MSF AIDS TREATMENT EXPERIENCE:

RAPID EXPANSION EMERGING CHALLENGES

Briefing Document

Médecins Sans Frontières' Campaign for Access to Essential Medicines

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MSF AIDS TREATMENT EXPERIENCE:

RAPID EXPANSION, EMERGING CHALLENGES

The AIDS treatment emergency was defined at the XIV International AIDS Conference in Barcelona two years ago: six million people were in urgent clinical need of antiretroviral (ARV) therapy, but a mere fraction had access to it. International activism and medical action had begun to highlight the feasibility of ARV treatment in resource-limited settings, and governments and international institutions came under pressure to confront the daily catastrophe of the AIDS pandemic and commit to mobilising a serious response. The World Health Organization (WHO) subsequently announced the goal of ensuring treatment for at least three million people by 2005.

Time to take stock: where are we today?

Two years on from Barcelona, only 440,000 out of the total of six million people needing treatment have access to it in developing countries, and one-third of those treated live in one country, Brazil. International initiatives remain under-funded, politically constrained, or suffer from slow bureaucratic processes and other limitations that delay implementation. Some of these initiatives threaten to create disruptive, parallel systems that waste scarce resources, circumvent national governments, disregard international standards and undermine confidence in existing programmes. Most governments, including donors, continue to move at a snail's pace.

As a result, only a small fraction – around 7% - of those who need treatment are getting it. In addition, recent international initiatives to fund and scale up treatment programmes generally do not address the vital need for new health tools and innovative strategies to tackle HIV/AIDS. This is a gap that needs to be filled urgently: there is no excuse for accepting the status quo.

This paper describes some of the progress as well as some of the emerging operational and clinical challenges from the perspective of a medical humanitarian organisation providing treatment to people living with HIV/AIDS in resource poor settings. These critical issues must be addressed and must not be allowed to divert attention or resources from the urgent need to expand treatment now.

PROGRESS: Rapid expansion of MSF programmes

"We have been able to dramatically increase the numbers of patients on treatment by creatively using the existing resources and customising our approach. If we tried to replicate treatment models from Europe and the US, we would never reach patients in rural or slum areas. If we hadn't gone out of hospitals, reached rural out-patient clinics and treated with clinical indications alone, we would have only brought treatment to well-heeled city dwellers."

Dr Arnaud Jeannin, MSF, Chiradzulu, Malawi.

Médecins Sans Frontières (MSF) was slow to respond to the urgent need for antiretroviral (ARV) treatment. Throughout the 1990s, MSF programmes had focused mainly on prevention and treatment of opportunistic infections.

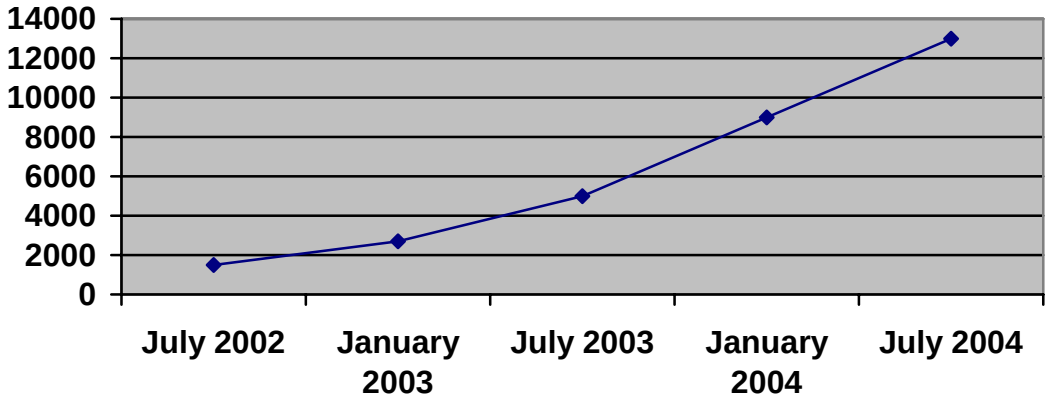
But in 2000, MSF began introducing antiretroviral (ARV) treatment into the package of services provided in our HIV/AIDS projects.

At the XIV International AIDS Conference in Barcelona in July 2002, MSF presented six-month data on more than 740 patients from nine ARV programmes in Africa, Asia, and Latin America[1]. Along with additional data from other programmes in developing countries, ours demonstrated decisively that ARV treatment is feasible and effective even in some of the poorest and most remote settings in the developing world.

[1] "From Durban to Barcelona: Overcoming the Treatment Deficit". MSF, 2002.

MSF and AIDS

Number of patients on antiretroviral treatment in MSF programmes worldwide



MSF has been caring for people living with HIV/AIDS (PLWHA) in developing countries since the mid-1990s, and the first MSF ARV programmes began in 2000 in Thailand and South Africa.

MSF currently provides antiretroviral treatment to more than 13,000 patients in a total of 56 projects in 25 countries: Benin, Burkina Faso, Burundi, Cambodia, Cameroon, China, Democratic Republic of Congo, Ethiopia, Guatemala, Guinea, Honduras, Indonesia, Kenya, Laos, Malawi, Mozambique, Myanmar, Peru, Rwanda, South Africa, Thailand, Uganda, Ukraine, Zambia and Zimbabwe.

MSF ARV programmes are run in diverse settings ranging from hospitals in the capitals to city slums to remote rural areas and areas hit by armed conflicts.

The aim of MSF ARV programmes is to provide a comprehensive package of care to PLWHA. Projects include prevention efforts (health education, prevention of mother-to-child transmission of HIV, condom distribution), voluntary counselling and testing, nutritional and psychosocial support, treatment and prophylaxis of opportunistic infections, and ARV treatment.

In most MSF ARV programmes, eligibility for ARV therapy follows WHO guidelines[2]. In many projects CD4 measurement is not available and some stage III patients are initiated based on clinical signs alone.

The profile of patients in places where MSF works is significantly different from those in wealthier countries. More than half of all patients treated within MSF programmes are women of childbearing age, and there are high numbers of children in need of ARV treatment. Patients tend to be in very advanced stages of HIV/AIDS before they seek treatment and are often afflicted with one or more complex co-infections, such as TB.

Another characteristic of providing ARV treatment in resource-poor settings is the lack of human resources. Due to AIDS-related deaths, lack of training capacity and difficult working conditions in high HIV-prevalence countries, most countries starting to expand ARV treatment are experiencing shortages of qualified medical professionals.

[2] Patients with WHO stage IV irrespective of CD4 count and stage III with a CD4 count less than 350; for children, criteria are WHO stage III irrespective of CD4 count and stage II for children with CD4 percentage less than 20%.

PROGRESS: Lives extended - benefits to individuals and communities

In MSF ARV programmes, simplification and decentralisation of care allow increased numbers of people to be put on ARV treatment. Most patients rapidly respond to treatment: they gain weight, stay healthy and resume their normal lives. This has had a significant impact on the individuals and communities with whom we work, and the results continue to demonstrate the feasibility of providing ARV treatment in resource-limited settings.

The availability of treatment helps lift the stigma attached to AIDS, and in many of our programmes people are now more open in their communities about being HIV-positive. This encourages others to go for testing to find out their HIV status[3].

Nearly all MSF ARV programmes provide treatment free of charge. MSF believes it is essential not only to ensure that the poorest people have access to life-saving treatment, but also to avoid treatment interruptions due to inability to pay.

MSF has gained substantial knowledge and learned important lessons that we wish to share with others, but we do not pretend to have developed a unique model for rolling out large-scale ARV treatment programmes to meet the vast needs confronting us. The responsibility for scaling up comprehensive HIV/AIDS treatment programmes rests with governments, who will continue to need massive sustained technical and financial support from international donors and WHO.

PROGRESS: Treatment is working

Two years on from Barcelona, MSF is presenting observational safety and outcomes data from 31 MSF programmes in 16 countries at the XV International AIDS Conference in Bangkok. The latest data demonstrate encouraging clinical and immunological responses at six months, one year, 18 months and 24 months.

Data were collected on 12,058 adults of whom 55.6% are women. Median age was 34 years. Most patients who initiated treatment were already in advanced stages of AIDS: 49% were in WHO stage III and 38.7% in stage IV. 40.4% had CD4 counts less than 50 cells/mm3.

In this MSF cohort 93.1% of patients were receiving ARVs for the first time and 94.9% were started on non-nucleoside reverse transcriptase inhibitor (NNRTI)-based combinations. Approximately 70% of those patients who started ARVs during the last six months received their treatment in the form of a triple fixed-dose combination (FDC).

Overall probability of survival at 24 months was 85.3% with a median follow-up of five months in the entire cohort. The proportion of patients who were lost to follow-up was 12.1%. The probability of survival of the patients who started ARVs either 18 or 24 months ago was 83.1% and 79.3% respectively. Among patients who started treatment 18 months ago, 16.5% patients have died, 7.4% were lost to follow-up, and 0.4% had to discontinue therapy. Of the patients who had been on ARVs for 24 months, 20.7% have died, 8.7% were lost to follow-up, and 1.2% have stopped their treatment.

A continuous increase of CD4 counts was observed. Median CD4 increases for patients who had been on ARV therapy for 24 months were 101 cells/mm3 at six months, 135 cells/mm3 at 12 months, 193 cells/mm3 at 18 months and 208 cells/mm3 at 24 months. Patients also gained three to five kilos during treatment.

Viral load is not available in most MSF treatment programmes, and is often not done routinely. But in the case of MSF's programme in Chiradzulu, Malawi, viral load was measured on 477 patients who had been on treatment for at least six months, and the results were analysed to monitor the effectiveness of the programme. Preliminary analysis of the data show that 407 (85%) had undetectable levels of virus (less than 400 copies/ml).

[3] Antiretroviral therapy in primary health care: South African experience. Case study. MSF and WHO, 2003.

PROGRESS: Simplifying treatment

According to WHO recommendations and MSF experience, the best choice today for first-line therapy is the fixed-dose combination (FDC) of stavudine (d4T)/lamivudine (3TC)/nevirapine (NVP). This combination is affordable due to competition between producers and is easier for patients to take because of the low pill count. It is also generally well tolerated and requires minimal laboratory monitoring. Using FDCs can also delay the development of resistance, and certainly facilitates drug supply management.

By May 2004, 76% of new patients within MSF projects started treatment on the generic one-pill-twice-a-day regimen of d4T/3TC/NVP.

Two generic nevirapine-based triple combination FDCs have been validated by the WHO prequalification project. This combination is not available from originator companies due to patent barriers that companies have been unwilling to overcome.

A recent study carried out by ANRS (Agence nationale de recherches sur le sida) in Cameroon confirms the safety and efficacy of a generic fixed dose triple combination therapy[4]. The study assessed short-term effectiveness, tolerability and quality of a generic FDC of d4T/3TC/NVP.

Results showed that the proportion of patients with undetectable viral load (defined as < 400/copies/ml) after 24 weeks of treatment was 80%. In addition to encouraging virological outcomes, the study found few side-effects and optimal pharmacological data. Drug concentrations in patients' plasma were measured and found to be comparable to those observed with originator products.

The debate on FDCs has become highly political, with the US and some other donors and treatment initiatives yielding to pressure from originator pharmaceutical companies to procure the more expensive and less practical originator medicines used in developed countries. This has consequences. Because FDCs are less expensive, many more people could have access to treatment for the same amount of funding.

Although patients are clearly benefiting from existing fixed-dose regimens, there is still an urgent need for new and alternative first-line FDCs that are better tolerated, easier to use, and even more potent.

LESSONS LEARNED

Simplification and decentralisation:

- MSF uses simplified drug regimens that reduce pill count and make adherence to treatment easier. The vast majority of new patients are started on WHO-approved triple fixed-dose combinations (FDCs): one pill twice a day.
- Inclusion criteria and follow-up protocols have been simplified. Some patients now begin treatment according to clinical signs without having CD4 counts measured (when CD4 is not accessible). In some locations, total lymphocyte (TLC) counts have been used.
- In some programmes care has been decentralised to the primary care level. A number of tasks have been delegated to nurses, clinical officers and community health workers.

Seeking out the least expensive quality drugs:

- By stimulating competition between producers and overcoming patent barriers when necessary, MSF and some governments have negotiated costs down to below US $300 per patient per year. MSF relies on the WHO prequalification project to identify quality drug sources. For drugs that have not yet been prequalified by WHO, MSF conducts its own quality assessments that follow standard procedures for pharmaceutical procurement.

Community participation:

- Many MSF programmes are working closely with associations of people living with HIV/AIDS (PLWHA) and other community activists to strengthen prevention, bolster voluntary testing and counselling, enhance treatment education and promote adherence to treatment.
- PLWHA play a pivotal role not only in convincing political leaders to provide ARVs to people in need but also in challenging drug companies' pricing policies.

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[4] Laurent C et al, Effectiveness and safety of a generic fixed-dose combination of nevirapine, stavudine, and lamivudine in HIV-1-infected adults in Cameroon: open-label multicentre trial. *The Lancet* 2004: 364, 29-34

EMERGING CHALLENGES

While data from our programmes are encouraging, MSF teams continue to face a series of challenges that need to be overcome.

CHALLENGE: Children – neglected patients

"HIV treatment for adults is slowly becoming easier, with increasing availability in developing countries of a three-drug cocktail in one tablet. But children who need treatment still have to drink large amounts of foul-tasting syrup or swallow large tablets - that's if they can actually access treatment at all. Children with HIV are generally not interesting for pharmaceutical companies, but some generic companies are developing more child-friendly ARV treatments. International agencies need to push this issue higher up the agenda and governments will need to remove barriers to the use of generic products."
Dr. David Wilson, Medical Coordinator, MSF, Thailand.

The estimated worldwide number of children with HIV/AIDS was over 2.5 million in 2003.[5] In the same year, 700,000 children under the age of 15 were newly infected with HIV/AIDS, 88.6% of whom live in sub-Saharan Africa.[6] Efforts to prevent transmission of the virus from mother to child have been largely successful in developed countries meaning there are relatively few children being born with HIV. The resulting lack of a profitable market for paediatric formulations in developed countries means that these formulations are in short supply despite the growing need for them. As a result, children with HIV/AIDS are neglected, and doctors treating them have very limited choices of drugs at their disposal. Around 50% of children with HIV/AIDS die before the age of two[7].

MSF began treating children with ARVs in early 2002. However, in March 2004 only 5% of MSF patients were children under 13. MSF is committed to doing better for children but our efforts are frustrated by the lack of proper tools.

Most serological methods used to diagnose HIV are not reliable for children under 18 months. Monitoring CD4 is also difficult, since most of the commercially available CD4 count machines are not adapted for use in young children.

The second critical challenge is the lack of paediatric formulations of ARVs, which makes determining and administering doses complex and burdensome. Currently, doses are determined according to weight or body surface, so doses must be adjusted as the child grows.

In developing countries, there are no standardised dosing schedules, and doctors and other health professionals have no simple guidelines for treatment of HIV in children. In most cases, bad-tasting, difficult to measure syrups are used for children under 10 kilos. For older children, a dosing chart is used to calculate dose by weight.

Syrups and oral solutions are not suitable for use in older children because of the large volumes needed, but low dosage tablets and capsules are not produced for most ARVs. In practise, this means that caregivers are forced to measure syrups and cut and crush adult formulations.

Paediatric formulations come at a high price. Both first- and second-line ARV treatment for children costs several times more than for adults. While the fixed-dose version of d4T/3TC/NVP for adults is available for about US$200 per patient per year, the best price for the same drugs in paediatric formulations is approximately US$1,300 (oral solutions and syrups). There are no paediatric fixed-dose combinations.[8]

For the second-line regimen of AZT/ddI/NFV, the adult yearly price is from US$1,228 but for paediatric dosages, the same regimen in powder and syrup formulations costs from US $2,846 ppy.[9]

Some studies are looking at once-daily tablet- and/or syrup formulations[10] for children. However, without a lucrative market, companies are not allocating enough resources to make quick progress. Unless there is

[5] Source: UNAIDS
[6] Source: UNAIDS
[7] Spira R, et al: Natural history of human immunodeficiency virus type 1 infection in children: a five-year prospective study in Rwanda. Mother-to-child HIV-1 Transmission Study Group. Pediatrics. 1999 Nov; 104(5):e56.
[8] Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries. 6th edition. MSF, May 2004.
[9] Nelfinavir is used because it does not need to be refrigerated. Lack of refrigeration is a major limiting factor in resource poor settings.

increased pressure on drug makers and intervention from governments, it will be years before these therapies are available. MSF is committed to fighting for the development of appropriate and practical diagnostics and drug formulations to facilitate widespread treatment of HIV positive children.

CHALLENGE: ARV treatment for pregnant women

Every year, an estimated 2.2 million women with HIV/AIDS give birth.[11] Antiretroviral monotherapy is used to help prevent transmission of the virus from mother to child. But experience has shown that exposure to a single dose of nevirapine (NVP) at delivery may induce resistance and therefore reduce the effectiveness of triple therapy for mothers who later receive NVP-based treatment.

When HIV develops resistance to NVP, it can also become resistant to efavirenz (EFV), a drug from the same therapeutic class. This means these women may not have any accessible options for first-line combination therapy, as both drugs are key components of WHO-recommended first-line combinations.

CHALLENGE: TB and HIV

In some countries in Southern Africa with high HIV prevalence, up to 70% of the people who have TB also have HIV/AIDS. Globally, an estimated 12 million people are now infected with TB and HIV, and TB is the number one killer of people living with HIV/AIDS worldwide. This experience is shared in MSF HIV programmes, where TB is the most common opportunistic infection.

One step towards improving AIDS treatment would be developing more effective means of diagnosing the various opportunistic infections related to HIV/AIDS. TB is a case in point: diagnosing TB is difficult in people with symptomatic AIDS because sputum smear microscopy will only be positive in 35-38% HIV positive patients[12],[13]. The proportion of smear negative cases – who might or might not have TB – is

increasing in most AIDS-affected African countries. Clinical diagnosis of TB is also more difficult in co-infected patients as weight loss, swelling of lymph nodes and pulmonary infections can be caused by various other infections. X-rays are not very reliable in HIV-infected people either. Similarly, there is no accurate means of diagnosing TB among HIV positive children: clinicians currently rely on a combination of x-rays and clinical symptoms and signs recorded on a score card.

In addition, nevirapine, a component of the most commonly used, WHO-recommended one-pill-twice-a-day treatment, cannot be used alongside a key TB medicine, rifampicin. Alternate regimens mean a higher pill count for anyone co-infected with TB/HIV. There is an urgent need for a triple drug fixed-dose combination that can be taken by people on rifampicin-containing TB treatment.

CHALLENGE: Beyond first-line treatment

"If we have no way of telling when first-line treatment fails and no affordable alternative for people to switch to, we will have failed our patients."
Dr Alexandra Calmy, MSF

From experience in developed countries, it has always been clear that the benefit of a first-line combination treatment will not be indefinite for most AIDS patients: sooner or later, people will inevitably develop resistance to the medicines they are taking.

Treatment failure rates in MSF programmes are similar to those observed in developed countries. The difference is that in wealthy countries, patients have access to CD4, viral load and resistance tests to monitor direct or indirect measures of treatment failure. This means that people can be switched to new combinations **before** they become sick again. In poor countries, there are very few therapeutic choices beyond the first-line, and the challenge is to know how long patients can be kept on first-line regimens without threatening their future treatment options and their long-term prognosis.

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[10] The Pediatric AIDS Trials Group (PACTG) has 2 trials for QD therapies: 873 (DDIec/EFV/FTC) and 1021 (DDIec/FTC/ATV) and is enrolling treatment experienced pediatric patients for a trial with Tipranavir, a nonpeptide protease inhibitor.
[11] WHO: World Health Report 2004
[12] Elliott AM, Halwiindi B, Hayes RJ, Luo N, Tembo G, Machiels L et al. The impact of human immunodeficiency virus on presentation and diagnosis of tuberculosis in a cohort study in Zambia. *J Tro Med Hyg* 1993; 96(1): 1-11.
[13] Harries AD, Nayngulu DS, Banda H, Kang'ombe C, Van Der Paal L, Glynn JR et al. Efficacy of an unsupervised ambulatory treatment regimen for smear negative pulmonary tuberculosis and tuberculosis pleural effusion in Malawi. *Int J Tuberc Lung Dis* 1999; 3(5): 402-8.

In developing countries, monitoring treatment failure is very difficult. Equipment routinely used in developed countries is often either unaffordable or impractical for use in resource-poor countries. There is a risk that CD4 machines, bought at great expense, remain idle because of lack of reagents, access to service and lack of trained staff. Viral load machines are even more expensive and more sensitive to heat, dust, unstable electricity supply etc.

Rather than bringing machines to patients, practical means are being developed to bring samples to machines. For example, blood samples can be stabilised so that they can be transported to laboratories with CD4 machines. A method detecting viral load from transportable spots of dried blood has been developed[14]. Transporting samples (dry blood spots for viral load and blood samples that can be conserved long enough for CD4) to capitals where high capacity machines run on "generic" reagents could bring down costs dramatically.

Lack of access to viral load or CD4 should not be used as an alibi for not treating. We must take up the challenge to improve access to monitoring as increasing numbers of patients are being put on ARVs. Operational research into means of improving clinical diagnosis is also needed to decrease reliance on high-tech equipment. In the longer term, simple and inexpensive rapid tests that would, for example, clearly indicate that a patient has a CD4 below 200 from a drop of blood, or would show that a viral load is above 1000 copies, are needed. The diagnostic/monitoring industry has yet to produce a simple, field-ready viral load methodology suitable to resource-poor settings.

However, there is no point in diagnosing treatment failure, whatever the method, if there is no affordable second treatment combination to prescribe.

Second-line treatments are currently up to more than 20 times more expensive than first-line therapies (see table below). Unless things change, the cost of treatment will increase dramatically over the next few years in most countries because of the need to switch to expensive second-line treatments. Mortality will also increase if people and the health systems that serve them cannot afford the treatment they would need to switch to.

In some countries, a WHO-recommended first line FDC (d4T/3TC/NVP) is now available at the price of US$140[15] per patient per year. The same regimen is available in Western countries as originator companies' separate products. For example, in Australia this regimen costs US$8773 per patient per year (see table below). This means that the price in developing countries for WHO-recommended first-line therapy is 98% lower than the same combination in Australia (where drug prices are typically lower than in Europe and the US due to price controls).

It would be logical to expect the same proportion of reduction for second-line drugs, but this is currently not the case: a WHO-recommended regimen in developing countries is only 70% less expensive than the equivalent in Australia. This is due to the lack of competition in the second-line drug market and the fact that individual components of the second-line triple therapy are available from certain producers only.

	3TC/d4T/NVP (1st line)	**TDF+ddI+LPV/r (2nd line)**	**2nd line vs 1st line**
Western country[16]	US$8773/year	US$13151/year	.5 times more expensive
Developing countries	US$154/year Cipla Triomune[17]	US$3950/year Originator products[18]	26 times more expensive
Reduction	**- 98 %**	**- 70 %**	

Even if second-line combinations were affordable, they are difficult to take. When people go from a first-line fixed-dose treatment regimen to a typical second-line treatment, their daily pill count goes from two to 16. In addition, drug availability is hampered by some manufacturers' reluctance to register and make their drugs readily available in certain countries.

[14] Bramilla D et al: Multicenter evaluation of use of dried blood and plasma spot specimens I quantitative assays for human immunodeficiency virus RNA: Measurement, precision, and RNA stability. Journal of Clinical Microbiology, May 2003, 1888-1893.

[15] The Clinton Foundation offer, which is available in several African and Caribbean countries.

[16] Australian EXW prices: "Schedule of Pharmaceutical Benefits for Approved Pharmacists and Medical Practicioners, May 2004. Exchange rate used for conversion (1Australian $=0.72213 US$, May 1, 2004)

[17] Clinton Foundation price (FOB) + 10 % due to transportation and importation taxes.

[18] There is an urgent need for a differential price on EC ddI for developing countries since they still have to pay a higher price. In the table, Australian EXW price is used for EC ddI since there is no differential price. TDF and LPV/r prices are FOB, from "Untangling the web" (MSF report) with an extra 10 % due to transportation and importation taxes.

Impact of the looming 2005 WTO deadline

Following the full implementation of the World Trade Organization (WTO) TRIPS Agreement in 2005, access to new drugs will become more difficult. All new drugs will be subject to at least 20 years of patent protection in all but least developed countries. Because this will affect producers in key manufacturing countries such as India, it will drive prices up and make new medicines inaccessible. Generic producers will also be blocked from development of fixed-dose combinations until patents have expired.

Patents must not be a barrier to accessing treatment. This means that public health safeguards in intellectual property laws, affirmed by the 2001 "Doha Declaration on the TRIPS Agreement and Public Health", such as compulsory licensing or government use, will become even more important[19]. National governments will need to issue compulsory licenses or use "government use" provisions to override patents when prices impede access.

Countries such as Thailand should not trade away these public health safeguards, which will be the only way to overcome patent barriers in the future (see also box on *Free Trade Agreements*).

Free Trade Agreements: New threat to drug access

The US government, pushed by the powerful pharmaceutical industry, is systematically negotiating bilateral and regional "free trade agreements" (FTAs) containing intellectual property provisions that go far beyond what is required in the WTO TRIPS Agreement. These provisions will require countries from Asia to Africa to Latin America to change their national laws in ways that dramatically reduce their ability to provide low-cost quality medicines. They do so by restricting or eliminating the flexibilities and public health safeguards in the TRIPS Agreement.

Some of the measures proposed by the US include: extending patent terms beyond 20 years, limiting grounds for issuing compulsory licences and imposing five or more years of exclusive protection over pharmaceutical test data (blocking generic registration even when there is no patent). These tough rules place company wealth above public health.

Countries that have already negotiated "TRIPS-plus" FTAs with the US include: Chile, Singapore, Morocco, Guatemala, Honduras, Nicaragua, Costa Rica, El Salvador, and the Dominican Republic. Countries currently or soon to be negotiating FTAs with the US include Panama, Bolivia, Colombia, Ecuador, Peru, Botswana, Lesotho, Namibia, South Africa and Swaziland, and Thailand.

For more than six years, Thai people living with HIV/AIDS and other community activists have been fighting to preserve Thailand's right to make use of TRIPS safeguards in order to ensure access to more affordable generic alternatives to expensive patented AIDS drugs. Success seemed possible in Thailand with local production of generic ARVs and a national plan to treat up to 70,000 people by the end of 2005. But the sustainability and expansion of this programme is threatened by the US-Thai FTA which will further restrict the production and use of generics ARVs and other medications.

[19] Boulet P, Garrison C, 't Hoen E. Drug Patents under the spotlight. Médecins Sans Frontières, 2003. Available at www.accessmed-msf.org

NEED FOR ACTION

On scaling up:
Increased attention for the need to expand treatment has as yet not been translated into real action in rolling out treatment in countries hit hard by the epidemic. Governments, international donors and other health providers, including medical non-governmental organisations, must mobilise the necessary financial and human resources to truly make ARVs available to those who need them.

ON R&D:
The HIV/AIDS pandemic will not be defeated with existing tools. We must be more ambitious and invest more resources into vaccine research (preventive and therapeutic vaccines), immunotherapy and other novel, easy to use therapeutic approaches. But at the same time we need to boost efforts to simplify current treatment regimens and monitoring tools. Pharmaceutical companies cannot be relied on to respond to the health needs of the poor. Governments need to take responsibility for leading the development of need-based health tools adapted to the needs of developing countries.

On paediatrics:
Governments must push both originator and generic companies to end discriminatory pharmaceutical development policies that stem from the lack of a profitable market in developed countries. WHO should provide clear, simplified technical guidelines for the treatment of children, and UNICEF must take on a leadership role in demanding that treatment for children is addressed as a matter of urgency.

On treatment for pregnant women:
There is an urgent need for the WHO to communicate a clear new policy and for countries and treatment providers to change practice so that women have the best possible chance to benefit from long-term therapy when they need it.

On TB/HIV:
New diagnostic tools to detect all forms of TB in all patients including PLWHA and children and people with extrapulmonary TB are needed, as well as fixed-dose combinations of ARVs that can be taken at the same time with key TB drugs.

On laboratory monitoring tools and diagnostics:
Now that easy-to-use methods of transporting samples have been validated by researchers, it is time for WHO to offer guidance on use of appropriate monitoring tools at different levels of care and prequalify diagnostic tests and monitoring tools for resource-poor settings.

On second-line treatments:
In addition to reducing prices for existing drugs, there is also an urgent need to develop formulations that can be used in typical developing country settings. For example there is an urgent need for formulations that do not need refrigeration, as well as triple drug fixed-dose combinations of second-line drugs.

Médecins sans Frontières (MSF) is an independent humanitarian medical relief organisation assisting victims of armed conflict, epidemics and natural or man-made disasters. Founded in 1971, with national branch offices in 18 countries, MSF delivers aid through over 500 medical programmes in nearly 80 countries around the world. MSF was awarded the Nobel Peace Prize in 1999.

CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

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