

# NO VALLEY WITHOUT SHADOWS

MSF AND THE FIGHT FOR AFFORDABLE ARVS IN SOUTH AFRICA





In the 1990s, even as the country celebrated its freedom from apartheid, South Africa descended into a chilling new crisis: an incurable disease was spreading so fast it soon became the fearsome stuff of myth and legend.

The fight against HIV/AIDS in South Africa was a war fought on many fronts: against fear and ignorance so powerful it could lead to murder; against profiteering pharmaceutical companies whose patents safeguarded revenues at the cost of patients' lives; and, most shockingly, against the South African government, which quickly emerged as the world leader in AIDS denialism.

To take its place in this battle, Médecins Sans Frontières/Doctors Without Borders would have to overcome internal resistance, seemingly impossible financial barriers, multiple lawsuits, and the shame and terror of the very people they were trying to help.

How could a coalition of activists, doctors, and patients beat the odds to bring about startling innovations in treatment protocols, end the pharmaceutical companies' legal challenges to low-cost drugs, and overturn an official policy of denial that originated in the nation's highest political offices?

This is the story.



# **No Valley Without Shadows**

## MSF and the Fight for Affordable ARVs in South Africa

Written by Marta Darder, Liz McGregor, Carol Devine and other contributors.



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“AIDS is a war against  
humanity.”

NELSON MANDELA

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Finally, our gratitude goes to all patients and activists who turned the fight between ‘David and Goliath’ into the victory described in these pages.



# Preface



© FARHANG GHAJAR / CBC

I visited Khayelitsha because everyone I spoke to in the Treatment Action Campaign (TAC) and at the UN in South Africa said that Khayelitsha was the model on which an eventual rollout of ARVs would be based. They realised that Khayelitsha was thumbing its nose at the government – and taking the government on. Their view was that not only was this an excellent example of a principled stand in the face of a curmudgeonly and denialist government, but that it was also a fascinating glimpse at the way in which ARVs could transform the situation of people living with AIDS.

That's why I was very anxious to see Khayelitsha in action. I was

fortunate enough to go there both with MSF's Eric Goemaere and with Zackie Achmat, head of the TAC.

The first word that comes to mind when I think about Eric Goemaere is integrity. I know that he'd be terribly embarrassed to be portrayed as a hero. There is no self-aggrandisement in Eric; there is no desire to burnish the flames of MSF. There is just this intense personal wish to tell you what is going on, what should be done, how it can be achieved, what it will mean for the people involved, and how invaluable it is to have organisations doing what MSF was doing in Khayelitsha.

Zackie accompanied me as I chatted with people in Cape Town before going on to Khayelitsha itself. Although my visit was short, I did at least get the chance to meet a number of patients. They talked to me about the transformation in their lives: how they were able to function in their families and go back to work and live productive lives again. It was thrilling and it was very moving.

I felt I was seeing the best experiment – certainly in South Africa and possibly in the whole African continent.

Midway through the visit, I received a phone call from the South African minister of health, Manto Tshabalala-Msimang. Even though I had never met her or talked to her before, she yelled and screamed at me as if she was a lunatic. It was only afterwards I learned that she really was a lunatic.

She was extremely angry that I was in Khayelitsha, but although she yelled and screamed and told me to get out immediately, I decided I wanted to complete enough of the visit to get a good sense of what was going on. So I went on and met with the patients and the doctors and got a feeling of what was happening and had the opportunity to be able to convey it to the world afterwards.

That whole Khayelitsha visit was invaluable for me because, almost at the outset of my work as Special Envoy for HIV/AIDS in Africa, it gave me a sense of what could be achieved. That was tremendously important, because it allowed me to confront governments with an example that was working, and say, “If you can do it in Khayelitsha, one of most impoverished settlements in South Africa, why the hell can’t you do it in your country?”

### **Stephen Lewis**

Stephen Lewis was the UN Secretary-General’s Special Envoy for HIV/AIDS in Africa from 2001 to 2006.



Over 10,000 people from around South Africa converged on Cape Town parliament to stage a march calling on the government to introduce a treatment plan for HIV-positive people. Cape Town, 14 February 2003. © ERIC MILLER

# Introduction

## **A Narrow Victory**

On a Monday morning in the autumn of 2011, Khayelitsha Site C Day Hospital was packed. Dr David Coetzee met with a patient, Thandeka, a pretty young woman, stylishly dressed in a tight t-shirt and long denim skirt, strings of golden beads twisted around her wrists and her waist, who had been on antiretrovirals (ARVs) for over a year. She saw Coetzee rather than a nurse or counsellor because she wanted to have a baby, and her ARV regimen would have to be changed to include nevirapine; efavirenz might not be safe for a foetus. Nevirapine affects the liver, however, so her enzymes needed to be checked. The doctor noted that she would be monitored throughout her pregnancy to ensure she stayed healthy and her baby was born HIV-free.

Thandeka, who lived in a shack, sharing a tap and toilet with several neighbours, did not finish high school and was unemployed, but she knew the names of the drugs she was taking, and understood how they fought the virus in her bloodstream. She was also aware how crucial it was to take them every day at the same time. She had daily reminders programmed into her cell phone.

The treatment Thandeka and all the other patients receive in Khayelitsha, Cape Town's largest township, is as efficient and

effective as any available in the developed world. It is also completely free, courtesy of the South African government.

Today, making HIV/AIDS treatment available to those who could otherwise not afford it appears a common enough goal: not just non-governmental organisations (NGOs), but governments, international organisations, transnational bodies, and public-private partnerships, from municipalities to the World Health Organization (WHO) to the Global Fund (GF), accept and promote it so regularly that one might be forgiven for forgetting it was ever in doubt.

Not that long ago, however, women such as Thandeka would have sought help from Dr Coetzee in vain. Drugs to treat the condition were available, but only to the rich. Since then, an extraordinary global battle has been fought that resulted in subtle but significant shifts of power, from medical specialist to patient; governments to civil society; and corporations to consumers. One of the most tangible results is the life-saving treatment that Coetzee has been able to share with his patients in Khayelitsha.

Even those of us who remember the day in April 2001 when the pharmaceutical companies withdrew their case against the South African government – effectively opening the door to a system of treatment that would circumvent international patent law – might not recall just how uncertain an outcome that was.

Pharmaceutical companies were courting the world's worst possible publicity: going on record to demand their profit, even if it meant people would suffer and die. Every penny they asked for looked, to the engaged observer, like a pound of flesh.

To make any appeal to public opinion even more difficult, a quirk of South African law specified that the president of the republic be named in the case as a respondent. This meant, at least on paper,

that the South African Pharmaceutical Manufacturers' Association (PMA) was pursuing their case not just against a particular law – or even against nameless patients and their caregivers – but against a man revered with almost religious fervour in his own country, a personal and political hero to millions around the world, a man who, like Ghandi or Mother Teresa, had come to stand for something far larger than himself: Nelson Mandela. In hindsight, the very idea of the case looks like public-relations suicide.



Khayelitsha, South Africa. © PETER CASAER

Pharmaceutical companies aren't like tour guides, however, or car manufacturers, or practically any other business, and while they are certainly image-conscious, patent laws mean that for many life-saving drugs, there is one source and only one, a *de facto* monopoly. If you find that source morally repugnant, your options are to deal

with the devil or – literally – drop dead. Multinational corporations hope and even assume that anyone who can afford to will set morality aside when it interferes with self-interest. The irreplaceable doesn't need to advertise, which is why you won't see billboards promoting such "monopolies" as the judicial system.

South Africa held its first fully democratic elections in 1994; the previous system, called *apartheid*, Afrikaans for "apart-ness", had restricted voting to only those deemed racially superior – whites of verifiable European ancestry. Indeed, everything in the country was defined and divided by race, from the places you could live to the jobs you could do. So detailed were race-based laws that black carpenters were allowed to hammer nails, but only white carpenters were considered legally competent to pull them out again. Radical conservatives loudly predicted that majority rule would bring an almost instant meltdown of systems, including – indeed, particularly – a complete failure of law and order. Some white supremacists even went so far as to engage in terrorism. When the new, multi-racial Republic of South Africa stepped out on the world stage, South Africans knew themselves to be the subject of much good will, but also of much careful international scrutiny.

It was certainly going to take more than goodwill to bring major investment to a country facing an uncertain future, one that had suffered sanctions and embargoes in a variety of areas, some for decades, affecting everything from international trade to scholarship and athletics. Each revoked sanction was a feather in the cap of the new regime, which could then take its place in the global village – but any new sanction would damage its credibility and play into the hands of critics, some eagerly awaiting its failure. To maintain the rule of law, to meet international standards, to be good global



citizens, were essential to the success of the South Africa reborn in 1994.

In a strictly legal sense, the case that became known as Big Pharma vs Nelson Mandela was a good one for the plaintiff: as we shall see, a series of international agreements had positioned patent law as the very backbone of international relations, and international relations were what the government of South Africa wanted and needed. The case therefore set a major multinational business with almost bottomless pockets against a young government with conflicted motivations. This, coupled with the denialism that became endemic in Pretoria, made it look for a long time as if there were little or nothing that could stop the pharmaceutical industry from having its way.



Khayelitsha, South Africa. © PETER CASAER

The movement for affordable treatment could easily have failed. This is therefore the story of a narrow victory, a near miss. The role Médecins Sans Frontières/Doctors Without Borders (MSF) played in that victory, and how – with a coalition of activists from South Africa and around the world, and organisations supported by mostly average people – the battle was won in the face of what seemed overwhelming opposition, is the story told here.



Global March for Treatment Access, Cape Town, July 2000. © NATHAN GEFFEN



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# The Cruellest of Ironies

In 1994, South Africa held its first free elections. In the cruellest of ironies, just as South Africa had freed itself from one enemy, another arrived: a disease that hadn't even been identified until 1983, human immunodeficiency virus (HIV), was exploding across the globe. By the end of 1998, an estimated 5.6 million South Africans were infected with HIV. Still today, HIV, which causes acquired immunodeficiency syndrome – AIDS – has no known cure; in 1994 it was also considered essentially untreatable because of the high cost of medication: because of patent protection, a year's prescription for one person cost between \$10,000 and \$12,000.

HIV treatment was also believed to be an extremely complicated regimen that could only be administered by specialist doctors in referral hospitals with specialised infectious diseases departments equipped with the latest diagnostic tests. One of the commonly accepted arguments used against extending the treatment to places such as Africa was that even if the cost could be reduced, Africans' lack of sophistication would make the drugs impossible to administer properly.

The country faced a terrible dilemma: meet international expectations to respect the rule of law, or meet citizens' needs. Absence of treatment options meant HIV was hardly mentioned in

political discourse; many victims, most of whom were black, relied on traditional healers.

Treatment appeared so difficult that in fact MSF had not been very active in tackling the problem. Dr Bernard Pécoul, formerly executive director of MSF in Paris, acknowledges that “In the first part of the 90s, we just rejected the possibility of doing anything.” There were a number of reasons for this, but the most important one was probably the lack of an effective medical approach. Given the limited options for treatment, HIV/AIDS organisations were focused almost exclusively on prevention, and according to Pécoul, “It’s relatively difficult for an international medical organisation to work only in prevention on this sort of disease because you have to understand a lot of social and cultural aspects. So we felt we were not the best organisation to do it.”

An activist movement within the association was devoted to reversing this assumption. In 1996, the provocative title of an internal MSF newsletter was “MSF – a white sero-negative organisation?”, an obvious call to arms, a challenge to the organisation to do more.

News of a treatment being tested in Thailand made it look as if medical intervention could soon to be a reality, if not for people already infected, then at least for children born to those who were. The protocol, PMCT (prevention of mother-to-child transmission), predicted you could reduce transmission rates from infected mothers to their children by 50 % – by giving AZT, one of the first antiretrovirals – to the mother twice a day after the first 32 weeks of pregnancy, with extra doses during labour and delivery. Some within MSF were anxious to prove to the scientific community that, contrary to accepted wisdom, ARVs could be safely administered

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# messages

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nov/décembre 1995

numéro spécial

sida

## MSF, organisation blanche, hétérosexuelle

Ce numéro de Messages est entièrement consacré au Sida et cela mérite un mot d'explication. Ce qui ressemble de près à un détournement de support de communication à des fins non strictement conventionnelles est en fait exactement cela. So, en lieu et place des informations habituelles sur l'action de notre association, nous publions ce numéro de Messages, c'est pour éveiller nos volontaires aux risques d'exposition au VIH qu'ils encourrent et aux moyens de prévention existants. Il y a été, douze ans, lors du tout début, on ne savait pas vraiment à quel s'attendir. Des millions de personnes parmi lesquelles quelques amis chers ont payé cette ignorance de leur vie. Aujourd'hui, on peut affirmer que le Sida est une infection virale, se transmet facilement, dont on pourrait limiter la propagation, en évitant la naissance et qu'on finira par vaincre en tant que maladie. Cependant, l'épidémie continue sa progression : en Afrique et dans de nombreux pays pauvres, l'épidémie reste principalement le fait de l'ignorance de la maladie, de son lien avec le virus et des modes de transmission. Mais combien peuvent aujourd'hui se faire dépister au Malawi ou au Cambodge ? L'essentiel des ressources contre le Sida est généré et utilisé dans les pays développés alors que l'essentiel des malades et des futurs malades se trouve dans les pays pauvres. En revanche, dans les nations développées, chacun de nous est concerné, non pas tant comme victime potentielle mais certainement en tant qu'individu responsable. Le combat contre le Sida est en passe d'être stérilisé par les seuls spécialistes autorisés : lobbies, associations "spécialisées" et scientifiques appelés. Nous savons bien qu'écrire ne serait-ce que deux lignes sur le Sida sans pouvoir se préoccuper d'appartenir au cercle, c'est risquer le pire : entre les excès de la capote et autres curettes récupérateurs, nous avons décidé de mettre notre petit grain de sel. Puisse-t-il ouvrir un espace de conscience afin de secourir la frilosité à en parler et la mollesse des réactions au sein de MSF. Une priorité !

■ Philippe Ribreau, président

## ...et séronégative ?

**ALERTE ROUGE** Jusque-là, on avait réussi l'exploit de vivre avec le Sida en l'ignorant, en le contournant, en évitant d'en parler. De fait, ensemble, on a fermé les yeux un bout de temps. Et puis, un jour, une lettre est arrivée aux Techniques médicales : elle commençait par « je suis plombée ». Enfin, on s'est pris les boules. Parce que cette histoire, c'était la nôtre, celle de quelqu'un que nous connaissions. On a entrouvert les yeux et commencé doucement à sortir de notre bulle. Cette lettre (lire en page 4) est depuis intégrée au document "A lire avant le départ" que nous remettons à tous les volontaires qui partent sur le terrain. Histoire de ne pas l'oublier. A l'occasion de la Journée mondiale de lutte contre le Sida, nous voulons parler tout haut du Sida et ne plus se défilier.

Lire Noëlle Lasne en page 2

société Sida

Messages MSF n°82 novembre/décembre 1995 1

to a poor African community, even outside of a hospital setting. A small project testing PMCT was just what they were looking for. Although the initial plan was to expand an existing MSF project in Kibera (Nairobi, Kenya's biggest slum) to include PMCT, Pécoul and director general of MSF Brussels Alex Parisel offered their colleagues several reasons to consider South Africa instead. The first



was a basic epidemiological calculation: South Africa contained the highest number of HIV-positive people in the world. The second was logistical: South Africa enjoyed a certain level of infrastructure and a level of medical competence not available elsewhere in Africa. There was also the *témoignage* aspect to consider: thousands of the world's leading scientists were scheduled to meet in June 2000 in Durban, South Africa, for the 13<sup>th</sup> International AIDS Society Conference. The conference would provide the perfect opportunity to demonstrate to the international scientific community that HIV/AIDS treatment, with combined antiretrovirals, was possible in a resource-poor setting. The schedule didn't give MSF much time to get its PMCT project established and running, but the publication of the protocol had initiated a wave of enthusiasm among members, and the chance to reach this particular audience certainly seemed worth the effort.



Durban Global March, Durban, South Africa, 2000. © SUSAN AMANDA / TAC



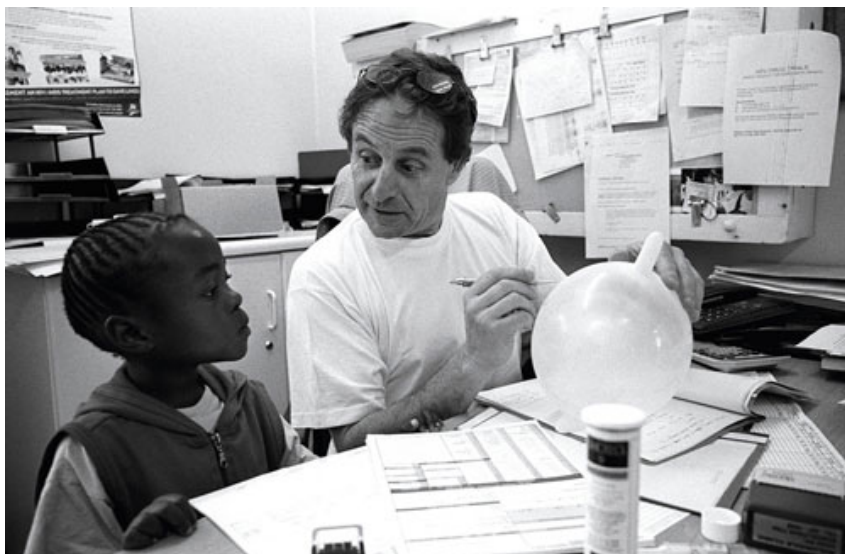
The final reason had to do with patents. MSF was generally interested in improving access to essential medicines, including outside of the field of HIV, and was about to launch the Access Campaign, known as CAME, under the direction of Pécoul. There had been particular difficulty in procuring new antibiotics; doctors would work in a hospital in Europe using the newest medicines and then be confronted with outbreaks in a developing country where those medicines were either too expensive or not available. The changes made to intellectual property regulation in 1994 were having an effect, and there was a growing consensus that patent issues were at the core of the problem. In an unprecedented move, MSF even hired an in-house patent attorney, Ellen 't Hoen, something no health organisation had previously considered necessary but which, given the effects of new patent agreements, is now standard practice ('t Hoen, a specialist in intellectual property law, later became the CAME advocacy director). When the association learned that the South African Pharmaceutical Manufacturers' Association was taking the government there to court over an anti-patent measure that would promote lower-cost drugs, MSF knew where it wanted to be. Durban would be an unmissable chance to rally support for access to essential medicines.

Dr Eric Goemaere, former director general of MSF Brussels, had spent a large part of his life living and working in Africa. He arrived in Johannesburg in August 1999 to find a partner clinic for a "simple PMCT programme" – only to learn that nothing about it would be simple. "We were still under the illusion," he says, "that, given the scale of the epidemic, treatment would be a number-one priority for the government." He was soon to discover just how mistaken they were.



Bernard Pécoul. © SANDRA ASLAKSEN

Goemaere, convinced MSF should bring its message to the AIDS conference in Durban in 2000, was excited to get started. “For the first time, we had this opportunity to say to the whole scientific world, thousands, all gathering there around HIV: ‘Listen, just next door, thousands of people are dying from that disease, and it can’t be treated because of the patents.’ We thought that we could gather momentum, which would create extremely strong pressure on some of the inventors of the drugs.” The doctor had one year in which



After taking blood Dr Eric Goemaere gives a blown up glove to a young HIV patient, Khayelitsha, South Africa. © FRANCESCO ZIZOLA / NOOR

to gather enough data. Instead, within a week, he was calling MSF headquarters in Brussels to tell them that his attempt to start a pilot PMCT programme had failed.

The organisation didn't have many contacts in South Africa, so Goemaere, armed with a *Lonely Planet* and his naïveté about the government's interest in HIV treatment, approached a health centre in Alexandra township near Johannesburg, chosen because it was in an extremely socially deprived environment. The centre was the perfect site for a project designed to establish that treatment could take place outside the context of wealthy Western hospitals, in what Goemaere calls "a real-life setting, with patients, outside a research environment."



MSF clinic, Khayelitsha, South Africa. MSF doctor Eric Goemaere examines an HIV patient. © FRANCESCO ZIZOLA / NOOR

“I didn’t like South Africa,” he admits. “I had been in transit in South Africa during the apartheid era because I worked next door in Mozambique, and I’d been arrested in the transit area because I refused to sit in the whites-only waiting room.” Despite his reservations, he found the doctors there extremely receptive: unable to provide any treatment for HIV, they had been reduced to promoting condoms, a strategy that had proven – in Alexandra as elsewhere – of strictly limited effectiveness. Within three days, Goemaere had signed an agreement: MSF and the health centre would work together to demonstrate that what had been done in Thailand in a research setting could also be done in a township.

He then contacted the Ministry of Health. MSF generally doesn’t work clandestinely, and standard procedure is to announce the organisation’s intentions to authorities and, if possible, to sign an agreement of understanding. While it wasn’t easy, Goemaere managed to get an appointment with the national director of the HIV programme, Dr Nono Simelela. At her office, he outlined the project, and told her about his primary contact in Alexandra. She appeared interested, so Goemaere was surprised when she interrupted him to ask, “Dr Eric, could you do a similar intervention reducing mother-to-child transmission, but not using AZT?”

Goemaere “didn’t understand the question,” he says, “because it made no sense”: only AZT had been shown to reduce transmission in a simple protocol. Assuming he hadn’t explained himself correctly the first time, he began again, and again she stopped him, this time saying she had understood perfectly, but that she needed to make a phone call.

“She came back to me and she looked very miserable. She said: ‘I’m sorry, I cannot allow you to do this in Alexandra.’” When Goemaere tried to find out why, she told him it wasn’t a priority. Later he

would learn she had spoken to the national director general of health, Dr Ayanda Ntsaluba, to see if they could take the risk of allowing MSF to go forward: the minister of health at the time, Dr Nkosazana Dlamini-Zuma, had already blocked the public-sector use of AZT when utilised to reduce mother-to-child transmission. In the course of a single meeting, everything had changed. Perhaps the project could be moved to Kenya, as previously conceived. Goemaere phoned Brussels with the news, and made plans to go home.

Before leaving, however, he phoned an email acquaintance, the activist Zackie Achmat, “as a courtesy”, and everything changed again.

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Zackie Achmat speaking at the Durban Global March. 7 September 2000. © SUSAN AMANDA, TAC

In 1998, Zackie Achmat and a handful of HIV activists had launched

the Treatment Action Campaign (TAC), which had rapidly become one of the most prominent HIV-advocacy movements in the world, so Goemaere accepted Achmat's invitation to visit him in Cape Town. During an all-night conversation about the frustrating fight for ARVs in South Africa, Achmat mentioned that the Western Cape provincial government might have started a PMCT programme in Khayelitsha. Khayelitsha was – and still is – a very poor township: home to an estimated 350,000 migrants, mostly from the Eastern Cape Province. At that time, over two thirds of Khayelitsha's population lived in shacks, and nearly half of the women and just over a quarter of the men were unemployed. While the most pressing difficulties reported were crime and unemployment, a sub-sample of pregnant women had been tested in 1998: 15 % reported HIV-positive; within ten years, that figure would rise to 30 %.

Intrigued, Goemaere stayed on, and a colleague of Achmat's took him to Khayelitsha, where, at Site B, they visited a recently launched PMCT pilot programme, one that looked exactly like the programme MSF had intended to start in Alexandra. The relative political independence of the Western Cape – which was one of only two provinces not to elect an African National Congress-led government in 1994 – made it possible for the provincial authority to take this kind of initiative without approval from the national government, although it made sure to at first keep a low profile. The Western Cape's provincial health department had asked the University of Cape Town (UCT) to monitor the Khayelitsha PMCT programme, and it was with the university that Goemaere negotiated MSF's involvement.

Unfortunately, Goemaere soon discovered that the project wasn't quite what he had hoped. Nurses administered AZT quite late, at

around 36 weeks, to pregnant women who tested HIV-positive. There was no post-natal phase for the babies, and it seemed that the medical staff were not very keen on the PMCT programme.

Their lack of commitment was manifest in their record-keeping, which Goemaere characterises as “just jotting information down on a single piece of paper.” There were no registers, lab results were often lost, and outcomes were not recorded at all, which meant that in a sense the very purpose of the pilot – to prove its effectiveness – was practically an impossibility. Goemaere set about establishing a proper records system, and instituted PMCT-specific training for the nurses. “We also established a postnatal phase so we could protect the baby from transmission of the virus during breastfeeding. At that time, the mothers were administered AZT, but there was no protection for the baby when they were breastfeeding. It was an incomplete programme.”

At the source of many of these problems was the fact that the staff didn’t know anything about HIV or the process of transmission, and as a result were extremely scared – so scared that eventually they announced that they didn’t want MSF there because MSF “attracted” HIV. Goemaere explained to them that HIV was already present: “It was sitting there. Of the people in the waiting room, at least 30-40 % were already HIV-positive given the selection bias.” Because patients were not being tested, many people – including health workers – simply could not imagine that they were already carrying the virus. Goemaere learned that by 1998, only 450 people in Khayelitsha, South Africa’s largest and fastest-growing township, had been tested for HIV (compared to approximately 54,000 HIV tests per year in 2011). Only patients who were already very ill were being tested, so HIV was associated with extreme sickness – and death.

Premature mortality was rising at a dramatic rate. Funerals in



Khayelitsha are important social events, but so many were taking place that the cemetery had restricted each service to half an hour – and things were still going to get worse. Deaths from HIV were attributed to diarrhoea or pneumonia; no one wanted to mention AIDS. The stigma was powerful and dangerous: one of the catalysts leading to the formation of TAC had been the murder of a Durban woman, Gugu Dlamini, after she had publicly disclosed that she was HIV-positive.



Funeral of an HIV activist in Khayelitsha. © COLWYN POOLE, TAC

Every day, Goemaere forced himself to go to Khayelitsha, only to meet with resistance. “There were a lot of missed appointments. They would say: ‘Doctor, we’re busy. Come back tomorrow,’ and the next day they would make sure that nobody was there.” With the

Ministry of Health and the nurses against the programme, and his fighting the suspicion that the programme itself was what caused the disease, Goemaere was engaged in an up-hill struggle. He was in a copy-shop one day, photocopying the simple register he had created for the PMCT programme, when he saw a television broadcast: a former colleague from Brussels was accepting the Nobel Peace Prize on behalf of MSF. Goemaere wondered then if he wasn't in the wrong place.

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Goemaere had been working in Khayelitsha for several months before he was introduced to the man who was responsible for initiating the PMCT programme there. Dr Fareed Abdullah was a former ANC activist, now responsible for vertical health services in the province, including HIV and tuberculosis (TB).

Dr Abdullah had attended a meeting in Johannesburg in 1998 where researchers revealed the early findings of the PMCT trial in Thailand. Impressed by evidence that there was an effective and affordable approach to PMCT, he immediately set about organising a programme in the Western Cape – including placing orders for AZT – only to read in the newspaper just before the programme's launch that Dlamini-Zuma had decided the country would not provide AZT for pregnant women. Abdullah chose to press ahead regardless. "I made a decision to continue with the programme because it was within the authority of the provincial government to make such a decision and it was within my delegated authority as chief director to introduce new drugs into the public service," he says. "I had no idea then that this would become such a big political issue. I was proceeding on the basis of the rules and regulations which established the parameters of my authority and what medical science was saying."

The decision was made possible by the fact that the provincial health minister, Peter Marais, was a member of the National Party, and so he didn't care about the prevailing policies in the ANC. Abdullah jokes that "the right was protecting the left from the centre." Abdullah himself had resigned all his ANC party positions because he believed "civil servants should be independent and serve the entire society, not follow narrow party interests." Using the political space provided by the situation to do something for his constituents that wasn't approved by the Ministry of Health brought him a good deal of criticism, and he was the subject of personal attacks first by Dlamini-Zuma, who accused him of betrayal, and later Dlamini-Zuma's replacement as minister of health, Dr Manto Tshabalala-Msimang. "I was shocked. I couldn't understand why the party of the liberation movement was denying life-saving treatment to poor people, but I also was very determined about going ahead, with or without national support," Abdullah recalls. He would tell the health minister, "I learnt to do the right thing from the ANC. I spoke to many leaders in the ANC whom I knew, and they all told me: do what you believe in your heart is the right thing."

At that moment, he was convinced the right thing to do was forge ahead, but keep a low profile. Goemaere says his first meeting with Abdullah was "quite cold, but, Fareed, being very clever and sharp, immediately identified a role we could play." The need for discretion was top of the agenda. Abdullah explained that while MSF was good at advocacy, he needed a partner who could keep quiet. In exchange for a promise to be that partner, Goemaere was allowed to expand MSF's involvement to HIV treatment beyond PMCT. Children whose mothers received PMCT treatment were being born disease-free, but they were also being left orphaned as HIV



Fareed Abdullah receives an award from TAC. From left to right: Nompumelelo Matangana (head nurse Ubuntu clinic), Fareed Abdullah, Vuyiseka Dubula (future TAC secretary general).

killed their parents. Goemaere was given use of a room at the day hospital at Site B in Khayelitsha, and labelling his work “private research” provided legal camouflage. Goemaere, named principal investigator, announced to his staff: “This is a clinic to treat HIV-positive adults, not prevent transmission. Do you understand the difference?”

Goemaere had originally requested three rooms. “I thought we could have a bit of a multi-disciplinary team: a doctor, a nurse, and a counsellor, which was more or less the standard at that time. The facility manager said to me, ‘Nobody’s going to queue in front of your door because you know, in our culture, people do not like to be identified as HIV-positive. You will see for yourself: one room is going to be big enough!’”

She was wrong. After two weeks, Goemaere’s room was packed. “As soon as the rumours spread that there was a doctor there accepting people as being HIV-positive, people literally came in masses. By

the middle of 2000, a few months after we had opened, we had registered several hundred people as HIV-positive.”

Indeed, Goemaere’s single room at Site B was so crowded that he invited another doctor to join him. He also found a skilled and dedicated nurse, Victoria Dubula – known as “Sis Dubs”. But patents meant ARVs were completely unaffordable.

Goemaere recalls, “We were only seeing the sickest of the sick; those who were absolutely desperate. People were brought in on stretchers. The waiting room was packed with people on stretchers. Some were brought in in wheelbarrows, carried like that into the waiting room, in front of everybody. Stigma dropped very rapidly because suddenly people realised – it’s not only me, there are thousands all around that are HIV-positive. But they were all extremely sick.”

Dr Francoise Louis, Goemaere’s new colleague, had started treating patients with HIV in the 1980s, and was familiar with ARV therapy. “I witnessed the introduction of [ARV] in France and what it meant to people. When I discovered the impossible levels of HIV prevalence in southern Africa I became obsessed. I sold all my belongings and travelled through Swaziland, Zimbabwe, Botswana, and South Africa looking for a job where my skills could be used.” She found working in Khayelitsha extremely distressing. “How does a clinician feel if whatever you do to care for your patient, he comes back sicker, thinner, the wretched headache does not go away, the excruciating diarrhoea does not stop? The situation was inhuman for them; it was inhuman for us who knew that a treatment to keep them alive was available. Patients suffered the unthinkable. As they were dying we felt we were dying ourselves.”

A highly effective anti-HIV regimen called HAART had been developed in the United States. It consisted of three different

antiretrovirals, which greatly increased the cost of treatment. HAART turned a death sentence into a chronic illness – but only if you could afford it. Goemaere’s goal was to eventually introduce this triple therapy at his clinics, but for the moment, that was a financial impossibility. Even the PMCT programme, which used patented AZT alone and for a limited period, was barely affordable.

Demand for the clinic’s services continued to expand. Goemaere poached a local doctor and TAC activist, Hermann Reuter, from Tygerberg Hospital; together with a local nurse, Veliswa Labatala, they opened a second clinic at Site C. The main problem remained the same, however: MSF could open as many clinics as it wanted, but without ARVs and other drugs there was very little concrete help it could offer their patients, and patents meant the drugs it needed were impossibly expensive.

Clinic head-nurses such as Victoria Dubula, Veliswa Labatala, and Nompumelelo Mantangana became central to the clinic set-up: more than nurses, they were activists who participated in establishing TAC branches in Khayelitsha. Able to speak Xhosa, their ongoing community interactions played a key role in bridging the cultural divide between white doctors and their patients.

Goemaere’s partner, the MSF epidemiologist Katherine Hildebrand, arrived in South Africa in December 1999. She joined the UCT epidemiological team chaired by David Coetzee. MSF was well aware of the need for a meticulous study backed by a local university and a journal to publish their study results, especially since the environment was very antagonistic. As late as 2001, prominent people maintained that ARV treatment in a low-resource setting was impossible: that year, Andrew Natsios, director of the United States Agency for International Development, told the US House of Representatives’ Committee on International Relations that “rural

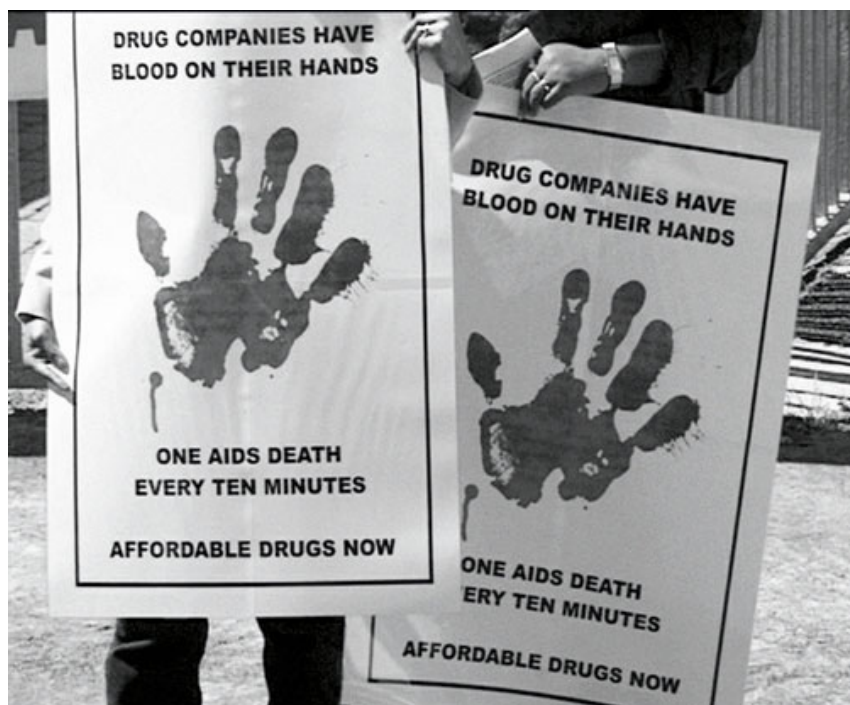
Africans do not know what watches and clocks are. They use the sun". The idea was they wouldn't be able to take medicines properly, and so should be denied access to ARVs.

Initially, Coetzee was asked to only help with monitoring, but his role soon expanded. The three clinics established in early 2000 by MSF to treat HIV-positive patients were overflowing. About 70 % of the first patients were women from the PMCT programme. The idea was that treated mothers would now live to care for the babies who had been saved from HIV infection by PMCT. It was tough going. "The patients were very sick," says Coetzee. "Some of them were being wheeled in in wheelbarrows. They were very thin, and dehydrated from persistent diarrhoea. Several of those patients died, as we still did not manage to have access to ARVs. We had one patient who had a form of scabies called Norwegian scabies, very contagious and only common in severely immuno-compromised patients. Eric and I got it from him, and Eric gave it to his whole family. The patient was a delightful guy but sadly he also died. We couldn't get these patients onto ARVs quickly enough."



Dr Hermann Reuter treating HIV patients in the MSF clinic, Khayelitsha. © SEBASTIAN CHARLES





TAC posters used during a Defiance Campaign. South Africa, 2000. © TREATMENT ACTION CAMPAIGN

## TRIPS and Treatment

Nelson Mandela originally trained as a lawyer, but when he was elected his country's first African president in 1994, it is unlikely that international patent law was uppermost in his mind. Nevertheless, a change to international patent and intellectual property regulation being finalised that same year would soon have a profound impact on South Africa, becoming an indelible part of the legacy of his time in office.

The agreement on Trade Related Aspects of Intellectual Property Rights (known as TRIPS) is an international agreement administered by the World Trade Organization (WTO). The agreement sets out minimum standards for intellectual property protection and enforcement, a set of rules that globalise intellectual property standards and make them enforceable. Many WTO member countries had not previously considered patents on products such as medicines and foods to be in the public interest. Some – including, for example, Spain and Norway – had actively excluded pharmaceutical patenting as against the public interest. TRIPS put to end any diversity among pharmaceutical patent policies and practices by mandating the granting of patents in all fields of technology, and requiring all member countries to introduce standard 20-year patents on medicines. TRIPS came into

force in January 1995; over the next few years, most countries introduced intellectual property reforms to meet TRIPS requirements, as required to retain good standing in the WTO.

As a developing country, South Africa was in fact not obliged to implement TRIPS before 2000, but in order to attract foreign investment that could provide desperately needed jobs, education, and healthcare, the new government was anxious to shed the nation's isolationist past and become fully integrated into the global community. To prove South Africa's dedication to international standards, the Ministry of Trade and Industry initiated a strengthening of its patent laws in 1997. An unforeseen consequence was the effect this would have on the Health Department's ability to provide universal healthcare.



Ellen 't Hoen, a specialist in intellectual property law and advocacy director of MSF's Access Campaign. © MARCELL NIMFUEHR

Under apartheid, a disproportionate amount of South Africa's health budget had been reserved for white people. In extending care to the formerly disenfranchised African community, the new government had to double the volume of drugs obtained with the same amount of money. Like MSF, the health services were at first mostly concerned with access to patented antibiotics.

According to Ellen 't Hoen, "The space that countries once enjoyed to design intellectual-property systems to meet their own development needs was rapidly shrinking." And yet, as 't Hoen points out, Mandela's government was far from alone in not foreseeing the outcome: "In the late 90s, the potential effect of changing intellectual property rules on access to medicines was little understood, and interest in intellectual property issues among the public health community was still rare."

Even under TRIPS, national governments preserve some of the traditional legal means by which they can at least bend the rules when necessary. The most important loophole is compulsory licensing, a system by which a government allows someone to produce a patented product without the consent of the patent owner, usually to provide generic drugs for a domestic market. Under TRIPS, anyone who applies for a compulsory licence is required to have tried to negotiate commercial terms with the patent holder.

An easier option is parallel imports. In India, for instance, generic drug production was still possible at that time because the Indian Patents Act did not provide for pharmaceutical patents until it absolutely had to. Before South Africa's patent protection laws were prematurely strengthened, they could have legally imported much cheaper generics from India.

Recognising this, in 1997 the South African government introduced

the Medicines and Related Substances Control Amendment Act. This changed the existing law to allow the minister of health, under certain circumstances, to cancel patent rights or initiate parallel imports of generic medicines. The act also imposed a transparent pricing mechanism. The purpose and the effect of the act were to make low-cost medicines more readily available.

To allow the introduction of constitutional challenges, South African parliamentary procedure traditionally leaves a delay between the passage of an act by the legislature and its signature into law by the president. In this case, a challenge was lodged by the Pharmaceutical Manufacturers' Association, a group representing 39 pharmaceutical companies, which claimed that the changes contravened both the constitution and TRIPS.

The 13<sup>th</sup> International AIDS Society Conference opened in Durban in June 2000. This was the first time that the conference had taken place somewhere so deeply affected by AIDS. KwaZulu-Natal recorded the highest antenatal prevalence in the world: in the township close to the conference hall, nearly 40 % of all pregnant women were HIV-positive.

In Thabo Mbeki's disappointing opening speech, he urged scientists to respect other points of view, even when those views contributed, through obfuscation and foot-dragging, to unnecessary death.

Prior to the conference, over 5,000 scientists and physicians had already signed the Durban Declaration, affirming that "HIV causes AIDS". TAC and the Global Health Access Alliance organised a march to coincide with the conference. Over 3,000 people, including local people living with HIV, demonstrated in favour of affordable medicines and AZT/nevirapine for pregnant women. The police



Entrance of the 13<sup>th</sup> International AIDS Society Conference center. Durban, South Africa, 2000.  
© SUSAN AMANDA, TAC



Durban Global March. Durban, South Africa, 2000. © SUSAN AMANDA, TAC

were initially instructed to block protesters from entering the conference centre, but the conference's organisers, Jerry Coovadia



Peter Piot, director of UNAIDS, (center) at the 13<sup>th</sup> International AIDS Society Conference. © SUSAN AMANDA, TAC

and Salim Abdool Karim, publicly called for them to be granted entrance. This moment sealed the alliance between activists and scientists.

Peter Piot, the director of UNAIDS, urged donor countries and businesses to dramatically increase money for HIV/AIDS treatments, including ARVs. Three billion dollars was needed for basic care and prevention in Africa – and that didn't even include ARV treatment.

MSF organised a satellite session to announce the initial outcomes of the Khayelitsha PMCT programme. Prominent figures were invited; these included Judge Edwin Cameron, from the Constitutional Court, who was openly living with HIV, and Peter Mugenyi, an HIV-treatment pioneer from Makerere University



MSF satellite session at the 13<sup>th</sup> International AIDS Society Conference, Durban, South Africa, 2000.

Hospital in Kampala, Uganda. Piot's succinct summary of the problem – that ARVs are present where the problem hardly exists and not available where it does – made headlines.

Former President Nelson Mandela closed the conference with a diplomatic yet desperate call for Mbeki to recognise the facts and set politics aside in order to address the needs of those suffering and dying, something that could only be done in partnership. It was Mandela's first public disagreement with his successor over HIV/AIDS policy. It would not be the last.

Most of the patients at the Khayelitsha clinics had very low CD4 counts and were therefore vulnerable to opportunistic infections, including cryptococcal meningitis and systemic thrush. Both can be treated. The drug of choice is fluconazole, available in South Africa under the name Diflucan. Fluconazole was under



patent at that time, however, and the manufacturer, Pfizer, sold the drug at the same price in the developing as in the developed world; voluntary licences were always refused. It was therefore far too expensive for use in the public health service.

In a letter to the *Lancet*, MSF pharmacist Carmen Pérez Casas and her colleagues had predicted that if South Africa were to import generic fluconazole from Thailand, the cost of one year's maintenance treatment would drop from \$2,970 to \$104. They also pointed out that Pfizer's fluconazole sales in 1999 had amounted to over \$1 billion.

Although the ultimate goal remained affordable ARVs, it was decided to first focus on a treatment for a common opportunistic infection, treatable only with a very specific molecule. When Christopher Moraka, a prominent TAC activist, died from AIDS-related infections – including systemic thrush – because he was unable to afford Diflucan and it was not available through the public health service, TAC asked MSF to put together a dossier on fluconazole. MSF, hoping to foster an alliance in the fight for fluconazole, requested the support of Wilbert Bannenberg, a WHO doctor seconded to the Ministry of Health, to develop an essential drug policy. A campaign named for Moraka was launched shortly after his funeral. Pfizer, already under tremendous pressure from activists in the US, announced it would provide free fluconazole to South Africans, but only on condition that its use be restricted exclusively to the treatment of notified cases of oesophageal candidiasis and cryptococcal meningitis. The offer was far too restrictive, so MSF and TAC decided that the most sustainable way of acquiring all the fluconazole they needed was to drive the price down by creating competition. To do this, they began their first deliberate patent-infringement campaign.



MSF joins AIDS activists in a protest march. Bangkok, Thailand. © MSF

MSF arranged for Zackie Achmat to meet Paul Cawthorne, MSF's head of mission in Bangkok. Fluconazole was not patented in Thailand. Under pressure from the United States, however, the Thai Food and Drug Administration implemented the Safety Monitoring Programme, which effectively conferred a period of market exclusivity, just as a patent would. When the Safety Monitoring Programme ended, three national pharmaceutical manufacturers began to produce fluconazole locally.

Locally produced fluconazole sold at a fraction of the cost of the brand-name drug. The original price asked by Pfizer had been around \$7 per 200-mg capsule. After fluconazole was released from the Safety Monitoring Programme, Pfizer decreased its price to \$3.60, but the generic product was nevertheless significantly

cheaper. Biolabís, for example, charged \$0.60 per 200-mg capsule. This obviously made an enormous difference to a patient who must take a capsule every day for life. In 2000, MSF started a limited ARV treatment programme targeting activists from the Thai Network for People Living with HIV/AIDS. Stewards working for Dutch airline KLM helped by “importing” small quantities of branded ARVs into the country.



MSF staff with a patient in MSF's HIV/AIDS project in Thailand. © STEFAN PLEGER

In October of that year, Achmat travelled to Thailand. With Cawthorne's help, he met with local pharmaceutical manufacturers, agreeing in the end to purchase 5,000 200 mg tablets of fluconazole from a company called Biolab. Achmat left 2,000 tablets with Cawthorne; the rest he packed in a suitcase and took with him.

The cost was R1.78 per tablet; the same medication would have cost R80 per tablet in South Africa. The whole process was videotaped, so that if Achmat were stopped by customs officials when entering South Africa, he could provide video evidence of how the drugs had been obtained. Cawthorne had some of the tablets sent to Europe for quality testing; the rest would be sent to South Africa in small bundles via DHL.

TAC and MSF ensured that Achmat's return with the drugs was extensively promoted in the media. As expected, Achmat was arrested, but not for patent infringement. Instead, the Medicines Control Council (MCC) had him arrested for bringing unlicensed medication into the country. The stunt gathered a lot of publicity – the *Cape Times* ran the headline “Rebels show smuggled drugs cost R100 less” – but had no lasting effect. Goemaere admits, “We thought naïvely that the MCC would close their eyes, but, as was explained to us afterwards, ignoring what we were doing would be equal to applying a double standard. The new South Africa was very cautious to keep its reputation as a country respecting the rule of law.”

Achmat was quickly released, but his 3,000 tablets of fluconazole were seized. For the next two years, the clinics would get their fluconazole quietly, couriered from Thailand by Cawthorne.



Left to right: Matthew Damane, Nomandla Yako and Zackie Achmat arriving at Cape Town Airport with Biozole, the generic fluconazole, imported by TAC. October 2000. © ELLEN 'T HOEN



Protesters demonstrate outside the Supreme Court in Pretoria, South Africa, as the pharmaceutical industry faces off in court against the South Africa government in what AIDS activists say is a landmark in the developing world's efforts to get cheap AIDS medication. 5 March, 2001. © CHRISTIAN SCHWETZ

## No Exit: The Need for Generics

Khayelitsha continued to grow, with a regular influx of people from the poorer and less developed Eastern Cape. Many of these new arrivals were HIV-positive.

The continually expanding scope of the problem put MSF Brussels in a difficult position. The decision taken in 1999 to launch the PMCT project had assumed limits to both scale and duration. Now MSF was confronted with the call for lifelong treatment of what might be thousands of patients. The financial commitment far exceeded what had been anticipated, especially given the South African government's unexpected opposition to ARV treatment. If MSF went ahead, it would be the first time an MSF board made a financial commitment that would extend beyond its own tenure and place an obligation on its successors.

MSF now faced an important issue: as a practical humanitarian organisation, it had to decide to what extent it could afford to engage in what looked more like long-term development. Alex Parisel, then director general of MSF Brussels, had been pressured by field teams, mostly non-medical staff. "They were saying, 'Our driver or our cook is dying from AIDS. What can we do?'"



Parisel felt MSF couldn't treat staff without treating all of its patients too. "How can we be focused only on ourselves and not on all the people we meet in our clinics whom we know to have AIDS?" The debate became very heated; some members felt very strongly that it was not within the association's mandate, as MSF didn't have the capacity to provide lifelong treatment.

In the 1990s, MSF treated only opportunistic infections while promoting prevention, although staff had access to post-exposure prophylaxis. The question of medical capacity remained central: doctors in the MSF Brussels medical department were afraid to venture into HIV treatment, which was perceived in Europe as requiring specialist care they didn't have the skills or knowledge to provide. As Parisel puts it, "MSF was all about one shot-emergency treatment." HIV/AIDS was a challenge to the MSF model.



Alex Parisel speaks at an MSF General Assembly. © MSF



The second challenge, Parisel noted, was one of scale: “You cannot treat patients if you cannot treat them all. It was the conflict between the public-health approach and the more disease-specific vertical approach. And we didn’t have the financial resources to go for a more public-health approach. We knew that if we went into HIV treatment, we would have to decide whom we would save and whom we would not. And that is a very difficult concept for a doctor to live with.”

It was not the first time MSF had had to deal with such dreadful choices: “During famines in the 80s, sometimes we did not have food for all the kids, so we had to decide who had a better chance of surviving.

“For five years, with AIDS, we closed our eyes and pretended not to know who had AIDS and who didn’t, because if we knew, we would have to treat them.”

Parisel was nevertheless convinced that MSF must begin treatment. Supported by Marleen Boelaert, the former president of the board and a prominent physician at the Institute for Tropical Medicine in Antwerp, he took on the medical department, challenging them in the weekly Monday meeting, which was attended by all MSF staff.

Parisel – who, unusually for a director general at that time, is not a doctor – told everyone that the problem with treating HIV/AIDS was medical. “I said in front of all the staff that I knew the medical staff in MSF were not able to treat people with AIDS. I challenged their professional pride. Most people in MSF HQ are not medical, so it was a shock when it was the medical staff who were identified as the blockage. That episode was very important. For me, that was the catalyst which allowed us to go beyond what MSF used to do.”

Through such tactics, Parisel managed to authorise treatment of an

initial one 118 patients. In order to reconcile this with the MSF mission, says Parisel, they had to declare AIDS an emergency. “If you did that,” he says, “You were in sync with the MSF way of thinking.” The idea of a pilot project to demonstrate feasibility, impact, and the capacity for reproduction of the model justified treating only a small number of patients in the first instance.

They were nevertheless aware, says Parisel, that by treating the first one 118 patients, they were setting in motion a process they would not be able to control. The next step would naturally be to double the number – which they soon did. The team came to a drastic decision: their responsibility would last for a maximum of five years. Patients would be informed that because of funding issues, treatment might not be available after that. “We thought that if we could save a woman’s life for five years and she could bring up her children for five years, it was worth doing,” Parisel says. It was believed this was the only way to limit institutional risk and meet the needs of patients, doctors, and the organisation as a whole. To ensure they could honour this commitment, MSF took another unprecedented step, setting aside sufficient funding to cover five years of treatment.

The MSF operation now included an office in Site B, the commercial, administrative, and transport hub of Khayelitsha, which was at the time the only place that combined a train station, a taxi rank, a large commercial area, a post office, a police station, and a public library. Site B was the only one of the three community health clinics in Khayelitsha with a trauma unit. Michael Mapongwana Community Health Clinic, located in the very centre of Khayelitsha, had a maternity unit. The smallest clinic was at Site C, situated in the most crowded area of the township.



MSF and TAC offices in Site B, Khayelitsha. © TREATMENT ACTION CAMPAIGN

The expanded MSF team in Khayelitsha included Toby Kasper, a young American passionate about the fight for affordable ARVs. Kasper began researching South African patent law; he learned that if a patent owner suspects an infringement, he has six weeks in which to report it. After that, the burden of proof is essentially reversed: the patent holder would have to prove in court that he



Site B Ubuntu clinic located behind the MSF office in Khayelitsha: the first clinic to have started ARV treatment in South Africa. © TREATMENT ACTION CAMPAIGN

was the rightful owner of the patent, and that his rights had been infringed.

Goemaere saw a lot of potential in this. “We thought that this was a fantastic opportunity. We would write letters to the relevant drug-patent holders informing them of our intentions and if by chance they aren’t paying attention and do not answer within the six weeks, they will have to go to court. And in court we will bring the TAC and all their activists and make a lot of noise. And we can delay the process. We’ll go on appeal.”

Letters were duly dispatched to Bristol-Myers Squibb, GlaxoSmithKline, Boehringer Ingelheim, Abbott, and Pfizer,

companies that held patents on drugs needed to treat HIV and related opportunistic infections. Almost all responded immediately. GlaxoSmithKline sent their answer by fax, letter, and courier, and had an extra copy hand-delivered, just to be sure. Some of the companies even requested meetings.

The chairman of Boehringer Ingelheim, Paul B. Stewart, unexpectedly agreed to come to Khayelitsha, where he arrived with a delegation including bodyguards. Goemaere met him at the Site B clinic, and invited him to attend a consultation. “He walked into the clinic and he was a bit aggressive,” says Goemaere. “The conversation was immediately very antagonistic. I hadn’t prepared this, but there was a young boy there, a nine-year-old orphan, brought in by his grandmother. He was slowly but surely dying from HIV. It was an extremely sad case. He was sitting there, on the examination couch, and he was emaciated.” After a long silence, Stewart, clearly embarrassed, asked if he could pay for the boy’s treatment. Goemaere replied that while it might be possible, there were thousands of children like this, dying slowly from HIV, and that only generic antiretrovirals would make it affordable. One child’s care wasn’t the issue.

“Mr Stewart must have felt really guilty which was, a little bit, the purpose of the whole move. He told me that he simply didn’t have the authority to make this kind of decision because patent protection was worldwide policy for the company and he had to ask his superiors. He said he would certainly do so but wasn’t very hopeful about the outcome so please for me to keep in mind his proposal to pay personally for the treatment of this little boy – and he left.”

GlaxoSmithKline’s area director for sub-Saharan Africa, J.P. Kearney, also requested a meeting, but refused to come to

Khayelitsha, so they met at a hotel in the city. Like Stewart, Kearney, too, showed up with a whole delegation. “It was interesting in that he was, of course, a decent guy.” Kearney offered to give MSF all the drugs it needed for the Khayelitsha project, as a pilot, for free.

MSF refused. Any offer of free drugs, Goemaere explains, “always comes with conditions, and amongst the conditions is that it was limited to MSF patients exclusively, limited in time and within the control of the giver.” Once the pilot stage was over, MSF planned to hand the programme over to the department of health; it needed to be sustainable for the whole country. Free drugs for a pilot would offer only a temporary reprieve. “We preferred to have generic competition, which drops the price in a sustainable way.”

Activists and developing countries therefore wanted generics, whilst the industry would do everything in its power to hold onto patents; many rich nations, supported by the WHO, supported them. South Africa’s government had hamstrung itself by its ill-advised rush to implement WTO rules, and was now trapped between the two sides. Meanwhile – every day – 250,000 people were dying in South Africa as a result of HIV.

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The company that was slowest to answer MSF’s letter was Bristol-Myers Squibb, and its response, received in December 2000, contained a surprise: while it leased the license for the antiretroviral stavudine, the patent was in fact owned by Yale University. Like most American institutions of higher education, Yale is a not-for-profit. MSF decided to approach it directly for a voluntary license, but a reply from the university re-asserted that the patent was licensed to Bristol-Myers Squibb: “only that entity may respond to a request of the sort included in your letter.”



18 December, 2000

Dr Eric Goemaere  
Médecins Sans Frontières - South Africa  
P O Box 27401  
Rhine Road  
SEA POINT  
8050

Dear Dr Goemgore

Thank you for your letter of November 8 relating to didanosine and stavudine. You inquire whether the use of generic forms of these drugs in South Africa would infringe on any rights held by Bristol-Myers Squibb Company. Unfortunately you do not tell us what the drugs will be used for (we assume they will be used to treat HIV infection) or how they will be formulated. Without this information it is not possible to provide a complete answer to your inquiry, but we will try to provide as complete an answer as possible based on the information you have set forth in your letter.

For didanosine, Bristol-Myers Squibb Company neither owns nor controls a South African patent covering the chemical compound didanosine, nor does it own or control any South African patents covering uses of didanosine.

For stavudine, Bristol-Myers Squibb Company neither owns nor controls any South African patent covering the chemical compound stavudine. South African Patent No. 87/7171 in the name of Yale University covers a substance or composition for use in a method for treating warm blooded animals infected with a retrovirus, comprising stavudine, alone or in admixture with a diluent or in the form of a medicament. As the complete specification states, the invention was made with U.S. Government support under grant CA-28952 from the NIH. The United States Government has certain rights in the invention. The above-mentioned South African patent is exclusively licensed to Bristol-Myers Squibb Company and Bristol-Myers Squibb (Pty) Limited is the only company in South Africa permitted to make, use, exercise, dispose of, offer to dispose of, or import the invention claimed.

This letter is being sent to you in reply to the requests which you made and the above information is being sent in terms of the proviso to Section 70(1) of the Patents Act No. 57 of 1978.

Additional inventions, including South African patents owned or controlled by Bristol-Myers Squibb Company, relate to certain formulations of didanosine and stavudine. As noted above, you have not told us what formulations of the drugs you will be using; without this information we are unable to determine whether our formulation patents are relevant.

It is the policy of Bristol-Myers Squibb Company to rely upon its patents to protect its interests.

Yours sincerely

**I J STRACHAN**  
CHIEF EXECUTIVE OFFICER  
Pharmaceutical Division  
South Africa

P. 00

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Letter from Bristol-Myers Squibb. 18 December 2000.

Toby Kasper contacted a law student he knew at Yale, Amy Kapczynski. She and another first-year law student, Marco Simons, immediately sprang into action. “I went to talk to the dean of the public health school, who had been the head of the Global Programme on AIDS (now UNAIDS),” recounts Kapczynski. “He understood immediately what an important issue it was. I suspect he talked to other administrators and probably also to Richard Levin, president of Yale University.”

The Yale AIDS Action Coalition, of which Kapczynski and Simons were members, alerted the *Yale Daily News Magazine*. Kapczynski and Simons then went a step further, tracking down the inventor, Dr William Prusoff. “He was initially worried about the cost of innovation but I think that conversation brought him over to our side.” Kapczynski urged Dr Prusoff to publish an open letter in the *New York Times*. Prusoff wrote a stirring piece reflecting on his position as a scientist contributing to the discovery of a lifesaving medication and later witnessing how commercial interests were protected so stringently that many in the world were blocked from benefiting from it.

Events progressed rapidly. “It was as if Yale had been waiting to burn over this issue. The fire spread very fast,” says Kapczynski. Only days after the *Yale Daily News Magazine* printed their story, the Graduate Students Union gathered about 600 signatures in support of MSF’s request. “This generated a lot of interest. I heard later that a wealthy alumnus called Levin and made it clear to him that he thought the university had to find a way to grant MSF’s request.”

The story hit the international media, raising the public profile of not only the Yale stavudine controversy, but also the broader issue of pharmaceutical patents. A Yale professor and member of a board overseeing the granting of patents was quoted anonymously in the



*Guardian*: “If Yale had sold its freedom of action to Bristol-Myers Squibb, it had made a mistake.” Dr Prusoff told the *New York Times*, “I wish they would either supply the drug for free or allow India or Brazil to produce it cheaply for underdeveloped countries. But the problem is, the big drug houses are not altruistic organisations. Their only purpose is to make money.” Yale, too, was making money: its stavudine license had been worth \$40 million in 1999.

MSF used the international attention to leverage its case, and, in March 2001, wrote again to the university, quoting Yale’s own policy on licensing agreements from February 1998, which stated that one of the objectives of such agreements was to pursue “the benefit of society in general”. The licensing policy also established that Yale should prepare its licensing agreements to “protect against failure of the licensee to carry out effective development and marketing within a specified time period”. MSF’s letter argued that since only a few hundred of the approximately 50,000 HIV-positive people in Khayelitsha were taking antiretrovirals, stavudine was not being effectively marketed there. (Stavudine was widely used by the private sector, but – given the cost – no public service was offering it, and in Khayelitsha, medical-aid coverage was non-existent.)

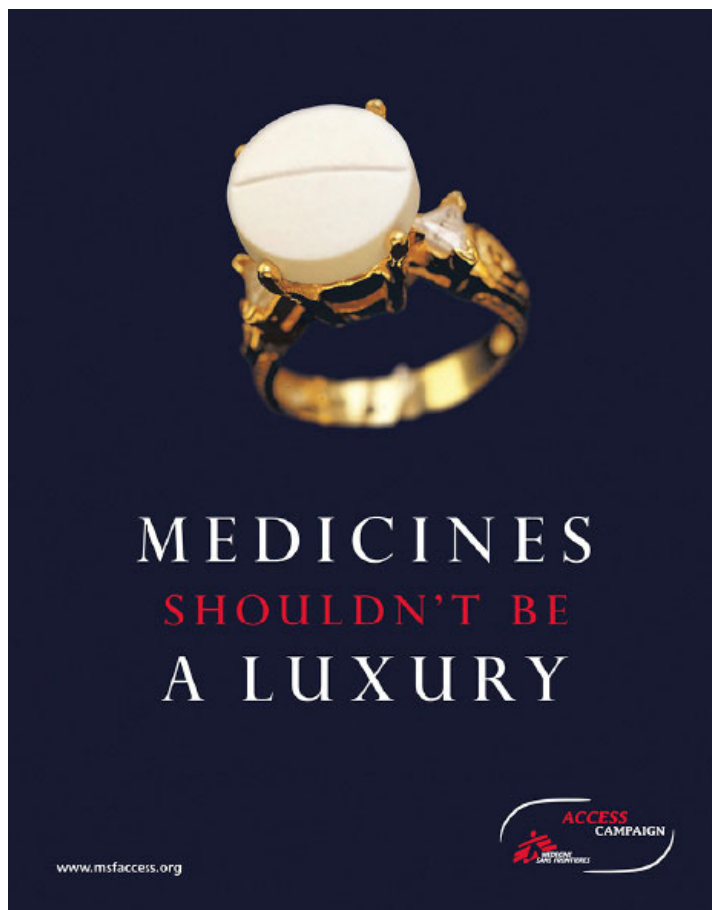
MSF also pointed out how little was at stake financially in South Africa: “the entire sales of nucleoside analogue reverse transcriptase inhibitors (the class of antiretrovirals to which stavudine belongs) in South Africa was a mere \$600,000 in 1998.”

Copies were sent to the president of Yale, Dr Richard Levin; the dean of the School of Medicine, Dr David Kessler; the dean of Yale School of Public Health, Dr Michael Merson; the director of the Office of Public Affairs, Dr Lawrence Haas; the editor of the Yale Alumni Magazine, Carter Wiseman; and the Yale AIDS Action Coalition.

A few days later, Bristol-Myers Squibb announced “emergency patent relief” for stavudine, and a number of voluntary licenses and relaxations of licensing conditions followed that year. Goemaere refers to this small victory as “the first crack in the industry’s fortress.” The Pharmaceutical Manufacturers’ Association was still intent on pressing ahead with its suit against the Medicines and Related Substances Control Amendment Act, however, and if the PMA won, it would mean that corporations rather than the government would retain control over when and how exceptions to patents might be granted.

When the WTO met in November 2001 in Doha, Qatar, it became clear that the effects of the on-going court case weren’t limited to South Africa – indeed, according to ‘t Hoen, “It changed everything at the WTO.” Bernard Pécoul had attended the 1999 WTO meeting in Seattle in an attempt to put access to medicines on the agenda, but the talks had all but collapsed when clashes between protestors and police turned into running street battles that essentially closed the city, and MSF’s first major bid at influencing WTO policy had ended with little or no effect. Now the situation had changed; the agenda in Doha was clearly a result of the international campaign that had sprung up around the case now universally known as Big Pharma vs Nelson Mandela.

One reason for this was that the situation was set to repeat itself. Both Brazil and Thailand, for example, had begun to experience the consequences of pharmaceutical patents, which significantly limited their ability to produce low-cost generic HIV/AIDS drugs. The cost of patent-protected drugs quickly overwhelmed their public health budgets. In Brazil, three patented medicines accounted for only 20 % of the products used by the national AIDS programme, but ate



MSF Access Campaign Poster before WTO Doha meeting, Spring 2001.

up nearly 75 % of their budget. While pharmaceutical companies announced the voluntary Accelerating Access Initiative, a joint initiative with UNAIDS, to improve access to more affordable HIV-related medicines and diagnostics for developing countries and those hardest hit by the epidemic, the discounts offered were still nowhere

nearly as great as the savings to be gained from generics. Voluntary discounts are also problematic because they exist at the discretion of the volunteer, and therefore aren't necessarily sustainable. Generic producers not yet hampered by patents could also offer products, such as Triomune, in fixed-dose combinations, which combined three medicines into one pill and thus greatly simplified treatment.

Doha represented a major shift in WTO culture. For the first time, NGOs were allowed a voice. Both 't Hoen and Bernard Pécoul were actively involved. It had previously been quite difficult for a medical NGO to get a seat at a WTO meeting, although it might be granted observer status. Now, says Pécoul, "We were able to meet directly with the head of the WTO. In fact they were afraid of us."

That year, the G8 paid unprecedented attention to health and access to medicines. In December, a three-day global summit in Okinawa on infectious diseases outlined an agenda to prevent the spread of AIDS, provide treatment and care for those affected, and enhance research and development (R&D) for international public goods. This included the establishment of the Global Fund and, of immediate importance for the on-going case in South Africa, new approaches to managing intellectual property: the Doha Declaration on TRIPS and Public Health. The Doha Declaration made clear that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." It was yet another landmark defeat in the industry's battle to strengthen intellectual property rights at the expense of poor countries. Clearly things were not going the way the pharmaceutical companies had hoped.

"The matter between the Pharmaceutical Manufacturers'



Protesters demonstrate outside the Supreme Court in Pretoria, South Africa. 5 March, 2001. © CHRISTIAN SCHWETZ

Association of South Africa... and the president of the Republic of South Africa, the Honourable Mr N.R. Mandela” had already dragged for three years, during which time the two sides had done nothing more than prepare their arguments. Mandela’s presidency had ended already. As the court reconvened, it looked like the case might drag on for years more. In a sense, any delay was a defeat for MSF and its allies, because generic ARVs remained unavailable as long as the suit was not settled. MSF brought in Ellen ’t Hoen, but it was generally agreed that the only way to win and to do it quickly was to take its appeal to the public, so TAC was invited to submit an amicus brief, and MSF launched a global advocacy campaign, Drop the Case. Drop the Case was probably one of the most successful on-line petitions in the history of the organisation: in a matter of weeks, MSF had collected 250,000 signatures from 130 different countries. Signatories included public figures such as David Ho (director and

CEO of the Aaron Diamond AIDS Research Centre), the novelist John le Carré (who would later write *The Constant Gardener* about pharmaceutical companies' actions in Africa), the actor Whoopi Goldberg, and Dr Prusoff, who had been so instrumental in the creation of stavudine.

MSF and TAC activists attended a highly publicised PMA press conference held the day before legal arguments were to resume. Goemaere was with them. "I had a printout of all 250,000 signatures. With their addresses, it was as thick as a telephone directory. And by total coincidence, the number of signatures happened to coincide with the number of estimated deaths per year in South Africa from HIV.



Dr Eric Goemaere of MSF speaking to protesters demonstrating outside the Supreme Court in Pretoria, South Africa. 5 March, 2001. © CHRISTIAN SCHWETZ

Ellen 't Hoen of MSF speaking at a press conference held by MSF, Oxfam, Cosatu, and the Treatment Action Campaign. Pretoria, South Africa. 19 April, 2001. © LORI WASELCHUK

"When I got a chance to speak, I said that, no matter how they tried

to spin it, they would never convince the world that there were any good intentions behind putting a patent above people's lives. And, as doctors working in the township, we were personally confronted with people's miserable deaths even though there was a treatment available and these pharmaceutical companies were the main barrier to their getting treatment."

Whilst he spoke, Goemaere produced his printout of the quarter of a million signatures. "I waved the book around, saying, 'You might think that we are just a few lunatic, leftist activists, but actually we are speaking on behalf of 250,000 people across the world, including some very prominent people. And they are all telling you: we don't understand your position.' Needless to say, all the TV crews had turned their cameras on me, because I was moving slowly forward, hoping that the bodyguards would not stop me before I reached the front. And that ended up on TV screens all over the world."

Goemaere's speech was picked up by the media, and was reported around the world, appearing on the BBC, Japanese TV, and CNN, among many other networks. When the court convened the next day, the Pharmaceutical Manufacturers' Association's attorney asked for another adjournment. He needed to consult with his clients.

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The Drug Action Programme at the South African Ministry of Health was overseen by Dr Wilbert Bannenberg. Bannenberg had been involved in the fluconazole campaign, and was so deeply involved in the movement for accessible ARVs that a number of MSF activists were living at his house, sleeping there by night and by day using it as a base for their media campaigns. The story reached Bannenberg through the ministry: the international pharmaceutical industry had by then realised how bad the case would be for its image, and representatives meeting with Kofi Annan said they

wanted it dropped. As Bannenberg heard it, “Kofi phoned Thabo Mbeki. Mbeki phoned his minister of Health, Manto Tshabalala-Msimang, and she phoned her legal adviser. The message was: the international industry wants to put pressure on the South African industry to drop the court case.” By 19 April, the case had formally been dropped.



Mirryena Deeb, CEO of the Pharmaceutical Manufacturers Association (PMA), speaks to a colleague. This conversation happens just before the judge dismisses a lawsuit against the South African government to prevent the production of cheaper generic medication. Pretoria, South Africa, 19 April 2001. © LORI WASELCHUK





South African AIDS activists celebrate inside the High Court and at a press conference after major pharmaceutical companies dropped a lawsuit against the South African government to prevent the production of cheaper generic medication. Pretoria, South Africa. Thursday, 19 April, 2001. © LORI WASELCHUK



Front page news after a group of 39 pharmaceutical companies, under international pressure, dropped its lawsuit against the government of South Africa. Pretoria Beeld, 20 April, 2001.

## A Brief Alliance

“I had a very strong sense of being really privileged to be there,” says Ellen ’t Hoen, who was present when the PMA announced an end to their suit against the government. “The court was filled with people and, while we were waiting for the judge, they started to sing. Every hair on my body was standing on end. It was in the air that they were going to drop the case, that we had won, but we didn’t know for sure until it actually happened. And when it did, the whole thing just broke out in one big dancing party. It was absolutely amazing.”

According to Bernard Pécoul, the history of the pharmaceutical industry worldwide can be divided into Before Pretoria and After Pretoria. “Even today,” he says, “when CEOs talk about success, they always refer to this pre-Pretoria period, where they made a lot of mistakes, and after Pretoria, when they started some sort of corporate social responsibility.”

The health minister, Manto Tshabalala-Msimang, invited everyone involved back to her house for a celebration that night. Members of TAC, MSF, and the legal team drank and ate with the minister at a massive party. With the dropping of the PMA’s case, the establishment of the Global Fund, and the drafting of the Doha Declaration, it would have been easy to see the war for affordable ARVs in South Africa as won. It was not, however – and the

problem would come from an unsuspected source: the government itself. For Toby Kasper, the revelation was chilling: “The minister pulled me aside as we were getting food from the buffet set up in her backyard to tell me in no uncertain terms that if MSF went ahead and started offering antiretroviral treatment at the clinics we were supporting – as we were planning to do the very next month – she would not hesitate to throw us out of the country.”

According to Wilbert Bannenberg, the South African government didn’t really want cheaper ARVs. “The victory was a great PR success,” he says, “but it didn’t do much for the fight against AIDS in South Africa.” The country now had the right to parallel imports and to break patents – but they never used it. Goemaere clarifies that before the end of the PMA trial, Thabo Mbeki’s denialism hadn’t really been made public, although many people harboured suspicions. “We were still wanting to give them the benefit of the doubt,” he explains.



AIDS activist Prudence Mabele congratulates South African health minister Manto Tshabalala-Msimang, right. Pretoria, South Africa, 19 April, 2001. © LORI WASELCHUK

There was no longer any doubt. The South African government made it clear that it was not interested in providing universal access



South African minister of Health Dr Manto Tshabalala-Msimang is surrounded by reporters inside the High Court in Pretoria Thursday 19 April, 2001. © LORI WASELCHUK

to ARVs. MSF dropped all plans to obtain ARVs from the public sector. Even taking advantage of Bristol-Myers Squibb's "emergency patent relief" would only get them one drug, stavudine. It took at least four drugs to be able to construct a triple-drug regimen because if a patient had tuberculosis, then nevirapine had to be swapped for efavirenz.

Goemaere's clinic had been running for a year by this time, and the situation remained dire. Among his patients, median CD4 count – used to measure the strength of the immune system – was 40; a normal CD4 count is upwards of 600, sometimes twice that. "A CD4 count of 40 effectively means there is no functioning immune system."

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South African minister of Health Dr Manto Tshabalala-Msimang meets with the CEO of MSD (Merk), Bob Armitage, inside the High Court in Pretoria. Pretoria, South Africa 19 April, 2001.  
© LORI WASELCHUK

The celebration at her house would be “the first and last time we drank champagne with Manto Tshabalala-Msimang,” says Goemaere. “We had assumed the victory would lead to universal public provision of antiretroviral treatment.” The government had been against ARVs, but many people had believed that the real reasons were cost and patent protection. These were no longer an issue.

“It was only afterward that we realised we had been extremely naïve

and that we had, at the time, absolutely no idea of what was really behind the denialism.”

As Tshabalala-Msimang knew, MSF was ready and waiting to set up its first ARV treatment programme – the first in South Africa’s public health system. The date they had set was 14 May 2001. The team had already begun tackling the first obstacle: meeting MCC regulations. They had learnt their lesson from the fluconazole campaign and were now going to proceed by the book.

MSF had asked the MCC to grant it authorisation to use unregistered – i.e., generic – medicines in the three HIV clinics run by MSF and the provincial government, within the government primary health-care centres in the township. The justification was that the clinical trial aimed to prove the medical feasibility of ARV treatment in a resource-poor setting with high HIV prevalence, and the affordability of such programmes, using low-cost antiretrovirals. It was an unusual application of Section 21, and the MCC was aware of MSF’s intention to use it for a patent challenge. By granting this authorisation, the MCC was sticking to its strict mandate of safeguarding the quality of drugs, but distancing itself from any role in policing commercial interests or patent issues.

Still, the process was far from easy. In order to acquire the Section 21 exemption, a clinician had to request the importation of a specific drug not registered in South Africa on the basis that it could benefit an individual patient, who had to be named. If permission was granted, it lasted six months only, after which the exemption had to be reviewed. Since MSF eventually intended to treat hundreds – possibly even thousands – of patients, applying individually for an exemption for each patient every six months would impose a nearly impossible bureaucratic burden.

It was Helen Rees, chair of the MCC, who found a solution, telling



MSF that she would agree to a Section 21 exemption if the organisation could provide a legal affidavit from a respectable law firm confirming that Section 21 was applicable. MSF found a lawyer who successfully argued that the clause could be applied when availability was linked to affordability. The lawyer also asked for an exception to the registration process, and requested that the number of patients who could be treated on a single exemption be expanded. Semesterly reporting was still required, but patient names would be supplied collectively.



Vigil organised by TAC in Gugulethu. August 2001. © ZACKIE ACHMAT, TAC

Rees was satisfied, and in September 2001, the MCC granted a programme-based authorisation to MSF to conduct a clinical trial in Khayelitsha using unregistered ARVs. Now MSF just had to pay for it.



The Indian generic-medicines producer Cipla had begun offering triple-therapy AIDS treatment for \$350 per patient/year to NGOs and \$600 to governments of developing countries. The Indian Patents Act did not provide patents for pharmaceutical products until it had to in 2005, so generic ARV production was still possible. Cipla's dramatic price reduction, which received widespread media attention, hammered home the message that many of the multinational drug companies were abusing their monopoly in the face of a catastrophic human disaster, and drew attention to the effects of generic market competition in reducing drug costs. Indian pharmaceutical manufacturers were positioning themselves to become the "AIDS pharmacy" of the developing world. Companies in other countries followed their lead.

MSF initially decided not to use Cipla in South Africa because the company was perceived by the pharmaceutical industry as unfair commercial competition, and no one wanted to wave any more red flags. Goemaere initially tried to order his drugs from Thailand, instead, but was told that pressure from the US government made exportation of their generics to South Africa "impossible." The team now looked instead to Brazil, a middle-income country much like South Africa, and the first to commit to universal access to ARVs. The Brazilian government had begun to produce ARVs locally, at a fraction of the price the pharmaceuticals companies were charging. In some ways Brazil was a better option than Thailand: Brazilian drugs had undergone bioequivalence studies, for example, which Thai drugs had not, and the tests were an absolutely non-negotiable requirement for the MCC.

The Brazilian government was also worried about American reactions to any export to South Africa, but Michel Lotrowska, who was with MSF in Brazil at the time, assured the Brazilian

government that this would be an undercover operation. MSF Brazil would buy antiretrovirals from the Brazilian government for its own programme: it was a domestic issue. Naturally, the government knew that MSF Brazil had no HIV treatment programme at that time, but MSF agreed to cover the debt and take on all the risks of the operation.

MSF signed one agreement with the Brazilian Ministry of Health and a second with Oswaldo Cruz Foundation (Fiocruz), a public research entity that includes Farmanguinhos, a state-owned company whose mandate was to develop essential medicines to be distributed freely to the Brazilian population through the public health system. The first agreement established a technical collaboration between the ministry and MSF for the exchange of knowledge on how to provide ARVs in resource-limited settings. The agreement with Fiocruz detailed MSF's intent to purchase ARVs manufactured by Farmanguinhos for its programmes, in exchange for a donation from MSF to be dedicated to R&D for drugs for neglected diseases.

Eloan dos Santos Pinheiro, whom Goemaere describes as “a pharmacist activist”, was the director of Farmanguinhos. Pinheiro was very keen to help export ARVs to South Africa. Since Farmanguinhos was funded by taxpayers to provide drugs needed domestically, it did not have a mandate to export drugs – or even to make a profit. After many delicate discussions about “donations” versus “payments”, Pinheiro cut short the negotiations, telling Lotrowska that she was tired of the delays. “If they want to sue me,” she told him, “they can. People are dying.” It was risky, but Pinheiro received at least some support from the Ministry of Health. “The guy



Press conference by MSF, TAC, COSATU and OXFAM announcing the illegal importation of Brazilian antiretrovirals as a public defiance campaign, January 2002.

in charge of international affairs at the time was HIV-positive,” says Lotrowska, “so it was difficult for him to say no.”

It looked as if the barriers to generic ARVs in South Africa had been lifted. It was clear from early on that negotiating and organising the deliveries would take quite some time. MSF could wait, but patients could not: clinics recorded dozens of deaths per week. The best way to ensure the project’s continuity in South Africa was to begin treating patients. “We were expecting very strong flak from the minister of Health. The best protection we could imagine was to actually start some patients on treatment, because once you’ve started, it’s very difficult to decide to stop.” Knowing that cheap generics were on the way, they decided to use some of the money that MSF had allocated to start treatment with brand-name drugs.

To buy enough drugs to start the first few patients on treatment, Goemaere visited one of the few pharmacies in Cape Town that

supplied them: Glengariff Pharmacy, on a corner of Main Road and Glengariff Road in Cape Town's Sea Point. Although the area is home to one of the city's most beautiful suburbs, in the late 1990s Sea Point was a gathering place for drug dealers and the unsavoury fringes of the sex trade. Goemaere's main concern now was not the government: it was being robbed. The dozen treatments he purchased that day cost more than the second-hand Toyota Tazz he was driving.

The first limited consignment of Brazilian ARVs arrived secretly via DHL in November. The first group of patients was switched to generic drugs. The excellent results turned many of them into allies, and some into activists.

This was at best a short-term strategy. MSF and TAC decided once again that open defiance was the only way to bring about the necessary change. They organised another trip for Zackie Achmat, one that would prove far more successful than his trip to Thailand. Accompanying him were Matthew Damane, one of the first patients put on ARVs – who until now had been taking only brand-name drugs – and Nomandla Yako, who was a patient and a TAC activist.

The delegation was taken by Michel Lotrowska and MSF's staff in Brazil to visit clinics providing ARVs, laboratories performing bioequivalence studies on generic ARVs, and finally the Farmanguinhos plant, where the drugs were manufactured. Damane, who was nervous about switching to generic drugs, was excited: "It was impressive to see how the ARV programme was flowing." In Brazil, there was no eight-to-ten-week selection process for ARV treatment. The government provided them to everybody in need.

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Patient with Brazilian ARVs in the MSF clinic. Khayelitsha, January 2002. © SEBASTIAN CHARLES

The Brazilians had been led to believe that MSF intended to conduct its export operation discreetly. This was no longer true. The project team had learned from the court case how to harness the media, and were anxious for publicity. Zackie Achmat, Matthew Damane and

the others returned from Brazil in January 2002 to a hero's welcome and a highly publicised press conference organised not just by TAC and MSF, but also OXFAM and the Congress of South African Trade Unions. They wanted to highlight the potential for treatment with generics; according to Lotrowska, some even hoped that the pharmaceutical companies might sue MSF, which would generate publicity about the cost of brand-name drugs.

The Brazilian government was not pleased. Eloan dos Santos Pinheiro was called to Brasília to explain how Brazilian generics had arrived in South Africa, as was Michel Lotrowska. He assured them that it was a one-off campaign for MSF, and that the organisation willingly carried all the legal responsibility. Lotrowska also thought that some people weren't all that upset. "We felt that the Ministry of Health was happy to get a bit of publicity for its innovative approach to AIDS."

The Brazilian government was not the only one to react: a few days after the press event, the Pretoria Department of Health sent a pharmaceutical inspector from the Law Enforcement Unit to Khayelitsha to check the clinics and seize any unregistered drugs. MSF had prepared for this by asking Farmanguinhos to provide guarantees of bio-equivalence, proving the drugs were strictly equivalent to the patented, brand-name drugs. The inspector was inflexible and technocratic, desperate to identify a legal crack in MSF's defence. He asked for clinical protocol, ethical approval, and patient consent forms, as well as all documents related to ARVs imported from Brazil: invoices, packing lists, and MCC exemption. The MSF team was very nervous, as the whole ARV consignment was at risk of being seized just as the fluconazole from Thailand had been a year before. After a few hours of desperate searching, the inspector claimed the MCC's approval was too vague; he would

advise the Department of Health to revoke it. When he told MSF to hand over the Brazilian drugs, they called the AIDS Law Project, a supportive legal NGO, which advised them to refuse, since the drugs were of proven quality and had received previous MCC approval.

Confronted with MSF and TAC's determination, the inspector had no option but to go home empty-handed.

The pharmaceutical companies also reacted, with several – particularly GlaxoSmithKline – putting pressure on the MCC. Law firm DM Kisch requested information about MSF's Section 21 exemption on behalf of certain pharmaceutical companies, including GlaxoSmithKline. The MCC refused to disclose any information, invoking the right to confidentiality of the exemption holder, and referred the matter to MSF. MSF naturally denied them authorisation to disclose the information requested by the industry, and Bernard Pécoul wrote to the CEO of GlaxoSmithKline, threatening another international campaign. DM Kisch let the matter drop.

This time, it wasn't the pharmaceutical companies or the MCC that would prove to be the most aggressive enemy in MSF's battle to import generic drugs: it would be the government. The ANC's head of communications, Lulama Smuts Ngonyama, released a statement in which he claimed that MSF was fomenting biological warfare in South Africa by experimenting with toxic drugs on black people.

Ngonyama was a classic denialist, who – in a press statement on behalf of the ANC – had previously characterised HIV/AIDS as “an electioneering tool” and “political ploy”, and ARV treatment as “total disregard for the well-being and safety of our people”. He said patients were “guinea pigs” whose health was being compromised by the drugs they received, and he compared ARV treatment to apartheid-era attacks on the black population. He even called on





often assumed that his position was a pragmatist's response to lack of affordability, coupled with a fear of drug-company reprisals, but his government's continued inaction following the success of the public movement to end Big Pharma vs Mandela – and the subsequent availability of generics – made it clear that this was not the case. Indeed, among many members of the Mbeki administration, including health minister Tshabalala-Msimang, official policy was not one simply of inaction, but of active opposition to the effective treatment of HIV.

The charitable view is to see their denialism as the result of a lifetime observing the violence and inequality of North-South relations: if TRIPS was a first-world strong-arm tactic to control the drugs market in Africa, who was to say that the WHO wasn't simply the means by which the same people made sure that there was a drug market to control? Tell healthy people they are sick, treat them with toxic chemicals to convince them they are ill, and you open a bottomless mine of profit. African self-sufficiency required a rejection of Northern-dominated institutions and ideas – and HIV could be dismissed (at least by those not infected) as a Northern idea, an extension of colonialism literally into the African body.

A more pragmatic view could be articulated around the “Virodene saga”, a well-documented story of a local AIDS remedy. It was promoted by a couple of Pretoria-based scientists who managed to get Thabo Mbeki's attention in 1999 with claims that it not only could treat but even cure AIDS. Despite strong opposition at the MCC to this unknown, untested compound, an ANC-held commercial company was established. When ultimately tested on Tanzanian soldiers in 2002, it appeared to be a very toxic industrial solvent, and was abandoned.

It is of course impossible to know for certain what motivated

Mbeki's thinking, but whatever the reasoning, there is no doubt that he and many cabinet members remained actively dedicated to opposing ARVs, and were firm in their belief that this dangerous course, which led to the deaths of thousands, was right and good.

The South African government's primary target in its war against ARVs was TAC, but there was a belief that TAC was financed and manipulated by MSF. Fareed Abdullah, as the man responsible for vertical health services in the province and the person who had first allowed MSF to start treating HIV with ARVs in the Khayelitsha clinics, came under a lot of pressure from the Ministry of Health. Although it didn't protect Abdullah from personal attacks by the minister, legally he and MSF were protected by the memorandum of understanding they had signed, allowing Goemaere to undertake private research testing generic drugs in a difficult environment and a public setting – which was indeed the purpose of the project.

The system used in Khayelitsha was very different from anything that had been employed previously, integrating TB and HIV treatment at Site B, for example, a move that met with resistance from some in the medical community: the WHO had a TB policy, and worried this would undermine it. Today, integrated HIV/TB treatment is standard, which makes sense considering that about 70 % of patients diagnosed with TB are simultaneously diagnosed as HIV-positive.

One central difference between ARV programmes in the developed world and the new programme in Khayelitsha was that doctors and nurses with no specialised training administered treatment. "American AIDS treatment was amazingly sophisticated," Coetzee explains. "Every conceivable test was done. The numbers were relatively small and treatment was individualised." There was no

budget for that kind of individual treatment in a South African township. Indeed, the point of the programme was to move away from individualised treatment to a standardised one. “The only way a mass programme like this can run is if it is standardised,” Coetzee says. The histories of patients who were accepted into the programme had to be meticulously recorded. Lack of administrative staff meant that Hildebrand, Kasper, and Coetzee worked together in the evenings on the tally-sheets from the day’s clinical work, which at that time were filled out by hand. They were looking to see how many patients left the programme or were lost to follow-up; how many patients died while on treatment; and how many achieved an undetectable viral load – which means the virus is no longer replicating in the body – as a result of treatment.

To respond to problems in the protocol, everyone had to be open-minded, and the approach was one of flexibility. It was one of the few benefits of such a small team: if something didn’t work, it could be changed straight away. In the early days, for example, when patients presented with a very low CD4 count, they were taken off ARVs. The team eventually learned that this was unnecessary, and their approach was immediately adapted to take this into account.

Of course, there are also problems with having a small team. When Spanish pharmacist Marta Darder arrived to replace out-going “dynamo” Toby Kasper, he handed her a job description that “looked impossible.” Darder had first become involved with treatment advocacy while working in Zimbabwe in a new MSF HIV programme, and moved to Cape Town to represent CAME in South Africa. In practice, this meant Darder would be responsible for procuring generic ARVs; following intellectual property and registration issues affecting access to generic ARVs; and creating opportunities for new MSF ARV sites and demand for generic

ARVs to support other sites in South Africa and the region. She was also to be the media liaison, act as a link between MSF and local activist organisations, and to support clinic-adherence counselling.

Goemaere had worked with South Africa's top AIDS specialists to establish the clinic's treatment and monitoring guidelines, which Coetzee describes as "good" but "very cautious". The implementation of new systems meant trial and error. At first the team thought that very sick patients needed to be nursed and strengthened before starting ARVs; the wait sometimes killed them. "We didn't know in those days," says Coetzee. "Today we put them on more quickly but because we had to show it worked, we decided we had to select patients." Treatment was limited to patients who complied with a number of conditions. For example, anyone seeking ARV treatment was required to bring a treatment assistant, and needed to have disclosed to someone that he or she was HIV-positive. A nurse, Nozizwe Mafilika, known as Sis Nozi, would perform a systematic preliminary home visit to evaluate if the future patient's environment was conducive to treatment. This included disclosure to at least one person, who would act as treatment assistant. This was a delicate criterion, given the possible harmful consequences of disclosure: discrimination towards people who shared their HIV status could have dramatic consequences, as the Gugu Dlamini tragedy had demonstrated.

Today, in Khayelitsha, a patient with a CD4 count of less than 100 will begin receiving ARVs within a week; in 2001, the process could take as long as eight to ten weeks – too long for some, who died. Many others simply couldn't be accommodated by the limited number of places.

Selection was run on a monthly basis, with about 30 patients a

month presented anonymously to a committee that included two people living with HIV, a nurse, and a local GP, Dr Tido August. Only one out of three patients presented could be accepted within the programme. The committee used a scoring system based on CD4 count, number of dependents, and financial need. A patient could only be presented once. For those who were not selected, explains Goemaere, “it meant death.” This dramatic process of deciding patients’ futures was described by Renée Fox, a Penn University professor emerita of sociology, who visited Khayelitsha on two occasions, as an “emotional and moral strain to all participants confronted with their overall reluctance to refuse anyone for treatment.”

Goemaere decided, with Abdullah’s help, to pressure MSF to increase the number of spaces to 400. “By the end of 2001, we had more than 2,000 people being treated for opportunistic infections. Their CD4 account was at a median of 42. The vast majority urgently needed ARVs.” When the project received MCC approval for an expansion of the programme’s Section 21 exemption, it was a small but important victory.

However upsetting the publicity surrounding MSF’s project may have been to the government, it worked well enough so that Stephen Lewis, the highly respected UN special envoy for HIV/AIDS, visited Khayelitsha in December 2001, because, he says, “it was the view of everyone I spoke to in South Africa that Khayelitsha was the model on which an eventual rollout of ARVs would be based.”

It wasn’t just the programme itself, either. According to Lewis, Khayelitsha provided “an excellent example of a principled stand in the face of a curmudgeonly and denialist government.” The trip

proved to be a valuable one. “I felt I was seeing the best experiment, certainly in South Africa, and possibly on the African continent at the time. It was everything all rolled into one: the community-based emphasis and the transformation in health when you took ARVs.”

Patients had prepared statements about the importance of ARV treatment. “They talked to me about the transformation in their lives and how they were able to function in their families and go back to work and live productive lives again. It was thrilling, it was moving.” Lewis would use Khayelitsha as an example in his work as envoy, asking governments, “If they could do it in Khayelitsha, one of most impoverished settlements in South Africa, why the hell can’t you do it in your country?”

If Khayelitsha was a demonstration of how well ARV treatment could be applied elsewhere in Africa and other resource-poor settings, the envoy’s visit provided an example of how antipathy and obstruction could impede that application in South Africa. Almost immediately after arriving in Khayelitsha, Lewis received a phone call from health minister Tshabalala-Msimang; the conversation did not go well. “She yelled and screamed at me as if she was a lunatic. It was only afterwards I learned that she was, indeed, a lunatic.” The minister was angry that the special envoy had chosen to visit a project she hadn’t sanctioned, but she also attacked him for visiting a province with a government antagonistic to the ANC, and ended by ordering him to leave. A planned day-long visit was reduced to two hours.

Lewis would later try hard to connect with Tshabalala-Msimang, but to little avail. “I met her in Durban at the Hilton. It was the only time I met a minister of health who brought along the minister of defence. It was if they had to bring along tanks to meet me.”

In hindsight, Lewis is unforgiving, calling Tshabalala-Msimang “a

criminal” and Thabo Mbeki “a man who has committed crimes against humanity.” If, for many members of the South African government, HIV/AIDS was a political issue, for Lewis the matter is strictly human: when you ignore science, he says, “people die.”



Stephen Lewis, UN Special Envoy for HIV/AIDS in Africa. © MARCELL NIMFUEHR



Nelson Mandela and Zackie Achmat (TAC) during his visit to Khayelitsha township. Khayelitsha, Cape Town. 12 December, 2002. © ERIC MILLER



## Growing Pains

In 2002 the new Brazilian government, led by Luiz Inácio Lula da Silva, got nervous about the use of Brazilian drugs by MSF for campaigning purposes. Pinheiro left Farmanguinhos that year as well, so MSF lost a key ally. Lotrowska advised Goemaere to look for a new supplier. Eventually the Brazilians said they would donate drugs, but MSF members refused on the grounds of sustainability; instead, they negotiated with Cipla, the Indian manufacturer, which gave them an even better price. There was some bitterness over the lost opportunity that the break with Brazil represented, not just because some felt da Silva had let them down, but because many had seen Brazil as a potential model for South Africa, which had the technical capacity – if not the political will – to manufacture its own generics.

While importing generics reduced the cost of treatment enormously, a *Lancet* article written by Ellen 't Hoen and Nathan Ford – an epidemiologist and medical researcher with MSF – showed just how much more cost-effective local production was: “In Brazil, the price of AIDS drugs fell by 82 % over five years thanks to such [production methods].” The Brazilian delegation to the WHO’s Council for TRIPS and Access to Medications cited a 71 % decrease in the number of deaths in some hospitals in São Paulo, and a

50 % decrease nationally, thanks to locally produced generics. The decrease in opportunistic infections was estimated to have saved the health service \$422 million in hospital admissions. Results were similar in Thailand, where between 2001 and 2003, the manufacture of ARVs by the Government Pharmaceutical Organisation allowed for an eight-fold increase in the number of people on treatment with only a 40 % increase in budget.

Many at MSF still seemed to hope or even expect that South Africa's minister of health would call upon her Brazilian counterpart for help in establishing a national AIDS programme, including technology transfer for the manufacture of ARVs in South Africa, but denialism and a policy of privatisation ensured that never happened. The government of South Africa had in fact made its approach very clear at the Durban International AIDS Conference, when Thabo Mbeki had famously claimed that AIDS was a result of poverty. Lack of interest in low-cost treatment was so blatant that Brazil didn't include South Africa in its later initiative to support implementation of ARV therapy in highly affected African countries.

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Zackie Achmat protested the government's position by personally refusing to take ARVs if they were not available through the public health service. This bold manoeuvre caught the attention of another bold activist, Nelson Mandela, who announced he would visit Achmat at home in the suburbs of Cape Town. Achmat invited Goemaere to be there when Mandela came. There was a large crowd present when the former president's motorcade arrived, but Achmat arranged for Goemaere to speak with Mandela, and Goemaere immediately put the case for generic ARVs, explaining that not only was treatment feasible, as proven right there in Khayelitsha, and that patients were adherent, but that it was effective and could

be affordable for South Africa because treatment existed in generic forms.

They spoke only briefly: Mandela was there primarily to tell Achmat that South Africa needed activists, not martyrs, and to ask him to take his medicine. (Achmat found himself unable to refuse a request from the man that many in South Africa call *Tata*, the father of the nation.) What little Goemaere said must have been effective, however, because a few months later he received a call from the Nelson Mandela Foundation. Mandela remembered their conversation; he wanted to meet.

“I rushed up there. When I arrived at his foundation’s office in Johannesburg, they explained that unfortunately he was off sick but would I go to his place and have breakfast with him? The answer was in the question! So I was taken to his house and he said, ‘I hope you don’t mind, I have invited a couple of other prominent people. I hope you don’t mind if I call you Eric?’ It was a bit humbling.”

Also present was the South African director general of finance, Maria Ramos. Dr Ayanda Ntsaluba, director general of health, was meant to attend, but he was prevented from doing so by the minister. Asked to elaborate on what he had said in Cape Town, Goemaere explained that it would be possible to bring the price of ARV treatment down to below \$200 a year. Mandela asked Ramos if she could explain how the government was able to find \$60 billion to pay for arms, but not a few billion to pay for drugs.

In fact, she could: Ramos claimed that the Treasury under Trevor Manuel had already provided for such a programme in the budget, but it was not its remit to design or implement it. That was up to the Ministry of Health. Mandela tried to call the health minister, but was told she was busy, which Mandela found upsetting.



Former South African president Nelson Mandela visits Khayelitsha's Site C clinic and listens to Eric Goemaere's explanations about the achievements of the Khayelitsha programme. © ERIC MILLER

It was decided Mandela's foundation would work with MSF to establish a programme in the Eastern Cape. In exchange, Mandela would visit Khayelitsha.

In August 2002, Nelson Mandela visited Khayelitsha's Site C clinic. After touring the clinic, Mandela would address the public from a marquee that had been erected in the parking lot. There was a plan to offer Mandela a TAC t-shirt reading "HIV Positive" as a gesture of thanks directly after his speech; that way, even if he didn't wear it, there would be a public image of his accepting it. One of the first patients to have received treatment was chosen to present the shirt to Mandela. Goemaere calls what happened then "a miracle": in front of everyone, the father of the nation pulled off what he was wearing, and put on the t-shirt. The next day, Nelson Mandela appeared on

the front of every newspaper in the country wearing the slogan “HIV Positive.” According to Goemaere, “You could not have had a more powerful political image. I know it stirred a lot of discussion and controversy within the ANC.”



AIDS activists during Nelson Mandela's visit to Khayelitsha. © ERIC MILLER

The fight for affordable ARVs was winning more than just public-relations victories. In early 2003 the South African Competition Commission handed down its ruling on a case brought by TAC, represented by the AIDS Law Project, against GlaxoSmithKline and Boehringer Ingelheim. TAC had argued that the prices charged by pharmaceutical firms for their AIDS medicines were still excessively high. The commission ruled that both Boehringer Ingelheim and GlaxoSmithKline had contravened the Competition Act by abusing their dominant positions in their respective antiretroviral markets



A TAC t-shirt reading “HIV Positive” is offered to Nelson Mandela by Mathew Damane, one of the first patients on ARV treatment in Khayelitsha. © ERIC MILLER

and engaging in restrictive practices. The drug companies agreed to settle by allowing generic ARVs from four different Indian companies into the South African market.

One year after initiating the first patient on ARV, the team believed they had enough material to present their findings to the scientific world. This was in many ways the point of the Khayelitsha project: not just to treat people in the township, but to prove that such treatment was possible, that resource-poor primary health-care clinics and non-specialist staff were capable of effectively delivering ARVs to a population that could and would understand the importance of adherence.

The results were published jointly by the University of Cape Town



Nelson Mandela and Zackie Achmat (TAC). © ERIC MILLER

and MSF in the WHO's *Essential Drug Monitor* in 2003. It wasn't an easy process. On the one hand, some journals didn't want articles that were based on the use of generics, either for fear of offending the pharmaceutical companies, or simply from prejudice: *AIDS* magazine, for example, informed the authors categorically that generics "don't cut the mustard" and refused to publish. On the other hand, Fareed Abdullah and others in the provincial government, who had worked so hard to initiate and maintain the projects in Khayelitsha, had to keep a low profile – they didn't want to highlight yet again the fact that they were acting against national policy – which led to some hard feelings when MSF got all the credit.

When the findings were published, they were explosive: at the end of two years, 91 % of patients were still adherent and had an undetectable viral load. Toby Kasper presented the results at the Barcelona AIDS Conference in 2002, and in 2003 Coetzee gave a presentation to the World Bank, admitting that although MSF was reluctant to deal with an organisation many in the development community view with suspicion (if not hostility), “all the key people were there, so it was important.”

Later that year, UNAIDS and the WHO published the Khayelitsha model as part of their best-practice series: the project now served as the bedrock on which resource-poor HIV/AIDS treatment programmes would be built worldwide. “In the medical world,” says Coetzee, “everybody knows Khayelitsha.”

TAC had, in the meantime, taken the health minister to court to force her to grant health facilities permission to dispense nevirapine for pregnant women. Although TAC had won the case, the government appealed, delaying all action until a Constitutional Court order in July 2002 forced them to prepare a plan, which went into effect in 2003. Some courageous doctor activists tried to organise public disobedience; Dr Costa Gazi in the Eastern Cape tried to administer nevirapine to pregnant women; he was arrested.

MSF was aware that Brazilian ARVs would never offer a long-term solution for Khayelitsha, even less so for the rest of the country. Commercial generic producers such as Cipla and Ranbaxy were the only long-term option available, despite anticipated resistance from the patent holders. The MCC had granted permission for Brazilian drugs only, which forced MSF back to the negotiating table just as the MCC was coming under renewed pressure from companies like GSK and Boeringher to withdraw the existing permit. Malebona Precious Matsoso, Registrar of Medicine, demonstrated her



independence from the minister of health by granting MSF a new import permit in October 2002, this time for Indian generics.

International pharmaceutical corporations were not pleased. Aware that they were losing the public-relations battle, they preferred to keep control of the market by granting local companies – such as the recently established Aspen Pharmacare – restricted licences over the conditions of which they would retain exclusive control.

To pre-empt that possibility, MSF, inspired by its experiences with Brazil and Thailand, launched an independent initiative to transfer ARV technology to South Africa. The project, the Initiative for Pharmaceutical Technology Transfer (IPTT), was designed to encourage local manufacture of medicines for AIDS, TB, and malaria. The South African Department of Trade and Industry (DTI) embraced the initiative, and in April 2003 it released the details of the project to the media. Andre Kudlinski, portfolio manager at DTI, claimed that “IPTT will establish a publicly controlled, transparent, sustainable system under which affordable, quality medicines are produced in required quantities, for Africa, by African countries themselves. [It] will also reduce the immense technology gap between the Western economies and Africa.” IPTT hoped to provide drugs not only to the South African public sector, but also to other African countries. The IPTT project appealed to the South African government since it presented the market for ARVs as a potential a source of wealth, instead of increasing dependence on the West. Ironically, considering the vilification of MSF in South Africa as “an agent for Western industry”, the DTI used MSF’s name in support of IPTT to stress its relevance and solid international support.

In 2003, conscious that such plans would not quickly become reality



Over 10,000 people from around South Africa converged on Cape Town parliament to stage a march calling on the government to introduce a treatment plan for HIV-positive people. Cape Town, 14 February 2003. © ERIC MILLER

– a decade later they have still not materialised – and confronted with increasing demands for generic ARVs, MSF, together with

several partners, launched yet another initiative: the Generic Antiretroviral Procurement Project (GARPP).

GARPP offered a shield against individual liability. Generic drugs were to be imported through neighbouring Lesotho, where ARVs were not patented. Any legal action by the affected pharmaceutical companies against a GARPP member would involve all the members of the coalition simultaneously. GARPP's board of directors included heavyweights from the activist community, academia, and the medical profession; Wilbert Bannenberg agreed to act as director.

GARPP was launched in Cape Town in February of that year, immediately after 10,000 TAC members marched on parliament, demanding ARV treatment through the public sector. GARPP took orders for generic ARVs from sites across the country. Each site had to obtain its own special Section 21 permit from the MCC. Despite promising negotiations with the Registrar of Medicines and other senior members of the MCC during the first half of 2003, other exemption permits were never granted. MSF's involvement was probably a step too far: when MSF's special exemption application became just one of many, the organisation's relationship with the MCC was weakened.

GARPP became redundant when the Competition Commission ruled on a case brought by TAC and the AIDS Law Project against GlaxoSmithKline and Boehringer Ingelheim. TAC and their allies maintained that prices were still excessively high. As indicated earlier in this chapter, when the commission decided that both companies had violated the Competition Act by abusing their respective, dominant market positions, the companies settled. Each would grant a voluntary license to four different Indian generic companies.

Even the denialists in Pretoria could no longer ignore the fact that

public opinion, like scientific opinion, was against them. On 8 August 2003, the South African government made the announcement so many had longed to hear: they were going to embark on a universal rollout of antiretrovirals.

This wasn't a full reversal of policy, however. Apparently unimpressed by the published findings and the enthusiasm of UNAIDS and the WHO, health minister Tshabalala-Msimang worked actively to undermine the adoption of ARV treatment by patients with HIV/AIDS, and continued to urge HIV-positive South Africans to cure themselves by eating beetroot, lemons, olive oil, and African potatoes. A year later, Tshabalala-Msimang found an ally in a wealthy German entrepreneur, Dr Matthias Rath, who was eager to peddle his multi-vitamin product, VitaCell, specifically marketing it to those with HIV. The government was so keen to find alternatives to ARVs that Rath was even appointed to President Mbeki's special advisory team.

Rath and the health minister chose Site C in Khayelitsha to launch their campaign. Zackie Achmat called Eric Goemaere with the news that the minister planned to visit the community hall there. "Zackie didn't know why she was coming, but anticipated something nasty, as it was unusual for her to come to Khayelitsha, stronghold of her fiercest enemy, without a purpose."

The purpose was quickly made clear: to a crowd organised by the local ANC, the minister introduced Dr Rath, and promoted VitaCell as an alternative to ARVs in a speech about the importance of letting patients choose. Rath, who had come with a wall of bodyguards, spoke about the toxicity of ARVs and claimed that people had died from them.

When the meeting was opened to questions from the floor, TAC



VitaCell. A multi-vitamin product marketed as an alternative to ARV treatment for people living with HIV by German entrepreneur, Dr Matthias Rath. © TREATMENT ACTION CAMPAIGN

activists tried unsuccessfully to question Rath's credentials. Goemaere was furious at the whole charade. As he left, a journalist asked him to comment on Rath's allegation that AZT was killing people.

"I answered that he was the killer, not me." It made the headlines the next day.

Rath responded by suing Goemaere for defamation. MSF looked on it as an opportunity and counter-sued. (Rath was apparently litigious by nature: he also sued respected HIV/AIDS specialist Dr Hoosen Coovadia; Heath-e news services; several newspapers,

publishers, and journalists; and former education minister Abdul Kader Asmal.)

Rath even opened a competing clinic in Khayelitsha, although his patients tended not to remain with him long after they understood there was no improvement to their health. Goemaere recalls that he took one of his clients to Europe, showing her off at press conferences. “She died shortly after coming back.”

Rath quickly dropped his suit against Goemaere and most of the others. In the unrepentant press release MSF distributed as a response, Goemaere is quoted as saying, “We are pleased that this phenomenal waste of time has ended.” The press release takes the opportunity to repeat Goemaere’s claims about Rath, reiterating that the suit was brought in response to his calling Rath a “killer” and a “liar.” It also repeats the claim that Rath’s activities were illegal, and notes that “Rath has been widely criticised by the South African Medical Association, the Southern African HIV Clinicians Society, hundreds of prominent health-care workers, and several prominent ANC members.”

Following an anti-VitaCell campaign organised by TAC, Matthias Rath closed his operations in South Africa, but he continues to use his credentials as a former special advisor to the South African government to promote his enormously successful on-line vitamin empire.



Activists in front of the court during the last days of the TAC versus Rath case, September 2005. © ZACH ROSNER



Nolutabalo Madondile, 29 years old and HIV-positive, is on ARV treatment. She has a 2 year old child who is HIV-negative. Nolutabalo is an MSF volunteer. Joe Slovo Village, Lusikisiki, South Africa. November 2003. © FRANCESCO ZIZOLA / NOOR



## Letting Go

The project Goemaere had discussed with Nelson Mandela became MSF's next major campaign. Mandela was obviously aware of how politically provocative it was to link himself with MSF, but he had already confronted Mbeki on his AIDS policy, and intended now to become actively involved in promoting treatment. In order for the universal roll-out to be effective, the Khayelitsha model had to evolve to show it could work in even more difficult circumstances: away from the relatively sophisticated infrastructure and regional politics of Cape Town. MSF wanted to prove that ARVs could be successfully delivered in a poor rural setting, and create a model that could be safely and inexpensively replicated by the national government throughout the country.

They chose the Eastern Cape, where Mandela was born, a poor and sprawling province several hours' drive up the coast from Cape Town. Most of the patients who came to the Khayelitsha clinics were from the Eastern Cape, and many were treatment migrants. If they could successfully be treated at home, they would not need to make the long and expensive journey.

Life in the Eastern Cape, an area of wild and pristine beauty, can be extremely difficult. The province has long suffered from poor management: it was starved of resources and neglected by the

apartheid-era government on the grounds that it was a separate ethnic homeland, and post-apartheid government has been characterised by incompetence and corruption. If ARV treatment could be successfully delivered here, it could be delivered anywhere in South Africa.

The clinic would be based in Lusikisiki, a town in Qaukeni municipality whose name in Xhosa means “the sound of the wind blowing in the reeds.” Lusikisiki had come to MSF’s attention through Zackie Achmat, who in turn had heard about it from a doctor the activist met by chance on a plane. Marta Darder remembers feeling suspicious of the round-about way the location was found. “There was something weird about MSF, the independent humanitarian agency, prioritising project opportunities following Zackie’s nose” – but Achmat was a good guide through the complexities of AIDS politics in South Africa, and TAC was an important partner, helping to reach out to the community in ways that an international organisation run by foreigners never could.

Darder performed the initial site visits, accompanied by Hermann Reuter. “We liked to rent the cheapest cars and I was told that the VW City Chico I booked was enough for our purposes, but at times I wondered aloud if we would make it to our destination. Hermann quipped: ‘It’s perfect! The wheelbase is so short that the entire car fits into each pothole.’”

Under-resourced, remote and rural, with a high rate of HIV infection, poor health indicators, and a weak health system, Lusikisiki indeed proved a good setting to explore what a comprehensive HIV/AIDS service would involve in most places in Africa. Qaukeni was among the ten poorest municipalities in South Africa: about 80 % of its population lived below the poverty line,

and fewer than half its inhabitants lived in formal housing. A single hospital – Saint Elizabeth’s Mission Hospital – and 12 clinics served all 150,000 inhabitants. With just five doctors per 100,000 people, Lusikisiki was well below the national average, and below the average for Sierra Leone, the Democratic Republic of Congo, or Zimbabwe. All but one of the doctors were foreigners. Patients with HIV could expect little help: the clinics offered no treatment at all, and even at the hospital there was limited access to drugs. Staff were still uninformed about HIV, and there was a general atmosphere of suspicion surrounding the disease.

Reuter organised an assessment of the clinics; this revealed that only four had electricity, and only one clinic had running water or a phone. Communicating between clinics was almost impossible, and ordering drugs and medical supplies or dealing with labs was slow and difficult. Only 5 % of clinics stocked the full complement of 25 marker drugs from the Essential Drugs List, and only 40 % of facilities had adequate consultation rooms and waiting areas; almost all required urgent structural repair. Furthermore, only 40 % of staff posts were filled. The high workload and poor infrastructure kept staff morale low, further undermining the service.

It was hardly any wonder that patients left for Cape Town to seek treatment, and nurses left for other, better-paid jobs in better-equipped facilities elsewhere in South Africa, or else in the US and Britain. Motivating the nurses who stayed to take on yet another layer of responsibility would not be easy. While training and equipping nurses to provide HIV care would help them offer better services, it would also dramatically increase their workload, further straining the overextended primary health services.

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Lusikisiki, in the former Transkei, South Africa. An HIV-positive support group gives AIDS education courses in the waiting area of the MSF village clinic. November 2003. © FRANCESCO ZIZOLA / NOOR

Like Khayelitsha, Lusikisiki had a high HIV prevalence rate (over 25 %), but the absolute number of people infected in Lusikisiki was much lower, and they were scattered: access to health services was a problem. The Lusikisiki model was built on the knowledge that visits from doctors to the clinics would be rare, and acknowledged the fact that it was impossible for people to travel to the hospital to get their monthly supply of ARVs: it was too far, and they simply could not afford the transportation costs. The plan, therefore, was to be deeply rooted at community level. Hospital referral would be only for specialised care for complicated cases. The scattered rural clinics had to form the backbone for HIV care.

So, says Darder, an entirely new hierarchy of responsibility was

evolved based on the dictum, “Delegate every task to the humblest member of the team capable of doing it satisfactorily.” The programme in Khayelitsha had proven that most health-care, including HIV care, does not need to be provided by specialised doctors. With well-developed protocols, nurses could absorb the heaviest burden of clinical care, with the backing of doctors only for complicated cases; every professional nurse was taught to evaluate eligibility for ARVs and monitor progress on the drugs. Community health workers would reduce the burden placed on nurses by absorbing non-clinical tasks, such as counselling and testing, preparation for treatment, adherence support, community-outreach work, and even drug management. Patients were encouraged to take responsibility for their medication and their own health. They learned about the benefits and side effects of ARV treatment prior to treatment initiation, and the need for a life-long commitment. They also nominated a treatment assistant and participated in support groups.

Reuter and the others worked with nurses and community educators from the Khayelitsha clinics – many of whom were originally from the Eastern Cape – to adapt the tools developed for the township programme to a rural setting. This ranged from the HIV clinical guidelines for nurses to monitoring tools and community-education programmes. “We went bottom-up to formulate policy recommendations that could be used at the time of hand-over. Clinic nurses were trained and supported to diagnose and provide medication for common HIV-related problems. They were also empowered to initiate and monitor ARV. Trainings and follow-ups on implementation were done on-site by a mobile team.” In October 2003, the National Department of Health gave the go-



MSF clinic, Lusikisiki, South Africa. November 2003. © FRANCESCO ZIZOLA / NOOR

ahead to provide antiretrovirals, and the first people were started on treatment. On 10 December, the ARV programme, called Siyaphila, was officially launched by Nelson Mandela.

“The name Siyaphila La is an appropriate [name] for this site,”

Mandela told the assembled staff and patients. “It means ‘We are alive’. The HIV-positive people we see here today are alive, they are healthy, and they are happy. What we see is proof that there is life after HIV/AIDS. Let us work together to send that message to communities across South Africa and around the world.”

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MSF clinic, Lusikisiki, South Africa. November, 2003. © FRANCESCO ZIZOLA / NOOR

Although drugs for treating opportunistic infections were available at the central depot, they were not being ordered by the clinics, often because of a lack of knowledge. One nurse admits that she had never heard of fluconazole; at her clinic, they treated thrush with mycostatic oral drugs. MSF established a new logistical system to ensure a reliable drug supply and a regular courier system for laboratory services. Mobile teams, which included a rotating health professional, either a professional nurse trained in HIV care or a

doctor, and a driver-logistician, visited all clinics at least once a week.

Initially, this led to a weakness in the system. Understanding that an experienced health-care provider would visit the clinic once a week, over-worked local nurses started to rely on the mobile teams to take on HIV care, booking HIV-related cases for the day of the mobile team's visit; it took an effort to reverse the pattern. Through confidence-building and coaching, the responsibility for HIV care was gradually transferred from mobile teams to local nurses and their support staff.

At the centre of the new staff model were adherence counsellors. According to Reuter, it was this innovative re-imagining of community health workers' roles and responsibilities that ultimately made the system work. "They reacted against anything they regarded as a possible threat to the programme at any level – managerial, administrative, medical, or political. They took responsibility for the programme as something that was good for them and for their families and friends, and defended it."

Each clinic had at least one adherence counsellor and one TAC volunteer. They worked hand-in-hand with the nurses, implementing an adherence-support strategy similar to the one developed in Khayelitsha. Adherence counsellors were trained first to prepare patients for ARV treatment and support adherence once they had been started, including running support groups, but they also had multiple other responsibilities, and tended to be actively involved in all aspects of the clinic: voluntary counselling and testing for HIV, encouraging prospective mothers attending antenatal care to join the prevention of mother-to-child transmission programme, and helping with record-keeping. Adherence counsellors often worked with TAC volunteers and other community actors:



volunteer workers (community care givers), various support groups, adherence and clinic committees, and treatment activists. Adherence counsellors were held accountable for the number of enrolments per month, adherence (as indicated by viral load), and number of patients “lost” to the programme (i.e., who disappear from the records) every six months.

Adherence counsellors served an important role as patient advocates, and participated in decision-making about health services. As a reflection of their being part of the community rather than embedded in the clinic hierarchy, counsellors did not wear uniforms.



MSF clinic, Lusikisiki, South Africa. Tobi Sandile, 32 years old and HIV-positive, at his first doctor's appointment at the MSF clinic. November 2003. © FRANCESCO ZIZOLA / NOOR

The other group of community health workers hired by MSF was pharmacy assistants. Some were based in the district central drug

store, where they took and dispatched orders for ARVs from the clinics. Others were allocated to Saint Elizabeth's Mission Hospital, which had a larger number of patients on ARVs than the individual clinics, and requested special support. Pharmacy assistants dispensed ARVs to patients already stable on treatment after their medical check-up, performed adherence checks using a standard questionnaire, and, if they suspected an adherence problem, referred patients back to their adherence counsellors.

The implementation of the new model was not necessarily smooth. Most clinics already had as many as five community health workers, known in Xhosa as *nomphilos*. *Nomphilos* received a monthly stipend of R600. MSF's adherence counsellors were paid more than that, and benefited from the standard MSF contract that secured them medical and pension aid, like any other employee. This inevitably led to tension. The *nomphilos* were supposedly supported by the Department of Health, but in fact received very little assistance. "Even if they were very committed and well-meaning," says Bavuyise Vimbani, one of the first new adherence counsellors recruited by MSF, "they often just sat in the clinic." One of the strategies used to win them over was to give them a real role. MSF adherence counsellors conducted numerous workshops and training sessions for the *nomphilos* and tried to open a clear role for them as counsellors and care givers.

There were also problems with nurses, who were overworked, under-paid, and generally neglected by the health services. When Vimbani joined nurse Sister Mbane at the clinic she ran in Palmerton, she had been working there for ten years with little or no support. "She was very frustrated," he explains, "because she felt she had been sort of abandoned there. She had worked for this long and never got a promotion. It was not easy to get her interested in

what we were trying to do. On top of that the clinic was too small, and Sister Mbane had little space for basic clinical care. There was only one consultation room and a small waiting area.”



Nozibele Mditshwa, 34 years old and HIV-positive, has three children and has just begun ARV treatment. Joe Slovo village, Lusikisiki, South Africa. November 2003. © FRANCESCO ZIZOLA / NOOR

It was Vimbani who suggested that MSF take the drastic measure of building an entirely new clinic.

On the one hand, says Darder, it could be argued that a new clinic is an expensive way to buy confidence, but “MSF saw that to break the patterns established during a long period of neglect required an engagement with the real conditions people had been facing day after day. Sister Mbane was right: Palmerton not only needed more nurses, it also needed more consultation rooms, storage space for drugs and medical supplies, and a larger waiting area before it could even dream of absorbing a tide of HIV patients.”

In December 2006, Reuter and others reported in the *Southern African Journal of HIV Medicine* that, within three years of starting the programme, they had managed to get 200 people, including 110 children, on ARVs, and that user attrition in the clinics was exceptionally low – only 2 %, compared to 19 % at the hospital. The report speculates that the higher drop-out rate at the hospital could be due to “sicker people starting treatment (higher early mortality), having to travel further, less preparation of ARV users, and less effective follow-up of defaulters” but that ultimately, “The very low rate of lost-to-follow-up in the clinics is... largely thanks to the work of the adherence counsellors.”

While the MSF model was central to the change in treatment in Lusikisiki, Reuter points out that it is important not to overlook the work of community members on their own behalf: “To put the HIV epidemic in the open there was no choice but to train people to be able to engage in all issues around HIV: medical, social, political, rights-based. We had to rely on community health workers. Besides a semi-skilled layer of adherence counsellors and pharmacy assistants, there needed to be a larger group of people trained in treatment literacy and motivated by a human-rights vision and a will

to survive. Putting this into practice, we obviously had to perform a fine balancing act: to not exploit people living with HIV by letting them do all the important community-mobilisation work which we as doctors needed, together with not remunerating them, as they should do it out of political motivation and their will to live.”

Today there are about 5,000 people on antiretroviral treatment in Lusikisiki. All points of care continue to enrol about 100 new ARV patients per month. Lusikisiki is no longer a pilot site, and it is no longer run by MSF.

Darder admits that she struggled with the decision to pull out. When Goemaere said in a staff meeting in 2005 that it was time to start preparing to leave Lusikisiki, she challenged him. “What is the argument that the model of care works? It may work today, but when instead of 2,000 people on ARVs there are 10,000?” She argued that no one knew how to sustain treatment for large numbers of people over a sustained period, or how to integrate HIV with TB care in the midst of two complex, interrelated epidemics. She also pointed out that the government was not making much progress with the national roll-out.

Goemaere responded that this was exactly the point. MSF had started a clinic in one of the poorest places in South Africa, and developed a model for comprehensive HIV care that worked in rural areas. If the government was interested in the model, it had to put in place the policies and the regulatory framework to sustain it and allow its growth. It was also important to alleviate anxiety within the organisation that all its resources would eventually be swallowed up by the epidemic. “Given MSF’s limited resources, the only way to open a programme in Lesotho, which was even more needy, was to be able to hand Lusikisiki over to the government. The previous

year, MSF had introduced an embargo on the opening of new HIV programmes because of fears of increasing financial commitment. The handover of Lusikisiki meant that embargo could be lifted.”

The exit from Lusikisiki was carefully planned, taking place over a period of 18 months, from May 2005 until October 2006. During this period, the elements of the programme that relied on MSF’s support were gradually handed over. It was a long list, one that included laboratory services, clinical staff, data-capture, basic infrastructure support, drug supply, and many other things. Charts were prepared about who was expected to do what and when, and the team held quarterly “exit strategy” workshops with their partners, who were held accountable for what they had committed to deliver from one meeting to the next.

Not all aspects were successfully handed over: pharmacy assistants were quickly absorbed by the Department of Health, but despite the revolutionary and crucial role played by the adherence counsellors, their role at the time of hand-over looked uncertain. The solution was to create an independent NGO, the HIV/AIDS Adherence Counsellors Organisation, known as HAACO. The nurses were not successfully taken over by the Department of Health, either, and another NGO, the University Research Council, took over support of the mobile teams.

While MSF had long been a thorn in the side of the Ministry of Health, there were mixed feelings among government officials about the pull-out. On the one hand, MSF could be a difficult partner, demanding and confrontational, and its presence was politically loaded; on the other hand, MSF offered what one pharmacy assistant called “a crowd of tireless people daily pushing every aspect of the



The Bodweni Support Group wearing “HIV Positive” t-shirts dance during Nelson Mandela’s visit to Siyaphila la HIV treatment programme hosted by MSF and the Nelson Mandela Foundation. © MARIELLA FURRER

programme.” Either way, the deadline for hand-over was set in stone.

A ceremony was held on site: in October 2006 Lusikisiki became the first programme in the history of MSF successfully handed over to a national government.



Nelson Mandela at a meeting with people on ARV treatment during his visit to Siyaphila la HIV treatment programme hosted by MSF and the Nelson Mandela Foundation. © MARIELLA FURRER





Treatment Action Campaign (TAC) activists wear “HIV Positive” t-shirts during Nelson Mandela’s visit to Siyaphila la HIV treatment programme hosted by MSF and the Nelson Mandela Foundation. Lusikisiki, South Africa. November 2003. © MARIELLA FURRER

# Epilogue

Looking back at these events ten years later, we are struck by how far treatment has progressed. We are now able to deliver life-saving care to large numbers of people living with HIV using the same effective, low-toxicity treatment provided in wealthy countries. It could be called a dream come true: what sounded like medical utopia in early 2000 is now the norm rather than the exception in most sub-Saharan countries. UNAIDS reported in 2012 that close to ten million patients had been initiated on ARVs worldwide; 2.5 million of these are in South Africa. HIV treatment is now available in the majority of primary-health clinics across the country. The same is true of most neighbouring countries.

Once we struggled to treat 400 patients, and faced the terrible dilemma of selecting who would live and who would die. What a relief for clinicians to be able to initiate any new patient on ARVs, some at their first visit, without having to worry about limited resources or toxicity.

This must be among the greatest-ever public-health achievements in the history of humankind. It was a struggle in which the best of science joined forces with the best of political will to change the course of the pandemic. The story told in this book is about a grass-roots victory, about people fighting for their rights and for human dignity, first against pharmaceutical companies and then, unexpectedly, against their own government.

Each year, on World AIDS Day, 1 December, a large crowd of people living openly with HIV join health staff and activists to march, sing, and dance through the streets of Khayelitsha, a celebration of their victory in the struggle against the virus – a radical change from the silence and stigma that prevailed only ten years ago.

Despite major progress, and contrary to some optimistic announcements, the end of the epidemic is unfortunately not yet in sight: there are 35 million people living with HIV worldwide, 1.6 million of whom die each year. Since mortality peaked in 1996, there has been a steady decline thanks to ARVs – as much as 33 % over the last decade. HIV is no longer a death sentence, at least for those who have access to health services. More people than ever now visit health clinics for HIV testing. Word has spread even to the most rural parts of southern Africa that while there may still be no cure for “the” disease, there is at least free treatment that can extend patients’ lives for many years.

Current treatment availability is the result of a tremendous transformation in HIV-treatment delivery: a majority of patients these days are initiated by a nurse in a small, non-specialised clinic – the same clinics dealing with TB, broken bones, and deliveries. This is a paradigm shift, moving HIV care from central hospitals and specialised doctors to primary health-care. Another major achievement is the continued decrease over the last decade in mother-to-child HIV transmission. UNAIDS recorded a reduction of almost 50 % in 2012 compared to ten years previously, and it is hoped that mother-to-child transmission will be virtually eradicated worldwide by 2015.

It is important to keep in mind that there are two epidemics occurring simultaneously: HIV and TB. HIV drastically increases

sensitivity to TB infection, and more than 50 % of all TB cases in sub-Saharan Africa are co-infected with HIV. The major cause of reported HIV deaths is TB. Drug-resistant TB, which demands prolonged, toxic, and very costly treatment, is also on the rise.

The next goal after reducing mortality is reducing transmission, or HIV incidence: The number of new cases each year was 2.3 million people in 2012; only 1.6 million were initiated on ARVs. We are still failing to prevent adolescents and young adults, mostly women, from becoming infected through sexual contact. Given the failure to find an effective vaccine, treatment has emerged as the most effective prevention: when a major study showed that ARVs reduce infectivity by 96 %, treating as many people as possible became the agenda of the day.

This raises a new debate: in the absence of an effective vaccine, can we treat ourselves out of the epidemic? Most field practitioners do not believe it possible, in the current circumstances, to treat everyone infected. To do so would require doubling the worldwide treatment target set by the UN Special Assembly in 2001 (and already unlikely to be met) to around 30 million by 2015. International funding, led by the Global Fund, has been capped for the last three years, whilst most rich countries reduced their contributions following the 2008 financial crisis, and domestic contributions in the lowest-income countries have, for the most part, reached their ceiling. Donor fatigue is probably the greatest barrier to HIV elimination.

Whilst there is potential for a cure through extremely sophisticated and costly procedures such as bone marrow transplants, these will only help a privileged few in the foreseeable future. For the huge majority, lifelong treatment remains the only option. We are



TAC and partners March to the U.S. Embassy to protest lack of funding, 17 June 2010. © ALON SKUY

therefore looking for community-based models of care to reduce clinic attendance to a strict minimum, while sourcing treatment closer to home. This requires innovative approaches to health service delivery, but would allow people autonomy while living with HIV.

MSF, as an organisation, now supports treatment for close to 220,000 people living with HIV globally and remains firmly committed to closing treatment gaps, launching new treatment clinics in the remotest parts of Africa, and pursuing research that makes treatment even easier. For an emergency organisation that only reluctantly became involved in the epidemic slightly more than a decade ago, this is no minor paradigm shift, but it is one by which



Global Fund Financing Crisis Rally, South Africa, 22 March 2012. © ZETHU MLOBELI/MSF

we proudly stand. MSF clinicians who remember the dark days of patient selection can only have one commitment: never again!

**Dr Eric Goemaere**