developed and made available at a competitive price, DRV/r has the potential to play an important role in the second-line market given its high tolerability, potency, and favorable resistance profile.

Highly commoditized ARVs are unlikely to see future price decreases

Given the funding limitations for HIV/AIDS care and treatment and the growing number of patients requiring lifesaving ARVs in LMICs, it is becoming increasingly important to maximize the value for money in delivering effective treatment to patients. However, although dramatic price decreases have been achieved for ARVs over the past decade, these trends are not expected to continue for highly commoditized ARVs, such as AZT, 3TC, and NVP, unless new, lower cost API manufacturing processes for these products are discovered, developed and implemented.

For all ARVs, there is a fundamental minimum price at which a product can be made and sold. At some point, significant price reductions will no longer result from increases in market volumes, greater efficiencies in product manufacturing, greater competition, or other factors. Some mature ARVs, including AZT and d4T, are already in this portion of their lifecycle. For highly commoditized products such as these, the largest factor influencing product price may be inflationary pressures, leading to possible price increases in the future.

New manufacturing regulations in China may also impact pricing for highly commoditized products. In the past 12 months, the Chinese government has increased environmental requirements for solid and liquid waste, as well as for emissions. To meet these requirements, Chinese manufacturers across the board have had to increase capital expenditure and operating costs. In some cases, manufacturers have had to decrease production or halt operations altogether. The costs associated with these regulations further lower the likelihood of price decreases for highly commoditized products.

Pediatric Market Trends

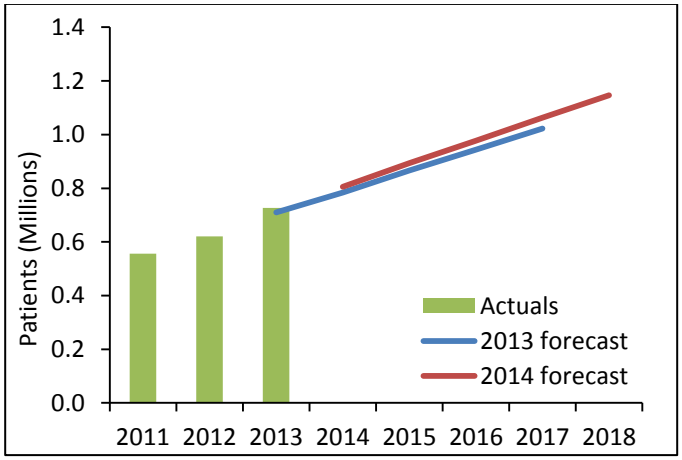
Patient Numbers, Regimen Mix, Formulation Mix, and Looking Ahead

Pediatric Patient Numbers

The 2013 WHO guidelines recommend initiating treatment for all HIV-positive children below 5 years of age, regardless of WHO clinical stage or CD4 cell count. The previous guidelines recommended treatment for all children below 2 years; with this change, 1.2 million additional children became eligible for ART. Several countries have since adopted the new guideline, though the impact on patient numbers by the end of 2013 appeared to be small.

Exhibit 3.1 shows the number of children on ART through 2013, as well as patient projections developed by CHAI in 2013 and 2014. The 2013 projections were finalized shortly before the release of the WHO guidelines, and actual patient numbers in 2013 were only 2 percent above the CHAI forecast. Although the difference is small, it may reflect the early impact of the expanded eligibility criteria. The 2014 projections account for this trend and reflect a 2-4 percent increase above the 2013 projections. Official patient numbers for the end of 2014 will give a better sense of the extent to which the guidelines have impacted scale up.

EXHIBIT 3.1: NUMBER OF PEDIATRIC PATIENTS ON ART, ACTUALS AND CHAI PROJECTIONS



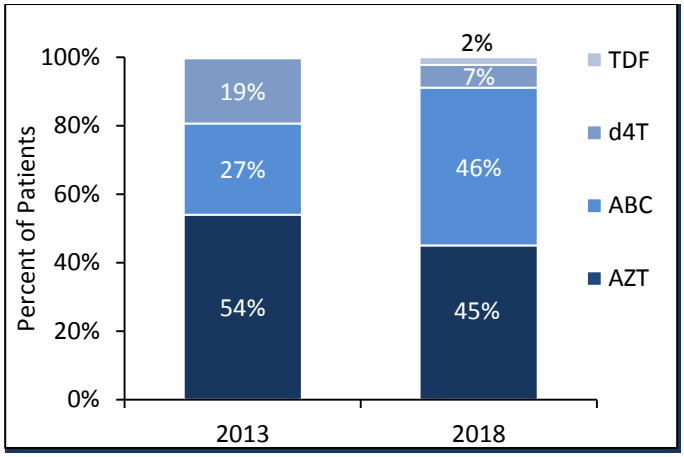
At the end of 2013, 740,000 children were on ART in LMICs, corresponding to a coverage rate of 23 percent of children living with HIV.[6] As has historically been the case, this is much lower than the coverage rate for adults, which was 37 percent among those living with HIV in 2013.[xxix] By 2018, CHAI estimates that the number of children on ART will grow to 1.2 million.

Pediatric Regimen Mix

AZT is the predominant NRTI, but ABC will gain market share

The WHO guidelines recommend ABC or AZT for children younger than 3 years of age, ABC for children 3-10 years old, and TDF for children over 10 years. Exhibit 3.2 shows the split between NRTIs for children in generic-accessible countries.

EXHIBIT 3.2: SHARE OF TOTAL PEDIATRIC NRTI MARKET IN GENERIC-ACCESSIBLE COUNTRIES



An estimated 54 percent of children were on AZT in 2013, up from 47 percent in 2012. Many generic-accessible countries have maintained AZT as their preferred first-line pediatric NRTI, driven by the

[6] The number of children on ART has continued to increase, but the coverage rate appears lower than in past years because it is based on all children living with HIV, rather than the proportion eligible for treatment.

availability of an AZT+3TC+NVP triple FDC dispersible tablet, as well as a lower price compared to ABC.

Though AZT is currently the dominant pediatric NRTI, use of ABC is expected to increase over the next five years. In 2013, 27 percent of children were on ABC, with the majority of those children (71 percent) located in Kenya and South Africa. In the coming years, the share of ABC will increase as additional countries, including Uganda and Zambia, transition to ABC. By 2018, the pediatric NRTI market is expected to be almost evenly split between ABC and AZT.

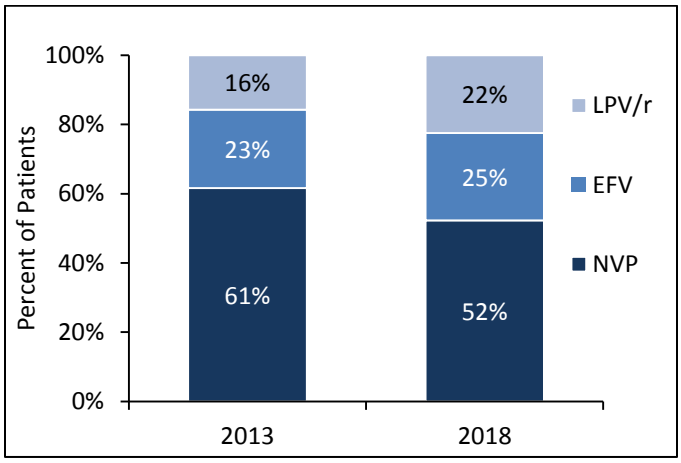
The share of d4T continued to decline in 2013, with 19 percent of children on a d4T-based regimen, compared to 27 percent in 2012, and 39 percent in 2011. While the current projections estimate a gradual phase-out of d4T to 7 percent of total market share by 2018, these projections represent the demand-side perspective of the d4T market. However, recent supply constraints for pediatric d4T-based FDCs have led to uncertainty about future projections. Countries that still have children on d4T may need to expedite phase-out due to the substantial supply disruptions that exist (and are likely to continue) with the dual and triple pediatric d4T-based FDCs.

Following the WHO recommendation of TDF as the preferred NRTI backbone for the treatment of adolescents, several countries, including Ethiopia, Malawi, Nigeria, and Zimbabwe, adopted TDF in their guidelines for children over 35kg. Zambia also adopted TDF, though extended the recommendation to include all children over 5 years of age. While adult TDF formulations can be used for children over 35kg, children in lower weight bands must use one of three available pediatric formulations (all of which are only available from the innovator): TDF 40mg scoop, TDF 150mg, and TDF 200mg; a child-friendly FDC is not yet available. Overall, the role of TDF in pediatric treatment in LMICs is expected to be minor, making up only 2 percent of demand by 2018.

NVP use will remain high among children

Although the WHO guidelines recommend LPV/r in first-line ART for all children younger than 3 years of age, challenges persist with providing the cold chain capacity required to transport and store LPV/r syrup. As a result, NVP has maintained high market share, bolstered by the availability of the AZT+3TC+NVP triple FDC, which provides significant advantages in terms of price and adherence. In 2013, an estimated 61 percent of children were on NVP.

EXHIBIT 3.3: SHARE OF TOTAL PEDIATRIC NNRTI AND PI MARKET IN GENERIC-ACCESIBLE COUNTRIES



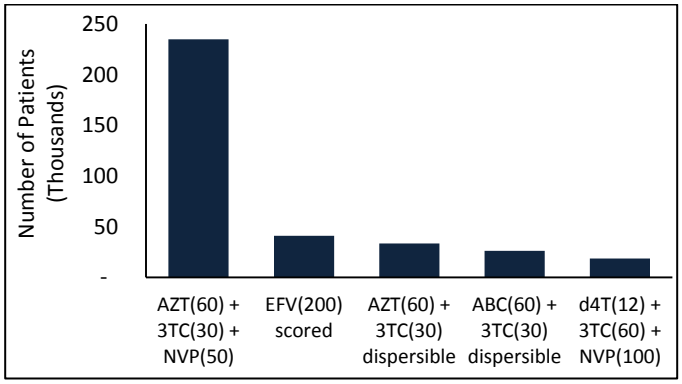
LPV/r formulations were used for 16 percent of children. South Africa remains the major driver of LPV/r volumes, and accounted for 54 percent of the demand in generic-accessible countries in 2013. Uptake of LPV/r is expected to increase in several countries over the next five years, most notably in Zambia, which is transitioning from NVP to LPV/r for children younger than 3 years of age. EFV share is projected to remain steady over the next five years.

Pediatric Formulation Mix[7]

In 2013, the top pediatric formulation by volume, as well as by revenue, was the AZT+3TC+NVP triple FDC. An estimated 32 percent of pediatric patients in generic-accessible countries used this formulation in 2013 (or 41 percent of patients outside of South Africa). Exhibit 3.4 shows the patient volume for the top five pediatric formulations, including the triple FDC. Although South Africa accounts for a high proportion of pediatric patients, it is an outlier in terms of its formulary given its high use of syrups and singles and thus was excluded from the analysis of top formulations. Overall, approximately 49 percent of pediatric patients in generic-accessible countries (62 percent excluding South Africa) were on at least one of these top five formulations in 2013.

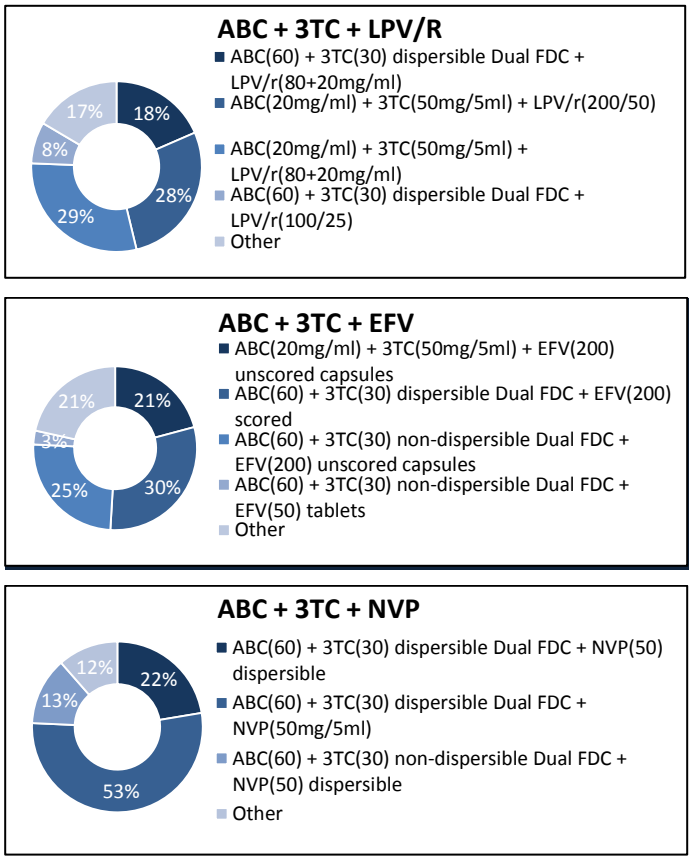
[7] Adult formulations used in pediatric patients were excluded from the analyses in this section.

EXHIBIT 3.4: TOP FIVE (EX-RSA) PEDIATRIC FORMULATIONS BY PATIENT VOL. IN GENERIC-ACCESSIBLE COUNTRIES[8]



While the vast majority of pediatric patients on the AZT+3TC+NVP regimen use the triple FDC formulation, fragmentation issues remain for other regimens. Exhibit 3.5 illustrates the formulation split for three of the highest-volume regimens.

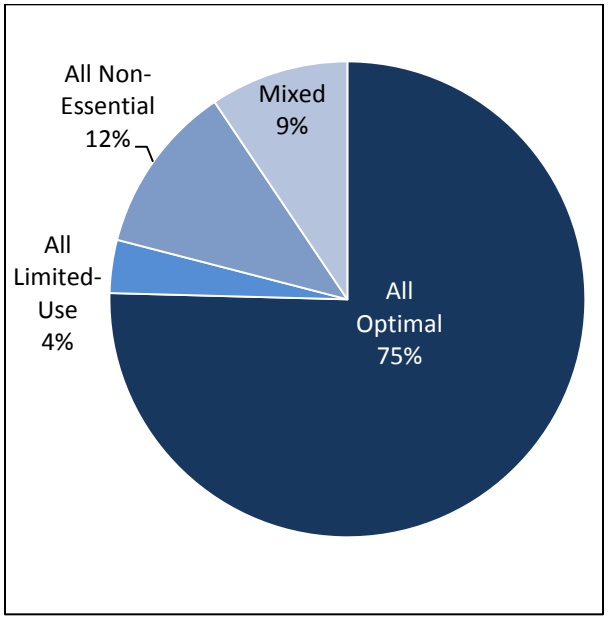
EXHIBIT 3.5: BREAKDOWN OF FORMULATIONS FOR HIGH-VOLUME PEDIATRIC REGIMENS[9]



The Interagency Task Team on Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and their Children (IATT) developed a list of preferred pediatric formulations in an effort to improve pediatric ARV supply security by consolidating the market around a limited number of key products that offer the highest standard of care for children of all ages on first- and second-line treatment. A revised list was released in 2013 to complement the updated WHO guidelines.[xxx] Products are categorized as "optimal," "limited use," or "non-essential."

By applying the IATT stance for each formulation used within a regimen, CHAI estimated the percentage of pediatric patients that are on regimens comprised of all optimal, all limited-use, or all non-essential formulations, as well as those where the regimen contained a mix of two or more categories (see Exhibit 3.6). The analysis focused on the approximately 377,000 children that are on regimens that contain only IATT-reviewed products (therefore excluding adult and non-reviewed products). Of those, it is encouraging to note that three-quarters of the children were exclusively on optimal formulations in 2013. Furthermore, four of the top five pediatric formulations by patient volume (reported in Exhibit 3.4) are optimal formulations.

EXHIBIT 3.6: BREAKDOWN OF IATT-REVIEWED FORMULATIONS WITHIN PEDIATRIC REGIMENS[10]



[8] South Africa is not included in the analysis of top five formulations; South Africa does not procure any of the five formulations.
[9] Graph includes South Africa volumes.
[10] Graph includes South Africa volumes.

As countries optimize their pediatric formularies and consolidate around a limited number of preferred products, including a shift from syrups and singles to dual and triple FDCs, procurement benefits may emerge, such as shorter lead times, lower shipping costs, and easier supply chain management. Also, the shift to optimal formulations should give suppliers greater confidence in entering the pediatric ARV market, since volumes for preferred products will be higher and more predictable. This will, in turn, support supply security for those products. This trend is already occurring, with additional suppliers recently receiving Stringent Regulatory Authority approval for AZT- and ABC-based FDCs that are considered optimal by the IATT.

Looking Ahead

Pediatric treatment continues to lag, but new efforts could accelerate scale up

As in previous years, a disparity in ART coverage persists between children and adults, with 23 percent coverage among children living with HIV versus 37 percent coverage for adults in 2013.[xxxi] Challenges with identifying and testing HIV-exposed children, and initiating and retaining treatment for those that test positive, have proven to be formidable constraints to scale up. Today, only 44 percent of HIV-exposed infants are tested by two months of age[xxxii] and less than half of children that test positive are initiated onto treatment.[xxxiii] However, emerging diagnostic products and new programmatic efforts could help accelerate pediatric treatment scale up in the coming years.

One of the challenges with early infant diagnosis (EID) is that current diagnostic products require transport of dried blood spots from the testing facility to centralized laboratories, thus requiring patients to return to the facility to collect their results; this process is highly susceptible to loss to follow up. Point-of-care (POC) products that deliver test results at the facility could significantly mitigate this loss, and ensure timely diagnosis and treatment initiation for infected children. Several POC EID devices will soon be available on the market, including those described in UNITAID's HIV/AIDS Diagnostics Technology Landscape document.[xxxiv]Although WHO has not significantly changed normative guidance on EID in several years, it will likely consider alternative testing algorithms and strategies for their 2015 guidelines.

In addition, several recently launched global initiatives are working to provide programmatic support needed to accelerate scale up. In August 2014, PEPFAR and the Children's Investment Fund Foundation (CIFF) announced the Accelerating Children's Treatment Initiative, which aims to double the number of children on treatment in ten sub-Saharan African countries,[11] thereby enabling 300,000 more children to receive ART. In December 2013, the Double Dividend, a collaboration between UNICEF, WHO, and the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), was launched in order to accelerate action toward the dual goals of ending pediatric HIV and improving childhood survival. In addition to these new efforts, partners such as UNAIDS, UNITAID, ELMA Foundation, and the Global Fund are continuing to play an important role in scale-up efforts. Coordination among partners at the global level will be critical to ensure that goals are aligned and resources are used efficiently. These initiatives and increased coordination will redouble efforts to improve access to pediatric HIV testing and increase the number of children on treatment.

The PAPWG continues to improve pediatric ARV market dynamics

The Pediatric ARV Procurement Working Group (PAPWG) was established by the Global Fund Board in 2011 to support a coordinated approach to the procurement of pediatric ARVs. The group is comprised of major financiers and procurers of pediatric ARVs, as well as technical bodies collaborating to improve pediatric ARV supply. The group made progress in several key areas in 2014, and continues to expand their activities to further secure the pediatric ARV market and minimize supply disruptions. Interested parties are encouraged to visit the PAPWG web page[12] for additional information about the group, including current and future activities.

[11] Cameroon, Côte d'Ivoire, Democratic Republic of Congo, Kenya, Lesotho, Malawi, Mozambique, Tanzania, Zambia, and Zimbabwe.
[12] http://www.theglobalfund.org/en/procurement/updates/2014-08-13_Update_on_Paediatric_ARV_Procurement_Working_Group/

New child-friendly formulations are in development, but more needs to be done

LPV/r oral pellets (40mg/10mg) from Cipla received Expert Review Panel (ERP) approval in September 2014, though production is yet to begin. The new formulation can be used for young children and offers benefits over syrups – including easier storage and transportation – because it does not require refrigeration. Early adopters may include countries without cold chain capabilities, and with a significant number of children on ART who are younger than 3 years old. Pediatric TDF-based FDC formulations are in development. In addition, there remains a strong interest in and need for development of a pediatric ABC+3TC+EFV triple FDC, as well as a need to begin development for pediatric formulations of the newer drugs discussed in the Adult Market Trends section, such as TAF, DTG, and DRV/r.

Appendix A

The graphs below show the estimated generic-accessible patient demand and API volume forecast for key adult ARVs. Note that all figures are based on demand for adults only. Patient years represent the average number of patients on treatment for a full year.

EXHIBIT 4.1: TDF

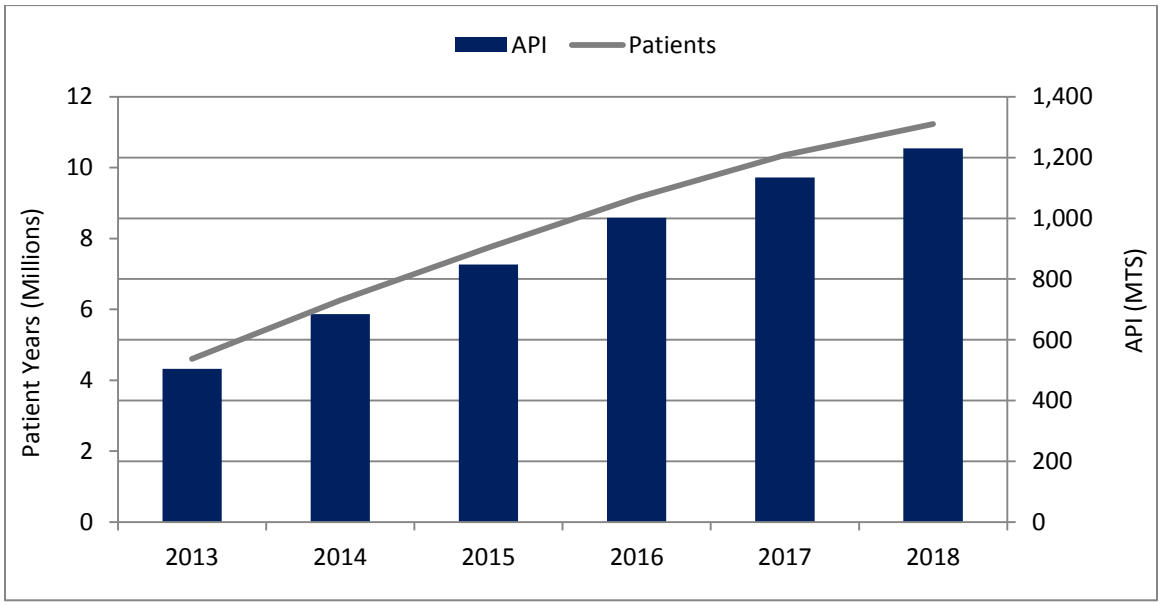


EXHIBIT 4.2: AZT

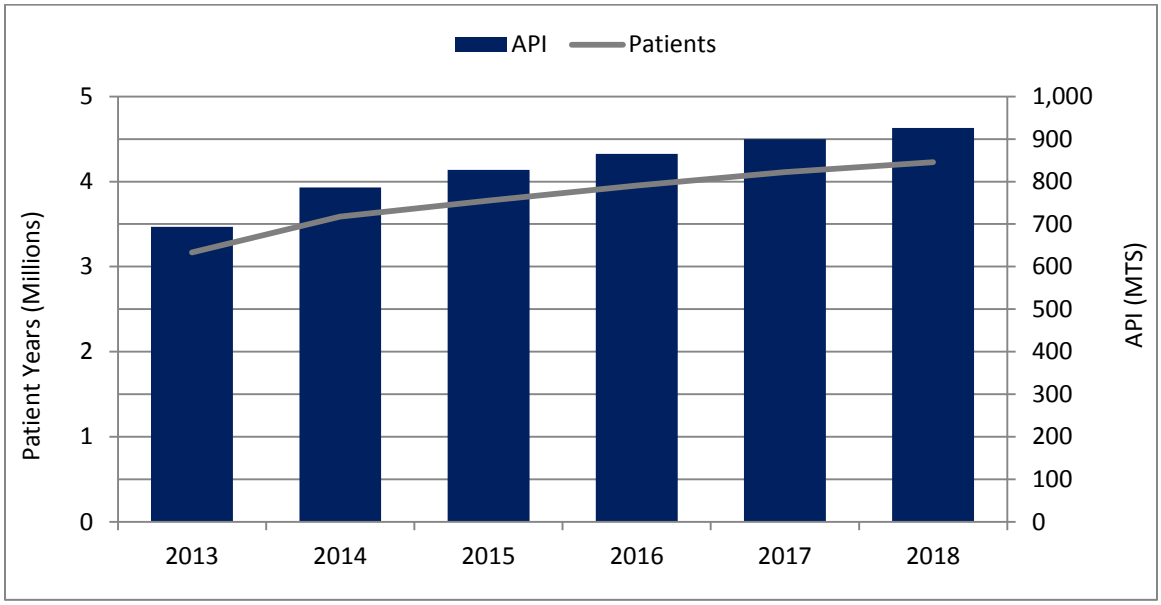


EXHIBIT 4.3: 3TC

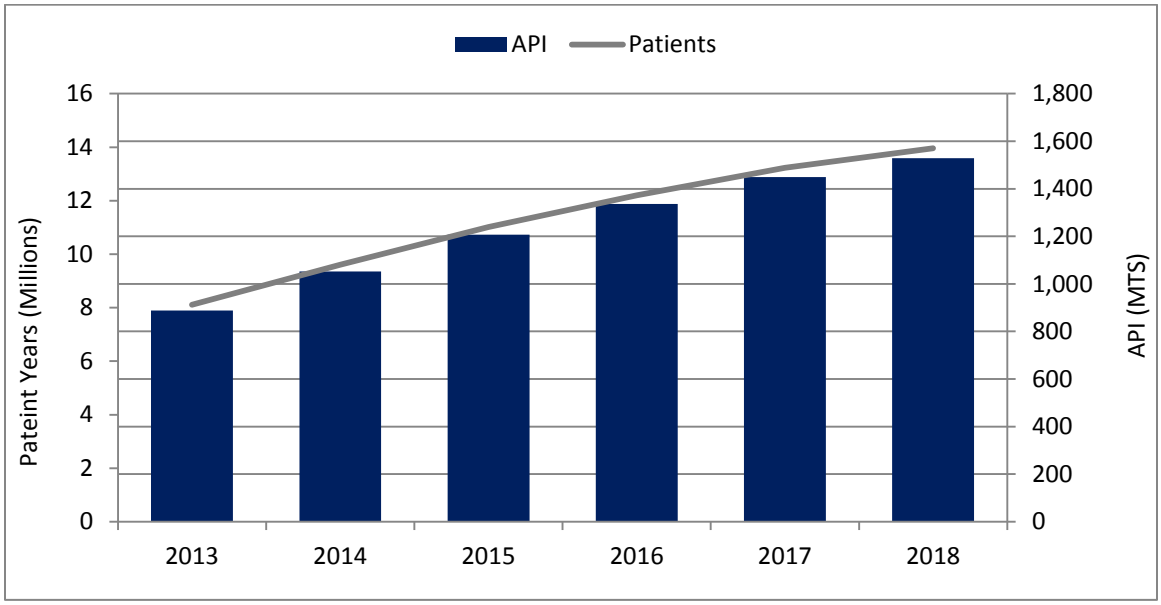


EXHIBIT 4.4: EFV

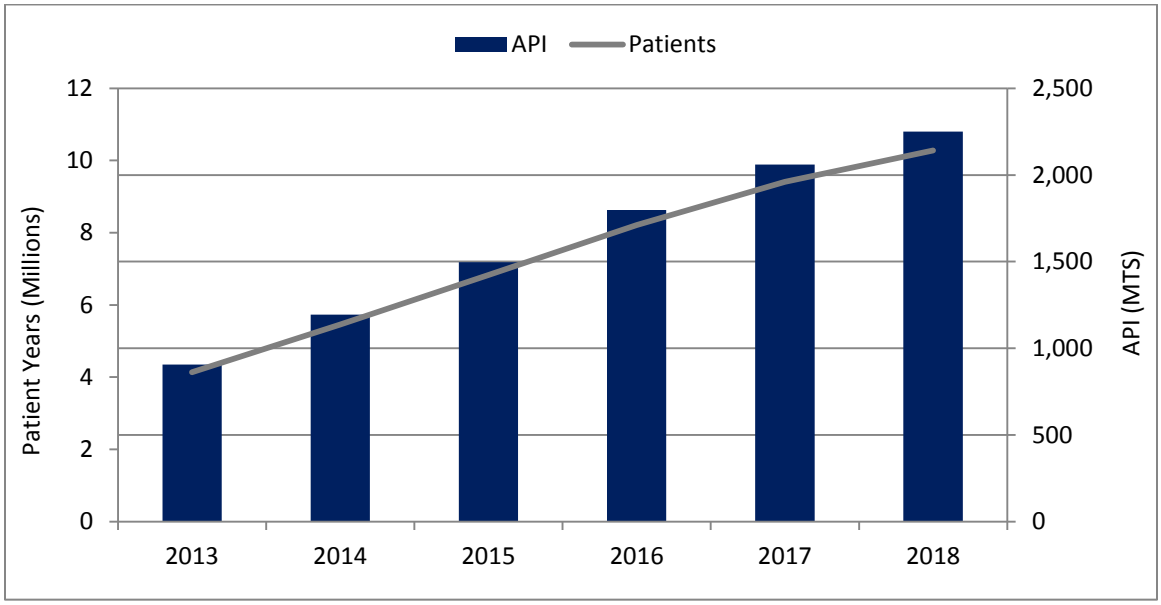


EXHIBIT 4.5: NVP

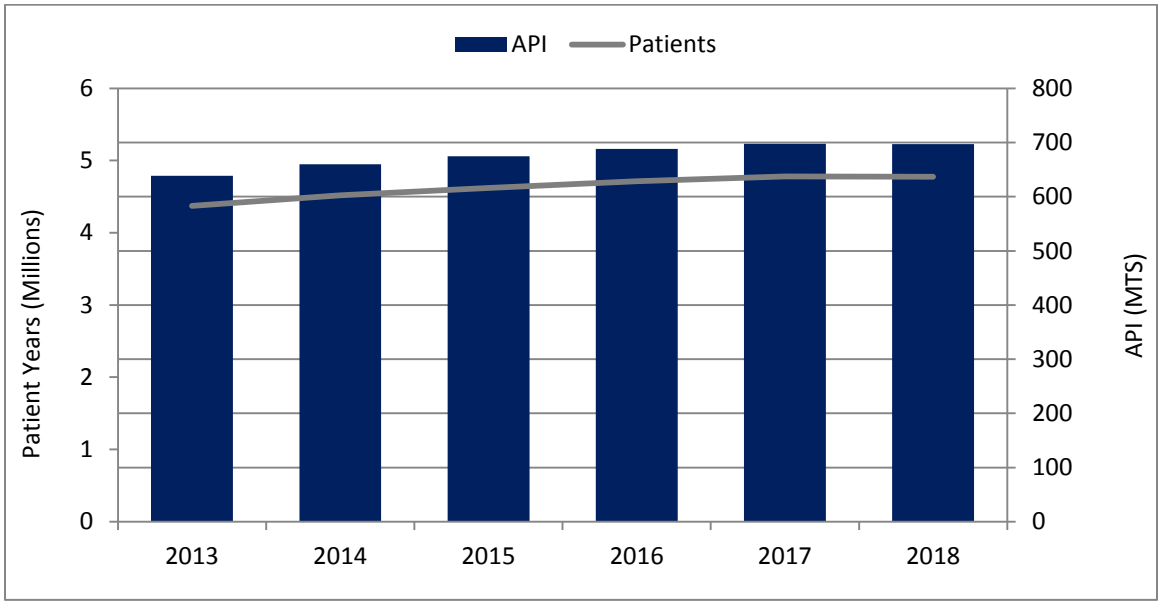


EXHIBIT 4.6: LPV

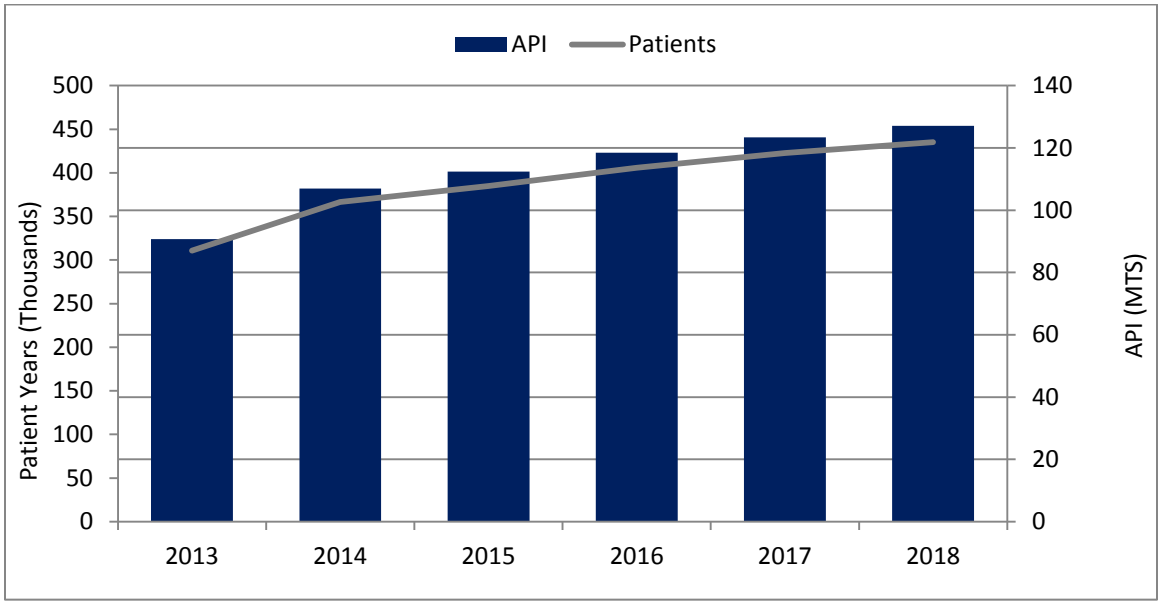


EXHIBIT 4.7: ATV

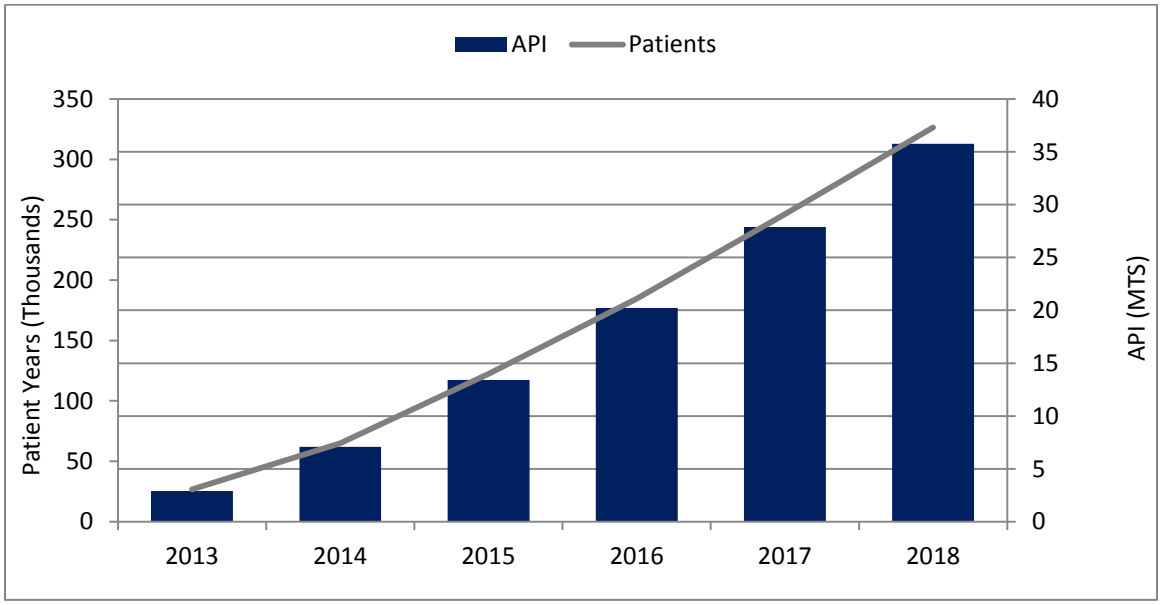
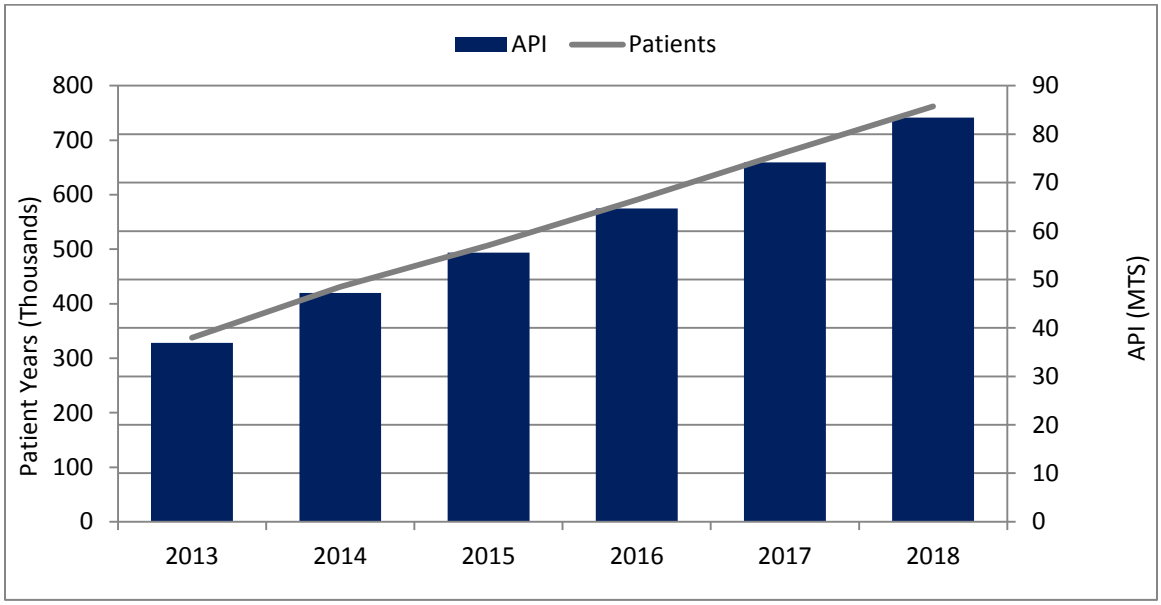


EXHIBIT 4.8: RTV



Appendix B

*IATT List of Optimal Pediatric Products**			
Product	**Dosage**	**Formulation**	**Stance**
ABC + 3TC	60/30mg	Tablet (dispersible, scored)	Optimal
ABC + 3TC + AZT	60/30/60mg	Tablet (non-dispersible, scored)	Optimal
AZT + 3TC	60/30mg	Tablet (dispersible, scored)	Optimal
AZT + 3TC + NVP	60/30/50mg	Tablet (dispersible, scored)	Optimal
EFV	200mg	Tablet (scored)	Optimal
LPV/r	100 mg/25mg	Tablet (heat stable)	Optimal
LPV/r	80/20mg/ml	Oral liquid	Optimal
NVP	50mg	Tablet (dispersible, scored)	Optimal
AZT**	50/5mg/ml	Oral liquid	Optimal
NVP**	50/5mg/ml	Oral liquid	Optimal

*Reflects current IATT list, as revised in the second half of 2013.
** For infant prophylaxis as part of PMTCT.

Appendix C

The reference price list below provides prices for key adult and pediatric ARVs included in CHAI's 2013 Ceiling Price list. Prices are based on the latest available data from a variety of sources, as noted below.

Reference Price List					
Adult Products	**SCMS price (USD) November 2014**[xxxv]	**CHAI 2013 price (USD)**[xxxvi]	**MSF (USD) July 2014**[xxxvii]	**GPRM price (median, USD) November 2014**[xxxviii]	**2013-14 RSA contracts (USD): Lowest Price**[xxxix]
3TC(150)	$1.74	$2.40	$1.98	$2.02	$1.08
ABC(300)	$11.09	$14.00	n/a	$12.42	$7.44
AZT(300)	$5.43	$6.50	$5.64	$5.76	$3.27
AZT(300) + 3TC(150)	$6.52	$7.60	$6.48	$6.94	$4.96
AZT(300) + 3TC(150) + NVP(200)	$8.11	$9.20	$8.22	$8.24	n/a
d4T(30)	n/a	$2.00	n/a	$1.57	n/a
d4T(30) + 3TC(150)	$2.49	$3.75	$3.12	$2.64	n/a
d4T(30) + 3TC(150) + NVP(200)	$4.32	$6.58	$4.74	$4.36	n/a
EFV(600)	$3.12	$4.00	$3.09	$3.37	$2.18
LPV/r(200/50)	$18.90	$25.00	$20.04	$20.76	$12.81
NVP(200)	$2.18	$3.00	$1.80	$2.28	$1.35
RTV(100) heat-stable	n/a	$7.50	$7.29	$14.30	$5.12
TDF(300)	$3.55	$4.50	$2.13	$5.12	$2.11
TDF(300) + 3TC(300)	$4.62	$5.50	$4.65	$4.66	$3.47
TDF(300) + FTC(200)	$5.74	$6.25	$5.79	$6.14	$3.80
TDF(300) + 3TC(300) + EFV(600)	$10.15	$10.90	$11.16	$11.30	n/a
TDF(300) + FTC(200) + EFV(600)	$10.51	$13.00	$11.76	$12.28	$6.50
ATV(300)/RTV (100)	$20.00	$20.00	$20.01	$20.28	n/a
ATV(300)/RTV (100) + TDF/3TC (300/300mg)	n/a	$25.50	n/a	n/a	n/a

Pediatric Products	**SCMS price (USD) November 2014**[xxxv]	**CHAI 2013 price (USD)**[xxxvi]	**MSF (USD) July 2014**[xxxvii]	**GPRM price (median, USD) November 2014**[xxxviii]	**2013-14 RSA contracts (USD): Lowest Price**[xxxix]
3TC(50mg/5ml)	$1.43	$1.85	$1.92	$2.21	$0.85
ABC(20mg/ml)	$6.83	$13.50	$8.64	$11.54	$3.40
ABC(60mg)	$5.50	$5.20	$4.98	$10.14	n/a
ABC(60) + 3TC(30) disp.	$3.95	$7.00	$3.96	$9.13	n/a
AZT(50mg/5ml)	$1.99	$2.10	$2.40	$6.39	$1.16
AZT(100mg)	$4.70	$4.75	$4.60	$2.76	$2.82
AZT(60) + 3TC(30) disp.	$1.99	$3.00	$1.98	$4.36	n/a
AZT(60) + 3TC(30) + NVP(50) disp.	$3.60	$4.00	$3.60	$7.89	n/a
d4T(1mg/ml)	$1.30	$1.40	n/a	$2.28	$0.85
d4T(15mg)	n/a	$1.40	n/a	$1.48	$0.91
d4T(20mg)	n/a	$1.45	n/a	$1.59	$1.04
d4T(6mg) + 3TC(30mg)	$1.90	$1.90	$1.98	$3.85	n/a
d4T(12mg) + 3TC(60mg)	$3.30	$3.30	$3.30	$2.10	n/a
d4T(6mg) + 3TC(30mg) + NVP(50mg)	$2.30	$2.30	$2.34	$4.66	n/a
d4T(12mg) + 3TC(60mg) + NVP(100mg)	$4.30	$4.30	$4.32	$3.87	n/a
EFV(50mg)	$2.24	$2.40	$2.01	$6.95	$0.89
EFV(200) scored tablets	$4.42	$9.30	$4.50	$2.40	$2.98
LPV/r(80+20 mg/ml)	$30.82	$57.75	$30.90	$19.77	$16.14
LPV/r(100/25mg)	n/a	$17.00	$11.88	n/a	$3.36
NVP(50mg/5ml)	$1.51	$1.90	$1.92	$4.94	$0.69

Appendix D

There are several CHAI analyses from which the majority of figures in this report are derived:

- *ART patient forecast* – Each year, CHAI derives a five-year forecast for the total number of patients on ART in low- and middle-income countries. CHAI compiles historic data on the number of patients on ART in the 21 highest-burden countries from the "Towards Universal Access" progress reports issued by the World Health Organization, UNICEF and UNAIDS – and then linearly extrapolates the data to estimate future patient growth in those countries. CHAI then extrapolates to the rest of the world and accounts for factors that may impact the pace of growth in certain countries, such as approaching universal access.
- *ARV demand forecast* – CHAI collects data on patient regimens, national guidelines, and anticipated future trends from our country teams and published literature each year. CHAI uses the data and an internally developed forecasting model to project ARV demand in low- and middle-income countries over the next five years.
- *ARV procurement database* – CHAI aggregates procurement data from several sources, including Supply Chain Management System (SCMS), the Global Fund, UNITAID, IDA, and national governments. The data is evaluated on an annual basis to understand pricing and volume trends by country and globally.
- *Market sizing analysis* – Each year, CHAI combines our ARV demand forecast with pricing data from our ARV procurement database to calculate the current size of the ARV market in dollar terms and to estimate the market size over the next five years.

References

[i] WHO, Global update on the health sector response to HIV, 2014
[ii] WHO, Global update on the health sector response to HIV, 2014; Médicins Sans Frontières (MSF), Untangling the web of antiretroviral price reductions, 2014
[iii] UNAIDS, Global Report, 2013
[iv] CHAI, Market Sizing Analysis, 2014
[v] CHAI, Market Sizing Analysis, 2013 and 2014
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