

Accessing life-saving medical technologies for HIV¹

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Abstract

The state has a constitutional duty both to increase access to safe, effective, quality medical technologies that prolong or improve life and to protect the public from unproven or dangerous ones. The state is failing to do this adequately for the HIV epidemic. This article explains the structure of the institutions responsible for these tasks and describes some of the critical medical technologies for managing the HIV epidemic that are not being made sufficiently accessible. It also identifies unproven and probably illegal medical interventions that are being marketed with impunity because either the state is not taking action to stop this marketing or it is actively colluding with such activities. The institutional framework for achieving the correct balance for medicine access appears to exist, though there is a shortage of staff in some of these departments. A key cause of the problem appears to be lack of political will. A commission of inquiry is needed to determine what must be done to rectify the situation.

The right to access safe, effective, quality medicines

The state must take reasonable measures to make medicines available that prolong life or improve its quality. The Bill of Rights states that everyone “has the right to have access to ... health care services” and that the “state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation” of this right.⁴ The Constitutional Court has expressly stated that access to health care services includes access to medicines.

The South African government's duties are reinforced by international treaties:

- Article 25 of the Universal Declaration of Human Rights states “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services ...”.⁵
- The International Covenant on Economic, Social and Cultural Rights compels states to take steps to “recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” To achieve the “full realization of this right” states must make provision for the “the reduction of ... infant mortality and for the healthy development of the child; ... prevention, treatment and control of epidemic, endemic, occupational and other diseases; ... [t]he creation of conditions

1 This document has been prepared for TAC members, especially treatment literacy practitioners and National Executive Committee members. It has also been prepared for the Ministry of Health, Parliamentary Portfolio Committee on Health, South African Human Rights Commission and Joint Civil Society Monitoring Forum.

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3 This document was first delivered to the South African Human Rights Commission on 30 May 2007. It was also made available at the South African AIDS Conference in Durban in June 2007. In this final version minor errors have been corrected.

4 South African Constitution. 1996. <http://www.concourt.gov.za/site/constitution/english-web/ch2.html>.

5 Universal Declaration of Human Rights. 1948. <http://www.un.org/Overview/rights.html>.

which would assure to all medical service and medical attention in the event of sickness.”⁶

An integral part of the duty to make life-saving medicines accessible is the duty to ensure the quality, safety and efficacy of medicines. The right to access health-care means not only that people can access effective medicines but that they are reasonably protected against being sold unproven remedies under false pretenses that potentially endanger their health or divert them from taking proven medicines.

This balance is further supported in the Constitution, legislation and policy:

- The Bill of Rights states:
“Everyone has the right to bodily and psychological integrity, which includes the right -
a. to make decisions concerning reproduction;
b. to security in and control over their body; and
c. not to be subjected to medical or scientific experiments without their informed consent.”
- The Medicines and Related Substances Act, 101 of 1965 (Medicines Act) provides that
“no person shall sell any medicine which is subject to registration”
and that no person shall
“publish or distribute ... any false or misleading advertisement concerning any medicine ... or ... in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any medicine is other than that stated by the [Medicines Control Council].”
- The goal of the National Drug Policy (NDP) is to “ensure an adequate supply of safe, cost effective drugs of acceptable quality to all citizens of South Africa and their rational use by prescribers, dispensers and consumers ...”.⁷
- The NDP states “Only drugs which are registered in South Africa may be imported, produced, stored, exported and sold. All companies which wish to register products for marketing in the country will be issued with licences if all registration and Good Manufacturing Practice (GMP) requirements are met.”

There are state institutions with the responsibility for making safe, effective, quality medical technologies accessible and protecting the public from unsafe, unproven or ineffective ones. The main function of the Department of Health's Pharmaceutical Policy and Planning Cluster (PPP) is to implement the NDP. The Department of Health also has a Medicines Regulatory Affairs Cluster (MRA) whose purpose is to “ensure that medicines reaching patients are safe, effective and meet approved standards and specifications.”⁸ The MRA supports the work of the Medicines Control Council (MCC), the statutory body whose main purpose is to “safeguard and protect the public through ensuring that all medicines that are sold and used in South Africa are safe, therapeutically effective and consistently meet acceptable standards of quality.”⁹

Yet, in spite of the right of access to health-care services in the Constitution and international treaties as well as the policy, legislation and state administrative structures established to enforce this right with respect to medicines, some key proven medical technologies are unavailable to people living with HIV and many unproven ones are illegally marketed and sold.

6 International Covenant on Economic, Social and Cultural Rights. 1966.

http://www.unhchr.ch/html/menu3/b/a_cescr.htm. South Africa has signed but not yet ratified this treaty.

7 Taken from http://www.doh.gov.za/department/clus_pharma-f.html

8 Taken from http://www.doh.gov.za/department/clus_medicine.html

9 Taken from <http://www.mccza.com/>

Numerous existing and easily developed medical technologies are unavailable to the majority of people living with HIV who need them. Making these technologies accessible through the public health system would extend or improve the quality of life for many people. By contrast, many unproven medicines are being unscrupulously sold or given to people with HIV. These marketing practices at best create false hope, but they can waste often poor people's money and cause serious side-effects. The state has the available resources to take measures to make these proven medical technologies available and to reduce the marketing and selling of unproven medicines. It therefore must do so.

The recently released HIV & AIDS and STI Strategic Plan for South Africa 2007-2011 (National Strategic Plan)¹⁰ is an important advance towards meeting the needs of people with HIV or at risk of HIV. This document makes recommendations that if implemented will increase the success of the National Strategic Plan.

This submission therefore has four purposes:

- It describes the state institutions tasked with making safe, effective, quality medicines accessible and stopping the marketing and selling of unproven medicines.
- It describes some critical medical technologies for HIV that either already exist or can be developed easily. The quality and length of life for many people will be improved if these technologies are made more available.
- It also describes some examples of unregistered medicines being marketed and sold as treatments for AIDS and the failure of the state to stop these practices.
- It makes recommendations for rectifying this situation.

In order to limit the already large scope of this document, we have not included a discussion of tuberculosis (TB). However, a document similar to this one that deals primarily with TB is necessary for two reasons: (1) TB is the highest single recorded cause of death in South Africa and this is due to high co-infection rates with HIV, and (2) and there is evidence of multi-drug and extremely-drug resistant TB epidemics.^{11,12}

State institutions tasked with making safe, effective and quality medicines accessible and preventing the marketing and selling of unproven medicines

The state has structures in place whose purposes are to register medicines, increase access to them through the public health system and prevent the distribution and marketing of unproven medicines. This is how these structures are currently supposed to work:

- The MCC is appointed by the Minister of Health in accordance with criteria set out in the General Regulations to the Medicines Act. Its main purpose is to “safeguard and protect the public through ensuring that all medicines that are sold and used in South Africa are safe, therapeutically effective and consistently meet acceptable standards of quality.” The council consists of ten committees: African Traditional Medicines, Veterinary Clinical, Biological, Clinical Trials, Pharmacovigilance, Complementary Medicines, Analytical, Clinical, Pharmaceutical Bioavailability and Scheduling.¹³ It is a

10 Draft 10, the version references in this document, is available at <http://www.tac.org.za/documents/NSP-Draft10-2007-2011.pdf>.

11 Statistics South Africa. 2006. Mortality and causes of death in South Africa, 2003 and 2004 Findings from death notification. P0309.3.

12 Nunn, P. 2007. Transmission of XDR-TB in South Africa: Discussion of the Global Implications. 14th Conference on Retroviruses and Opportunistic Infections 25 February 2007.

13 Taken from <http://www.mccza.com/>. According to one source, this list is incorrect. There are Pharmaceutical and Analytical and HIV Clinical Trials committees, and there is no Pharmaceutical Bioavailability and Scheduling committee.

statutory body whose functions are governed by the Medicines Act. Its members are volunteers (i.e. unpaid except for remuneration of expenses) headed by a chairperson.

- The MRA is situated in the Department of Health and provides administrative and technical expertise to the MCC. It is the administrative arm of the MCC and consists of paid staff under the direction of the Registrar of Medicines. It must implement the instructions of the MCC. It consists of five directorates: Medicines Evaluation and Research, Clinical Evaluation and Trials, Operations and Administration, Inspectorate & Law Enforcement and Traditional Medicines.¹⁴
- The Inspectorate & Law Enforcement Unit (LEU) of the MRA must protect the public from breaches of the Medicines Act. It must therefore investigate and stop unethical marketing practices and the distribution of unregistered medicines.
- The PPP's "main functions ... are centred on implementation of the [NDP] in support of other National Programmes. The goal of the NDP is to ensure an adequate supply of safe, cost effective drugs of acceptable quality to all citizens of South Africa and their rational use by prescribers, dispensers and consumers as well as issues related to Food Control and Safety." The PPP has five sub-directorates: Affordable Medicines, Pharmaceutical Economic Evaluation, Health Technology, World Trade and Intellectual Property and Food Control. While the MCC and MRA are responsible for the registration of medicines and the enforcement of the Medicines Act, it is the PPP's responsibility to make registered medicines accessible, e.g. through the public health system. It develops treatment guidelines, manages the Essential Drugs List, implements national drug policy and manages public information on drugs. It is the PPP that must negotiate favourable pricing, supply and licensing with the pharmaceutical industry.

Problems with state institutions and recommendations for addressing these

PPP

This article describes several medical technologies which have not been introduced into the public health system but need to be. It is the PPP's responsibility to identify important new medical technologies, encourage the owners and manufacturers of these technologies to register them and use negotiations and litigation to drive down the prices of medical technologies that are expensive. Yet it is not doing this sufficiently. There is insufficient effort by the PPP to make the medical technologies discussed here more accessible. Furthermore, the major efforts to reduce HIV medicine prices over the last decade have been initiated and carried out by civil society with very little support from the state, or the PPP in particular.

Recommendation: The PPP must be instructed by the Minister of Health to be proactive about making new medical technologies accessible, as required by the NDP.

Recommendation: The PPP must be staffed with experts on medicines, medicine pricing and the medicines legislative framework.

MCC and MRA

This document describes several medicines for which registration has been slow. It also describes how violators of the Medicines Act act with impunity. These failures are the

¹⁴ See <http://www.doh.gov.za/department/index.html> and <http://www.mccza.com/documents/MRA%20Structure.doc>. Note that the MCC and Department of Health websites use different terminology to describe the MRA.

responsibility of the MCC and the MRA. The public perception of the independence of the MCC is compromised by these failures. The MCC is unable to carry out essential functions efficiently. Possible causes of this are that the MCC is under-resourced, that the MRA is not acting under the instruction of the MCC to the extent that it should and the MCC is not acting independently of political influence to the extent that it should.

Currently, the Registrar of Medicines, who heads the MRA, is also the director of the PPP. Both the MRA and PPP have heavy workloads. They also have different purposes which can lead to conflicts of interest. For example it would be inappropriate for the MRA to be involved in some of the recommendations directed at the PPP in this document. The PPP must actively engage industry, while the MRA should serve the MCC which must be much more cautious in its dealings with industry.

The MCC should act independently and in the public interest. It should only consider the safety, efficacy and quality of medicines in determining whether or not to register them. It also should act swiftly. But in recent years, the MCC's independence has become questionable because of an increasingly close relationship with the Department of Health.

Recommendation: The head of the MRA should be a different person to the head of the PPP.

Recommendation: Currently Section 21 authorisations for the use of unregistered medicines are done on a named patient basis. This is a slow, time-consuming process and has to be repeated for every patient. There is nothing in the Medicines Act which prevents a more flexible process from being introduced. For example, The MCC could grant Section 21 authorisations to a medical institution to treat any patient that the institution services with a particular medicine for a specific set of conditions on condition that medicine is listed on the World Health Organisation's pre-qualification list or it has been registered by another reputable medical regulatory authority. This would facilitate access to new life-saving medicines before they are registered in South Africa.

Recommendation: The Medicines Act should be amended to authorise the use of drugs for life-threatening diseases if approved by another stringent drug regulatory authority or pre-qualified by the World Health Organization. Registration should be contingent on the submission of any additional data the MCC may need, within a reasonable time period, such as a year. The MCC should also have the authority to revoke authorisation if, without good cause, this data is not submitted timeously, or new evidence puts the safety, efficacy and/or quality of the medicine in doubt.

Recommendation: Steps must be taken to make the MCC independent of the Department of Health and all vested interests.

Recommendation: A commission of inquiry, possibly under the auspices of the South African Human Rights Commission, is needed to determine the causes of the institutional failures described in this document and to propose appropriate measures to rectify them.

Maternal health and mother-to-child transmission prevention

Antiretroviral regimens for mother-to-child transmission

It is now possible to eliminate the vast majority of new cases of paediatric HIV.

Currently the public health system, in eight provinces, uses the single-dose nevirapine prophylaxis to reduce the risk of mother to child transmission. This strategy is used in many resource limited settings and in a trial setting reduced the risk of transmission from HIV-positive women to their babies to approximately 12% at delivery.¹⁵

¹⁵ Guay et al. 1999. Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of

Although some programmes have reported similar results to the trial, some operational sites show considerably higher rates of transmission. For example, in a study in Kwazulu-Natal the transmission rate for mothers who reported that they were HIV-positive and had taken single-dose nevirapine was 15.3%.^{16,17}

The Western Cape supplements single dose nevirapine with zidovudine. This dual-therapy strategy is sanctioned by the National Strategic Plan.¹⁸

In a Thai study, short course zidovudine given to the mother from 28 weeks of pregnancy with a single dose of nevirapine at delivery (and short course of seven days zidovudine and single dose nevirapine to the baby) was found to reduce mother to child transmission to less than 5%.¹⁹ Good results were also found in a study in Cote D'Ivoire.²⁰

With single dose nevirapine alone, or in combination with short course zidovudine only, resistance develops rapidly in approximately 50% women who receive it. The World Health Organisation (WHO) recommends adding a week of zidovudine/lamivudine post nevirapine dose. Although more complex, this strategy could be initiated with adherence support for women and innovative co-packaging of drugs (single dose nevirapine plus seven days zidovudine/lamivudine) thus preserving their future treatment options.^{21,22,23}

Appropriate short course antiretroviral treatment for women not indicated for treatment and who stop treatment after delivery carries very low transmission risk. It is recommended in US, Europe and Brazil. Good monitoring however is necessary, because women who initiate nevirapine treatment with a CD4 count greater than 250 have a higher risk of nevirapine hepatotoxicity.²⁴

Treating maternal health appropriately has been the best strategy for prevention of mother-to-child transmission of HIV to date.

Recommendation: The Department of Health must modify the National Antiretroviral Treatment Guidelines (treatment guidelines)²⁵ to include a continuum of care and treatment

mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. *Lancet*. 1999 Sep 4;354(9181):795-802.

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=10485720&query_hl=7&itool=pubmed_DocSum

16 For a summary of the studies on this issue see Clayden, P. *Nevirapine and MTCT: the single-dose backlash*. <http://www.i-base.info/pub/htb/v4/htb4-7/Nevirapine.html> as well as its accompanying references.

17 Rollins N, Mzolo S, Little K et al. HIV prevalence rates amongst 6 week old infants in South Africa: the case for universal screening at immunisation clinics. XVI International AIDS Conference, Toronto, Canada. 13-18 August 2006. Oral abstract THAC0104.

18 See p. 143 in particular.

19 Lalletment M, Jourdain G, Le Coeur S. *et al.*, for the Perinatal HIV Prevention Trial (Thailand) Investigators. A randomized double-blind controlled equivalence trial of shortened zidovudine treatment regimens to prevent mother to child transmission of human immunodeficiency virus type 1 in Thailand. *New Engl J Med* 2000, 343: 982 -991.

20 Effectiveness of a short course of zidovudine + lamivudine and peripartum nevirapine to prevent HIV-1 mother-to-child transmission. The ANRS 1201 DITRAME-Plus trial, Abidjan, Cote d'Ivoire. *Antivir Ther*. 2003; 8 (Suppl.1): abstract no. 219.

21 For a summary of the studies on this issue see Clayden, P. 2004. *Single-Dose Jeopardizes Long-Term Therapy*. *Gay Men's Health Crisis*. <http://www.thebody.com/content/treat/art13303.html>

22 WHO. 2006. Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: towards universal access. Recommendations for a public health approach <http://www.who.int/entity/hiv/pub/guidelines/pmtctguidelines3.pdf>.

23 McIntyre JA *et al.* Addition of short course Combivir to single dose Viramune for the prevention of mother to child transmission of HIV-1 can significantly decrease the subsequent development of maternal and paediatric NNRTI-resistant virus. 3rd IAS Conference on HIV Pathogenesis and Treatment, Rio de Janeiro, 2005. Abstract TuFoO2O.

24 See <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=26>

25 National Department of Health. National Antiretroviral Treatment Guidelines. First Edition, 2004. <http://www.doh.gov.za/docs/factsheets/guidelines/artguidelines04/>

for HIV-positive pregnant women as follows:

- Pregnant women who are indicated for treatment for their own HIV must receive highly active antiretroviral treatment.
- Women not indicated for their own treatment must receive the best possible antiretroviral prophylaxis intervention available to ensure their own future health and an uninfected infant. This is in line with goal seven of the National Strategic Plan which commits to various interventions to address the special needs of pregnant women and children through introducing women-specific interventions and other measures.²⁶

Recommendation: The Department of Health must instruct provinces to allow health facilities with capacity to implement more complex interventions as described and to better link mother-to-child transmission prevention and antiretroviral treatment programmes. Health facilities should have greater autonomy to determine when they have the capacity to improve their mother-to-child transmission prevention programmes.

Polymerase Chain Reaction (PCR) testing

Currently, the vast majority of HIV-positive women who go through the public health system's mother-to-child transmission prevention programme have to wait at least nine months to determine the HIV status of their child. This is because the antibody tests used in the public health system can falsely give an HIV-positive result to infants who have acquired their mother's HIV antibodies, but not the virus itself. Nine months after birth, the antibodies have cleared in most HIV-negative infants and by eighteen months a false positive becomes extremely unlikely.²⁷

However, it causes mothers unnecessary anguish to have to wait so long to determine the HIV status of their children. 35% of HIV-positive children in Africa die before they are a year old and 53% by two years. Therefore many infants with HIV would benefit from having their status determined earlier. Furthermore, it is policy to give all children born to HIV-positive women cotrimoxazole until their HIV status is known, even though this antibiotic is only necessary as a prophylaxis against pneumonia²⁸ and, to a lesser extent, TB in children who are infected with HIV.

Therefore, there are several advantages to determining HIV status of infants much earlier. It is possible to do so at six weeks after birth using a polymerase chain reaction (PCR) test, the same technology used to measure viral load. It does occasionally give false positive results but the risk is low compared to the benefits. PCR testing on dried blood spots on filter paper for diagnosis of infants as young as six weeks of age has a high specificity (99%) and sensitivity (100%).²⁹ Using dried blood spots on filter paper rather than whole blood makes for easier transport to centralized laboratory facilities and is an important procedure for expanding infant diagnosis, particularly in rural, resource poor settings and in clinics without the tools or infrastructure for standard phlebotomy.

This technology has been available in South Africa for years. The factors preventing its wider use to determine the HIV status of infants is the cost of the tests themselves, the automated blotting paper punches needed to conduct the tests and the complexity of conducting the test

26 See p. 90 in particular.

27 For a summary see, Carter M. 2007. *Newer, more sensitive HIV antibody tests producing false-positive results in uninfected infants.* <http://www.aidsmap.com/en/news/8CB638BC-AE0F-4698-9F67-B39B5C23C915.asp>.

28 Chintu C. et al. 2004. *Co-trimoxazole as prophylaxis against opportunistic infections in HIV-infected Zambian children (CHAP): a double-blind randomised placebo-controlled trial.* The Lancet, 364(1865).

29 Sherman GG. et al. 2005. *Dried blood spots improve access to HIV diagnosis and care for infants in low-resource settings.* J Acquir Immune Defic Syndr 2005 Apr 15;38(5):615-7

in laboratories with limited infrastructure. The price to the state of a PCR test to determine an infant's HIV status is R433.³⁰

Recommendation: Widespread, routine deployment of dried blood spots is needed.

Recommendation: The mother-to-child transmission prevention programme protocol must be changed to include PCR tests as standard. Many facilities already use PCR tests, but they should be standard throughout the country. This is in line with the National Strategic Plan which provides for determining “the HIV status of infants, children and adolescents as early as possible.”³¹

Recommendation: The PPP must negotiate with various manufacturers of PCR tests to lower their prices substantially.

Recommendation: The PPP must work with the MRC and the NHLS to investigate emerging alternatives to standard PCR methodologies

Antiretroviral treatment

The state began rolling out country-wide implementation of antiretroviral treatment in 2004. The public health system provides for first and second-line regimens. However, a number of new antiretrovirals with better side-effect and resistance profiles should be introduced into the programme. Also, some of the antiretrovirals the state purchases remain overpriced and at risk of supply shortages. Several combination pills need to be introduced to improve patient adherence.

Tenofovir

Tenofovir Disoproxil Fumarate is an antiretroviral that was registered in the United States in October 2001³² and in numerous countries, including developing ones, since then. Tenofovir has a better side-effect profile than stavudine, a drug used in the first line of the public sector antiretroviral programme. In particular, it is less associated with peripheral neuropathy and lactic acidosis, two serious side-effects of stavudine, of which the latter is sometimes fatal.³³ The President of the Southern African HIV Clinicians Society has called for the introduction of tenofovir into the public health system.³⁴ Tenofovir is also advantageous because it has a different resistance profile to other antiretrovirals in its class (nucleoside reverse transcriptase inhibitors) and can therefore be used by patients who are resistant to drugs such as zidovudine (AZT). Three large clinical trials have demonstrated the efficacy of tenofovir. One clinical trial has shown a tenofovir-containing combination to be as effective at achieving HIV suppression as AZT-containing combination at 48 weeks. Another showed tenofovir to have patient outcomes at least as good as stavudine at 144 weeks.³⁵ There were

30 Boule A. and Cleary S. 2006. HIV and AIDS Scenarios for South Africa: 2005-2025 . Public Sector Health Cost Projections.

31 National Strategic Plan, p. 12.

32 See

http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#pphist

33 See Gallant et al. Tenofovir DF, Emtricitabine, and Efavirenz vs. Zidovudine, Lamivudine, and Efavirenz for HIV. N Engl J Med 2006 354: 251-260; Gallant et al. Efficacy and Safety of Tenofovir DF vs Stavudine in Combination Therapy in Antiretroviral-Naive Patients A 3-Year Randomized Trial. JAMA. 2004;292:191-201; DHHS. 2006. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents October 10, 2006 - particularly page 18. A side-effect associated with tenofovir is renal impairment, but it is uncommon. See <http://www.fda.gov/cder/foi/label/2006/021356s016lbl.pdf>.

34 See Beresford B. 2007. MCC stalls new Aids drugs. <http://www.corpwatch.org/article.php?id=14342>. There are differing views on whether tenofovir should replace stavudine completely or only for a subset of patients at higher risk of lactic acidosis.

35 See Gallant et al above. See <http://www.fda.gov/cder/foi/label/2006/021356s016lbl.pdf> for a description of

fewer deaths and fewer discontinuations of treatment due to adverse events in the tenofovir arms. As discussed below tenofovir is also formulated in combination with other antiretrovirals, thereby reducing the number of pills patients have to take and possibly improving adherence. The introduction of tenofovir into the public health system would likely improve patient outcomes.

Tenofovir was only registered in South Africa in April 2007. Before that it was available only to a limited number of patients under Section 21 authorisation from the MCC. Gilead Sciences, the originator company, filed for registration of tenofovir in January 2004. Subsequently registration was taken over by Aspen Pharmacare who entered a technology transfer, marketing and distribution agreement with Gilead. Aspen applied for registration in November 2005.³⁶ That tenofovir was only registered in South Africa over five years after registration in the US, a country with a proportionately much smaller HIV epidemic, is a consequence of tardiness by the MCC, Gilead Sciences and Aspen Pharmacare. However, the PPP also has a duty to proactively remove the hurdles to tenofovir registration, or any essential medicine.

Gilead's access price per month per patient is \$17 (approximately R119). It appears that this is the price that tenofovir will be made available to the public sector. This is a similar price to the entire current first-line regimen of stavudine, lamivudine and nevirapine from Aspen Pharmacare on the state tender. Also, with only one manufacturer, there is a possibility of supply shortages due to stock-outs, as has been seen with other first-line public sector antiretrovirals such as efavirenz. Tenofovir is not patented in South Africa so there are no intellectual property barriers to more generic companies manufacturing and selling it. With more competition, the price is likely to come down.

Recommendation: The PPP needs to negotiate with various drug companies to sell tenofovir in South Africa.

Recommendation: The Department of Health needs to organise a meeting of clinicians and HIV activists to revise the treatment guidelines. This meeting should be held regularly, at least once a year. It should also be possible for urgent ad hoc meetings to take place to revise the treatment guidelines, if important new research findings or drug developments occur.

Lopinavir/ritonavir

The treatment guidelines recommend that lopinavir and ritonavir, both in the class of antiretrovirals known as protease inhibitors, comprise part of second-line antiretroviral treatment. They are co-formulated and branded by Abbott as Kaletra, the only available version of this medicine in South Africa. The role of ritonavir is to boost the amount of lopinavir that is available to the body by slowing down the drug's metabolism.

There are three critical concerns about Abbott being the only supplier of ritonavir/lopinavir that the PPP needs to address: (1) Ritonavir is needed to boost other protease inhibitors including atazanavir (see below) but it is only supplied by Abbott, giving the company concerning power over the protease inhibitor market, (2) the price of Kaletra is too high (the state pays R414 per patient per month and the private sector price is R359 incl. VAT per

these clinical trials.

³⁶ Communication between Aspen, MCC and TAC.

patient per month³⁷) and (3) there is a danger of stock-outs as more patients move to second-line regimens and demand increases.

The price of Kaletra is almost three times the state tender price of the entire standard first-line regimen of lamivudine, stavudine and nevirapine.³⁸ While protease inhibitors are more expensive to produce than the other antiretrovirals recommended in the treatment guidelines, it is implausible that lopinavir/ritonavir is being sold at its lowest possible price. However, generic drug prices remain higher than Abbott's.³⁹ Nevertheless with economies of scale and competition, the price of lopinavir/ritonavir could likely fall well below the current Abbott price.

The AIDS Law Project (ALP), acting for the TAC, has attempted to negotiate with Abbott to grant licenses to several generic manufacturers. Abbott has been intransigent and therefore TAC and ALP are preparing to file a complaint with the Competition Commission.

A further issue with lopinavir/ritonavir is that the version registered in South Africa must be refrigerated. Abbott have developed a new heat-stable version that does not need refrigeration. Cipla manufactures a generic version of this medicine in India. This means people without refrigerators or consistent electricity supplies should now be able to use this medicine. It is also more convenient for health facilities and even people with refrigerators and consistent electricity supplies. Additionally the heat-stable version is possibly associated with fewer gastro-intestine side-effects and can be taken without food.⁴⁰

When lopinavir/ritonavir is taken with rifampicin, a key drug used to treat TB, there is a large (>90%) reduction in lopinavir concentration. This interaction must be overcome with a higher dose of ritonavir.⁴¹ Since some TB patients using rifampicin will also use lopinavir and ritonavir, a heat stable stand-alone formulation of ritonavir is also necessary. The price of ritonavir as a standalone drug also needs to be reduced.

Abbott has applied for the heat-stable version of lopinavir/ritonavir to be registered in South Africa. It was not registered at time of writing. Registering a variation of an already registered medicine should be much quicker than registering a new medicine compound.

Recommendation: The PPP should negotiate with Abbott to grant multiple licenses of ritonavir and lopinavir/ritonavir in combination to generic manufacturers.

Recommendation: The MCC must prioritise consideration of the registration of heat-stable lopinavir/ritonavir.

Atazanavir

Atazanavir, like lopinavir, is also a protease inhibitor. The second line regimen used in South Africa recommends two protease inhibitors, ritonavir and lopinavir, as described above.

37 State tender prices used in this document were obtained from the tender documents titled RT 71 2004 Contract Price Schedule, RT71-2004MF Contract Circular, and communication with Aspen Pharmacare. These are available from the authors upon request. South African private sector prices were obtained from the Southern African HIV Clinicians Society newsletter, Transcript, March 2007. The state tender price for Kaletra according to the documents we have is higher than the private sector price. If this is correct, it indicates that the tender process that is too inflexible because public sector prices should not exceed private sector prices.

38 The combined state tender price for lamivudine, stavudine and nevirapine is R110.92 per patient per month. The combined price of stavudine, lamivudine and efavirenz is R276.80 per patient per month.

39 See the Clinton Foundation HIV/AIDS Initiative price list for 8 May 2007 available from <http://www.clintonfoundation.org/>.

40 See Klein C et al. 2005. The effects of efavirenz on the lopinavir/ritonavir pharmacokinetics from a new tablet formulation. Program and abstracts of the European AIDS Clinical Society 10th European AIDS Conference; November 17-20, 2005; Dublin, Ireland. Abstract PE4.3/2.

41 La Porte C. J. L. et al. 2004. *Pharmacokinetics of Adjusted-Dose Lopinavir-Ritonavir Combined with Rifampin in Healthy Volunteers*. *Antimicrobial Agents and Chemotherapy*, May 2004, p. 1553-1560, Vol. 48, No. 5. <http://aac.asm.org/cgi/content/abstract/48/5/1553>

Atazanavir has three advantages over most other protease inhibitors: it is stored at room temperature, not in a fridge, it is taken once a day either as one 300mg or two 150mg capsules, though only the 150mg capsule version is registered in South Africa. It is less likely to cause increased lipid levels (cholesterol and triglycerides) than other protease inhibitors.⁴² Patients using atazanavir must also use ritonavir, albeit a lower dose (100mg) than when it is used with lopinavir (200mg). This provides yet another reason for the urgency of heat-stable ritonavir.

Atazanavir was registered in 2003 in the United States. It was registered by the MCC in November 2005. It was however unavailable until recently for general sale because the MCC had not approved a package insert modification that had to be made during the registration process. A drug cannot be brought to market without an approved package insert.⁴³

The drug is patented by Bristol Myers Squibb (BMS). BMS has also licensed it to Aspen and an Indian company, Emcure. Only the BMS version is registered at this point.

Atazanavir costs R284.18 (VAT inclusive) for 60 x 150mg capsules in the private sector, i.e. one month's supply. When combined with a 100mg ritonavir pill taken once a day, the price of the two drugs together comes to R310.26 per month. This is lower than the private sector price of lopinavir/ritonavir, though still too high.⁴⁴

Atazanavir is listed as a preferred protease inhibitor by the United States Department of Health and Human Services.⁴⁵

Recommendation: The use of atazanavir in the public sector should be considered in the next revision of the treatment guidelines.

Efavirenz

Efavirenz is an antiretroviral in the class of non-nucleoside reverse transcriptase inhibitors. The treatment guidelines specify that either it or nevirapine should be prescribed to patients as a first-line treatment regimen for HIV. It is manufactured by the patent holder Merck Sharp & Dohme (MSD), a subsidiary of Merck based in the United States.

MSD manufactures several versions of efavirenz which are registered and sold in South Africa. The notes here refer only to the 600mg version because it is taken as one pill once a day. MSD has also licensed Aspen to market its own stand-alone efavirenz products in South Africa, but these are not yet registered.

There are two critical concerns about MSD being the only supplier of efavirenz that the PPP needs to address: (1) The price is too high (R214.31 per patient per month on state tender and R262.08 incl. VAT per patient per month in the private sector) and (2) there have been drug stock-outs with patients put at risk of not receiving their pills on time.⁴⁶

As with Abbott and lopinavir/ritonavir, the AIDS Law Project (ALP), acting for the Treatment Action Campaign (TAC), has attempted to negotiate with MSD to grant licenses to several

42 See http://www.aidsmeds.com/archive/Reyataz_1563.shtml and <http://www.fda.gov/cder/foi/label/2007/021567s012lbl.pdf>

43 This MCC document indicates that atazanavir was registered in November 2005: <http://www.mccza.com/documents/12.25%20Notification%20of%20Registration%20Nov05v2.zip>. We determined the cause of the delay in availability by corresponding with various sources.

44 A heat-stable version of ritonavir is not registered in South Africa, consequently the ritonavir referred to here is not heat-stable..

45 Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. 10 October 2006. See <http://www.hivatis.org/Guidelines/GuidelineDetail.aspx?MenuItem=Guidelines&Search=Off&GuidelineID=7&ClassID=1>

46 See Letter from the AIDS Law Project on behalf of the TAC to MSD calling for more generic licenses for Efavirenz following reported failure to meet stock orders. http://www.tac.org.za/newsletter/2004/ns17_11_2004.htm

generic manufacturers. There has been insufficient progress and therefore TAC and ALP are preparing to file a complaint at the Competition Commission.

Recommendation: The PPP should negotiate with MSD to grant multiple licenses of efavirenz to generic manufacturers for both standalone and combination products.

Co-formulating and co-packaging combinations of antiretrovirals

Co-formulated antiretroviral medicines are two or more antiretrovirals manufactured in one pill. Co-formulated antiretrovirals reduce the number of pills patients have to take (known as pill count). Pill count has been shown in a South African study to be a key factor affecting patient adherence.⁴⁷ Therefore co-formulated antiretrovirals will likely lead to better patient outcomes. The logistics of dealing with co-formulated medicines in the public health system would also be easier, because fewer pills need to be acquired, secured and distributed.

Some combinations of drugs cannot be co-formulated, either because the dosage requirements are different (e.g. if one drug must be taken once a day and the other twice a day) or because of technological barriers due to the chemistry of the drugs. In such cases the various drugs can be co-packaged into blister packs to increase convenience for patients.

At the moment, no combination or co-packaged medicines are used in the public health system, even though these are used extensively in the private sector and in other countries.

Combination stavudine/lamivudine/nevirapine in the public sector

The treatment guidelines recommend the combination of stavudine, lamivudine and either nevirapine or efavirenz as the standard first-line treatment regimen for people with HIV. A large percentage of antiretroviral patients in the public health system therefore use the combination of stavudine, lamivudine and nevirapine.

Aspen Pharmacare won the tender for this regimen and provides it to the public health system. Using the Aspen regimen, patients have to take three separate pills twice a day, i.e. six pills a day. Yet, a competitor, Cipla, manufactures a 3-in-1 combination pill of these drugs branded as Triomune. Patients using this brand only have to take two pills a day. It is much more convenient and would likely result in better adherence than the Aspen combination. The state tender cost of the Aspen regimen is R101 per patient per month. The private sector cost of Triomune is R207 excluding VAT, but it is cheaper than the private sector price of the equivalent non-co-formulated Aspen products. Due to licensing issues as well as delays in Triomune's registration, the Cipla combination only became available in South Africa after the antiretroviral tender was awarded.

Recommendation: The antiretroviral tender process is being implemented inflexibly. It must be able to cater for technological improvements that occur while the tender is ongoing. Patients should not have to continue using outdated technologies simply because improved drugs or drug combinations cannot be purchased until the tender period expires. Furthermore, the current tender process cannot easily take advantage of price reductions that occur through negotiations or pressure on pharmaceutical companies. Either the tender period should be shortened or the terms of the tender should be made more favourable to the state so that the state and patients benefit from technological innovations as well as price

47 See Orrel et al. 2003. *Adherence is not a barrier to successful antiretroviral therapy in South Africa*. AIDS. 17(9):1369-1375, June 13, 2003. <http://www.aidsonline.com/pt/re/aids/fulltext.00002030-200306130-00011.htm;jsessionid=GRJRvFKQvzKQGXRshvmwSy08qBhcbdQIRP4zTKshYy2riQSYZYF!302003643!-949856145!8091!-1>

reductions. Also, there is no need for a tender where there are no competitors for a product. In such cases, the state should simply obtain quotations.

Recommendation: The PPP must negotiate with Aspen and other companies to co-formulate and/or co-package the main combinations used in the public health system.

Tenofovir/emtricitabine

Gilead Sciences is the developer of tenofovir/emtricitabine. It is branded as Truvada. It combines the advantages of tenofovir with a medicine that is pharmacologically very similar to lamivudine, a drug with relatively few side-effects that is already used in the first-line regimen in the public health system. As with tenofovir, Gilead entered a contract with Aspen Pharmacare, who applied for tenofovir/emtricitabine to be registered with the MCC. And as with tenofovir, the registration process took far too long. This combination was registered in April 2007. The Gilead access price is \$26.75 (approx. R184) per patient per month⁴⁸.

There is no patent on tenofovir and Gilead has undertaken not to enforce the patent on emtricitabine.

Recommendation: The PPP must negotiate with generic companies to get them to register tenofovir/emtricitabine in South Africa. Competition between companies will drive the price of this combination down.

Tenofovir/emtricitabine/efavirenz

Tenofovir/emtricitabine/efavirenz is the first one-pill once-a-day complete antiretroviral combination. It was registered by the FDA on 12 July 2006.⁴⁹ It is branded as Atripla. The complex patents and licensing rights of the constituent medicines involved three companies: Gilead Sciences, Merck and BMS. The companies have agreed that this pill will be distributed by Merck wherever Gilead or BMS do not have sales forces or distribution networks.⁵⁰ In South Africa, Merck's subsidiary, MSD will be the distributor and must apply for its registration.

Tenofovir/emtricitabine/efavirenz has two important advantages:

- The low pill-count is much more convenient for patients than any other existing and combination medicine approved by a regulatory authority. It is likely to impact positively on adherence.
- It has a better side-effect profile than the treatment guidelines standard first-line antiretroviral regimen of stavudine, lamivudine and efavirenz. This is because emtricitabine is pharmacologically similar to lamivudine and tenofovir is likely better than stavudine for most patients, as described above.

First-line patients for whom efavirenz is indicated instead of nevirapine in the public health system would therefore benefit substantially from using a one-pill-a-day combination.

Merck has announced that Atripla will be sold for \$50.40 (approximately R350) per patient per month in countries with HIV prevalence greater than 1%.⁵¹ This is more than three times the price of the treatment guidelines first line regimen when it includes nevirapine. It is also about more expensive than the first line regimen when it includes efavirenz.

48 See <http://www.gileadaccess.org>.

49 See the package insert at <http://www.fda.gov/cder/foi/label/2006/021937lbl.pdf>.

50 Acorn, K. 2006. Gilead will license tenofovir to Indian companies; Merck to take *Atripla* to Africa.

<http://www.aidsmap.com/en/news/A0A4B076-31C9-49DF-B04A-911C85C1B483.asp>

51 See http://www.kaisernet.org/daily_reports/rep_index.cfm?DR_ID=43061.

The Clinton Foundation price list indicates that a cheaper version is available from Matrix at US\$32 (approximately R224) per patient per month.

Recommendation: The PPP needs to negotiate with MSD to license multiple generic companies to provide this combination.⁵² It also needs to encourage MSD and generic manufacturers of this combination to apply to register their products.

Recommendation: The MCC must be given the resources it needs to fast-track the registration of Atripla and any bioequivalent generic versions.

New combinations

At present there are several combinations of medicines which would be beneficial to co-formulate or co-package, but are not yet developed or registered with any regulatory authority. These are:

- Tenofovir/lamivudine/efavirenz, which can be co-formulated as one pill taken once a day
- Tenofovir/lamivudine/nevirapine, which can be co-packaged as one co-formulated tenofovir/lamivudine pill and two nevirapine pills taken daily.
- Emtricitabine/nevirapine, which can be co-packaged as one emtricitabine pill and two nevirapine pills taken daily.
- Zidovudine/didanosine/lopinavir/ritonavir, the second-line regimen currently recommended by the treatment guidelines, which can be co-packaged as one zidovudine/didanosine pill taken twice daily and two lopinavir/ritonavir pills taken twice daily.
- Zidovudine/didanosine/atazanavir/ritonavir, which can be co-packaged as one zidovudine/didanosine pill taken twice daily and one or two atazanavir pills taken once daily.

Recommendation: Priority should be given to developing combinations that are or will likely be used in the public health system.

Paediatric antiretroviral formulations

Paediatric antiretroviral options lag behind adults. This is because of the lack of markets in developed countries for these medicines as well as additional issues involved in prescribing appropriate treatment of children.

According to a WHO panel, there are several technological issues with paediatric antiretroviral formulations.⁵³

- Several medicines need to be manufactured in smaller doses.
- Solid tablet forms should be scored (easy to break), to allow accurate division of the tablet, crushable and soluble in water. This will make it easier for children to take them.

⁵² Only the efavirenz patent is relevant for licensing. Tenofovir is not patented and the FTC patent is not enforced.

⁵³ See the following: WHO. 2006. WHO recommendations on ARV medicines for treating and preventing HIV infections in younger children . <http://www.who.int/hiv/paediatric/technicalsummary113006.pdf>; WHO. 2006. Expert working group meeting to determine preferred ARV medicines for treating and preventing HIV infection in younger children. October 23 -25, 2006. <http://www.who.int/hiv/events/paediatricmeetingreport.pdf>; WHO. 2006. Antiretroviral therapy of HIV infection in infants and children: towards universal access . Recommendations for a public health approach. <http://www.who.int/entity/hiv/pub/guidelines/paediatric020907.pdf>.

- For infants taking medicines as part of a mother-to-child transmission prevention the WHO indicated that zidovudine 12mg sachet granules and nevirapine 6mg sachet granules are a priority.⁵⁴
- For treating infants and young children, the WHO describe the following formulations as urgent (all scored): abacavir 60mg, efavirenz 100mg, 600mg, AZT 60mg, abacavir/lamivudine 60mg:30mg and zidovudine/lamivudine/abacavir 60mg:30mg:60mg.
- The WHO described these as high priority: stavudine 7mg scored; didanosine 125mg and 200mg enteric coated; lamivudine 30mg scored; efavirenz/emtricitabine 100mg:35mg scored and emtricitabine 35mg scored. Also, a heat stable 100mg RTV was considered important.
- A range of fixed dose combinations are currently manufactured. The WHO expect these to offer practical advantages over the current practice of using existing liquid single drug formulations and divided adult fixed dose combinations. There are five new generic fixed dose combination tablets and one solution (containing nevirapine, stavudine and lamivudine) produced by Cipla Ltd, Ranbaxy Laboratories Ltd, Emcure Pharmaceuticals and the Thai Government Pharmaceutical Organisation.
- The WHO listed these as priority fixed dose combinations for development (all scored): zidovudine/lamivudine/nevirapine 60mg:30mg:55mg, zidovudine/lamivudine 60:30, stavudine/lamivudine 7mg:30mg, stavudine/lamivudine/nevirapine 7mg:30mg:55mg, nevirapine 55mg and LPV/r 90mg:22.5mg.

Particularly important for paediatric HIV treatment in the South African public health system are a scored, chewable and/or soluble efavirenz mini-pill and a heat-stable lopinavir/ritonavir mini-pill. Abbott have developed a solid formulation tablet lopinavir/ritonavir, 100:25mg, scored. Also, a drug manufactured by GlaxoSmithKline, Abacavir, is part of the second-line regimen for children in the South African public health system. Abacavir is likely advantageous over stavudine, which is currently used for first-line treatment, because it is less associated with the side-effects lipodystrophy and hyperlactaemia.⁵⁵ GlaxoSmithKline have developed a formulation which will be tested with a lamivudine mini-pill.

Recommendation: The Department of Health should work with the WHO and scientists to implement the WHO recommendations.

Recommendation: The Department of Health should hold a regular meeting, at least once a year, to revise the treatment guidelines for children. Abacavir should be considered for first-line treatment and made available at all facilities providing antiretroviral treatment to children.

Opportunistic Infection medicines

Several medicines for treating opportunistic remain inaccessible to many people with HIV.

Fluconazole

Fluconazole is used to treat candidiasis (including the AIDS-defining oesophageal candidiasis, aka systemic thrush) and cryptococcal meningitis.⁵⁶ It is donated by Pfizer to the public health system. This donation was a consequence of a TAC campaign in 2000. Yet it is available only at a fraction of health facilities more than six years after the programme began. Furthermore, although the drug is registered as a schedule four medicine, it is managed in the public health system as a schedule five medicine in order to make it harder

⁵⁴ We pay more attention to dosing in this section, because it is both important and complex for paediatric treatment.

⁵⁵ Communication with Dr. T. Myers.

⁵⁶ See <http://www.fda.gov/cder/foi/label/2004/19949s30,32,35,19950s31,33,37,20090s12,14,17lbl.pdf>

for nurses to dispense it so as to reduce the risk of it being resold illegally in the private sector. Unfortunately, this measure also means many patients requiring fluconazole cannot access it. The TAC has sent correspondence to the Department of Health requesting this situation to be addressed, but the Department has failed to take these steps.

Recommendation: The Department of Health must send a memorandum to all health facilities explaining how they can obtain fluconazole and that the drug should be dealt with as a schedule four drug (i.e. according to its registration) and not schedule five.

Recommendation: The Department of Health needs to audit the number of facilities with fluconazole and determine which facilities struggle to prescribe the drug because of logistical problems.

Recommendation: If fluconazole continues to remain unavailable at a large number of health facilities after the above recommendations are carried out, the PPP should reconsider whether it is necessary to continue with the Pfizer donation. It might be more efficient for the Department of Health to pay for one of the generic versions available and use the standard drug supply logistics to distribute fluconazole to public health facilities.

Acyclovir

Acyclovir is used to treat Herpes Simplex Virus (subtypes 1 and 2), which causes genital herpes, and Herpes Zoster Virus, which causes shingles, both common opportunistic infections in people with HIV. It is also used to treat Varicella Zoster Virus, which causes chickenpox.⁵⁷ The drug is available at few public health facilities.

Recommendation: The Department of Health must take steps to make acyclovir available at all public health facilities.

Ganciclovir

Ganciclovir is used to treat cytomegalovirus (CMV) retinitis.⁵⁸ It is branded by Roche as Cymevene and sold at an exorbitant price. A 70kg private sector patient with CMV would pay between R7,000 and R11,000 to be treated. The patient would then have to pay approximately R7,600 per month for maintenance therapy.⁵⁹

Recommendation: The PPP must encourage generic manufacturers to register their versions of ganciclovir in order to drive the price down. Roche does not enforce any patents on HIV-medicines in South Africa, including opportunistic infection drugs.

Azithromycin

Azithromycin is effective against several bacteria, including chlamydia, hemophilus and streptococcus.⁶⁰ It is only sporadically available in the public health system. Generic versions of this medicine are available.

Recommendation: The Department of Health must take steps to make azithromycin available at all public health facilities.

57 See http://www.fda.gov/cder/foi/anda/98/74975_Acyclovir_Pmtlbl.pdf and <http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a681045.html>.

58 See <http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a605011.html>.

59 We calculated this using dosage information from http://www.rxlist.com/cgi/generic/cytovene_ids.htm and prices of Cymevene quoted by a pharmacy. Cymevene is sold as 84x250mg capsules for R2,309.13 or five 500mg vials for R1,861.40.

60 See <http://www.aids.org/factSheets/530-Azithromycin-Zithromax.html>.

Pravastatin

Pravastatin is an anti-cholesterol drug that is also used to treat HIV patients with hyperlipidemia (high lipid counts – cholesterol and triglycerides) caused by protease-inhibitor antiretrovirals.⁶¹ It is only sporadically available in the public health system.

Recommendation: The Department of Health must take steps to make pravastatin available at all public health facilities.

Controlling proliferation of unproven medicines

The HIV epidemic has provided an unfortunate opportunity for the proliferation of untested medicines. The response of the Department of Health, MCC and the LEU in particular to this problem has been inadequate. On the contrary, a number of actions of these institutions have probably encouraged the proliferation of quackery.

The problem of quackery in relation to South Africa's HIV epidemic is specifically mentioned in a World Health Organisation report, which states "It is necessary [for South Africa] to address issues related to stigma, the fear of treatment side-effects, and quackery."⁶²

There are numerous examples of quackery against which state institutions have failed to act:

- Matthias Rath has distributed vitamins as an alternative treatment for AIDS to antiretrovirals. The state has supported Rath in several ways. For example, Rath's agents have presented to the National Health Council at the invitation of the Minister of Health, the Minister of Health has refused to condemn Rath in written statements before Parliament, his products have been allowed illegally into the country under instruction by the Director-General of Health and the Medical Research Council organised workshops with him.⁶³
- Tine van der Maas distributes a garlic concoction as a treatment for AIDS and various other diseases. She has made a marketing video that has been shown on SABC Africa. The marketing video includes footage of the Minister of Health, apparently supportive of what van der Maas is doing.⁶⁴
- Zeblon Gwala distributes a concoction called Ubhejane as a treatment for AIDS. He has a factory that produces it. The Ministry of Health has issued two statements in support of him.⁶⁵
- Stephen Leivers distributes a product called Secomet as a treatment for AIDS. The TAC lodged a complaint against him with the South African Police in October 2006. Apparently, due to lack of resources in the LEU, action against Leivers has still not been taken at the time of writing.

These are just a few examples. There are many more. Numerous advertisements are distributed on the streets of Cape Town, either explicitly or implicitly claiming to be able to

61 See <http://www.nlm.nih.gov/medlineplus/druginfo/medmaster/a692025.html> and <http://gateway.nlm.nih.gov/MeetingAbstracts/102240489.html>.

62 World Health Organisation. 2007. Towards Universal Access: Scaling up priority HIV/AIDS interventions in the health sector. Progress Report, April 2007. p. 60.

http://www.who.int/entity/hiv/mediacentre/universal_access_progress_report_en.pdf

63 See http://www.tac.org.za/Documents/Court_Cases/Rath/Interdict/Geffen-1.pdf, http://www.mg.co.za/articlePage.aspx?articleid=276515&area=/insight/insight__national/ and <http://www.cssr.uct.ac.za/papers/wp149.pdf>.

64 See <http://www.cssr.uct.ac.za/papers/wp182.zip> for further details.

65 See the above document. The two government statements are *DA undermines indigenous knowledge* on 13 February 2006 and *Traditional medicine is here to stay* on 18 February 2006. Both are available from the corresponding author upon request.

treat AIDS or its symptoms. At 58 Loop Street Cape Town, a company treats people with AIDS with what it calls “Ozone Rectal treatment”. In Longmarket Street, another company markets what it refers to as “Chinese medicine” for the treatment of AIDS.

Recommendation: The LEU must be given additional staff, particularly investigators, so that it can take action against violators of the Medicines Act.

Recommendation: The Department of Health must issue a statement condemning all forms of quackery and breaches of the Medicines Act. It must pursue the prosecution of the above people and set examples which send a message to potential violators of the Medicines Act that they will be prosecuted.

Conclusion

The state must do more to make essential medical technologies accessible. The state must also take action against people who distribute unproven and unregistered treatments for AIDS in violation of the Medicines Act. This will save lives and make it easier to realise the National Strategic Plan. The TAC is willing to assist the state in both these undertakings.
