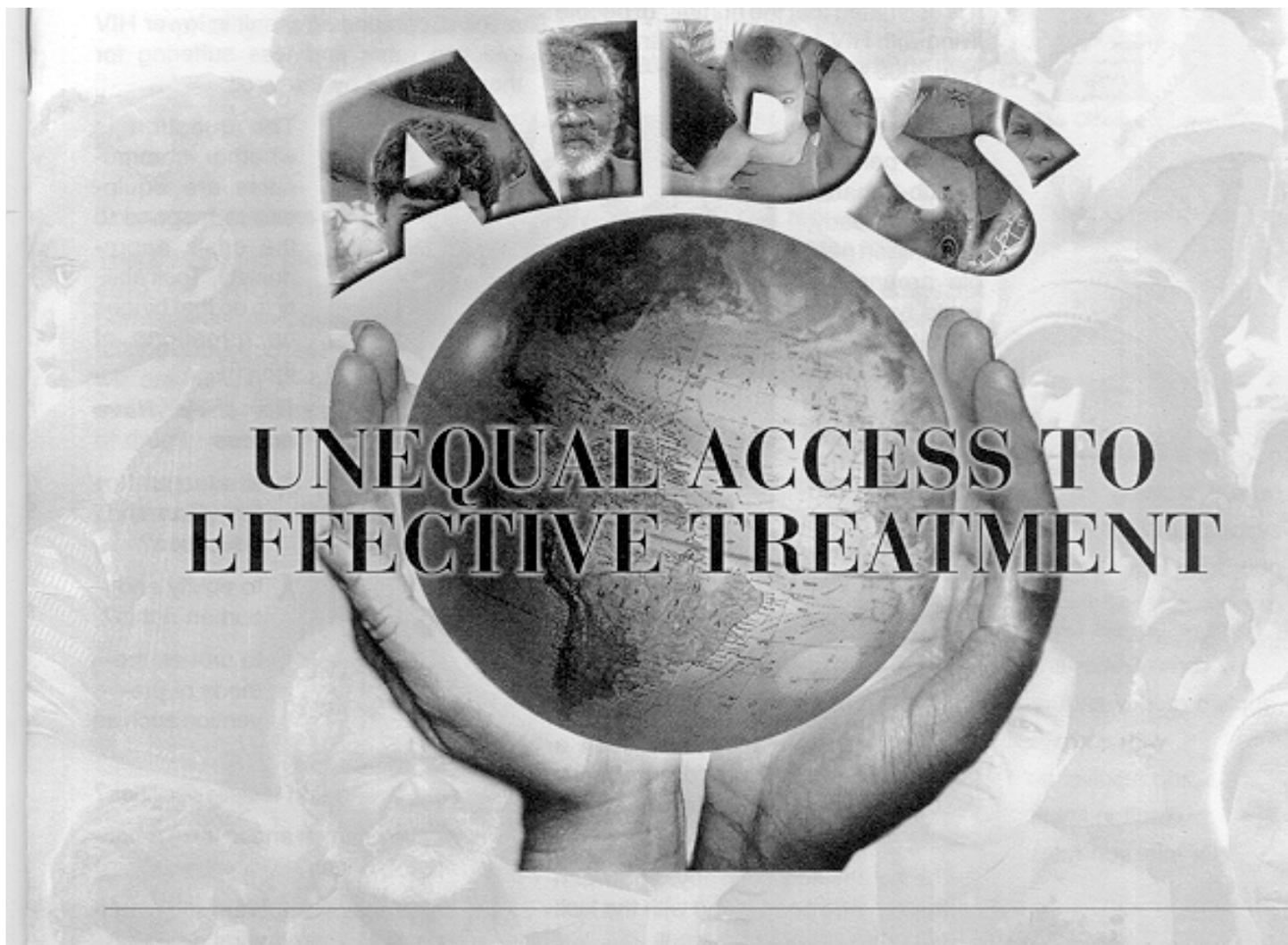

contact

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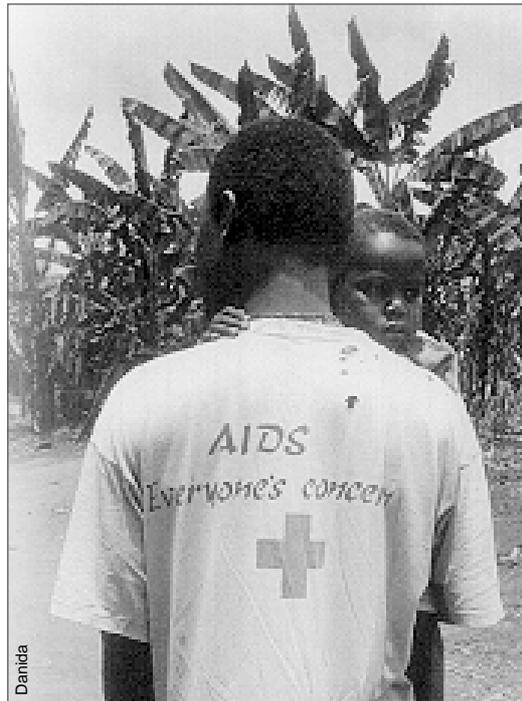
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-
- | | | |
|----|--|---|
| 2 | Editorial | Experiences |
| 3 | Introduction | 14 All is not lost |
| | Access to drugs for HIV patients | 15 Second to none |
| 8 | Interview | 17 It is all very well |
| | "I wanted to do my bit" | 18 Build bridges not walls |
| 9 | Testimony | 19 Review |
| | Goodbye Mama... | Patent indicators |
| 10 | Opinion | 20 Bible study |
| | "Affordable drugs are within reach" | "Do you see the trouble..." |
| 12 | Update | 22 NETWORKING |
| | We shall overcome | Useful publications,
letters and announcements |
-

When AIDS emerged two decades ago, it could not be predicted how the epidemic would evolve. Now, it is obvious that apart from the colossal loss in human lives and the suffering the pandemic brings to societies, it can devastate whole regions and wipe off decades of national development. In consequence the poor and marginalized become poorer, pushing them further to the fringes of society.

It is estimated that the number of people living with HIV or AIDS at the end of the year 2000 stood at 36.1 million — 90 per cent in developing countries and 75 per cent in sub-Saharan Africa. Already, 21.8 million people around the world have died of AIDS, 4.3 million of them children. This pandemic has also orphaned 13.2 million children. The recent estimates show that in the year 2000 alone, 5.3 million people were newly infected with HIV.



Right responses taken by communities and applied quickly enough with courage and resolve, do result in lower HIV infection rates.

The HIV/AIDS pandemic has been a great revealer. It has dramatically exposed a spectrum of gross flaws in our societies

- Ⓜ the increasingly deep abyss between the rich and poor, along with the lack of commitment to bridge it
- Ⓜ the non availability of the basic health services and the collapse of existing systems in many parts of the world
- Ⓜ the lack of women's rights and opportunities to resist infection, or to assert their reproductive choices or to demand safe sex
- Ⓜ the long and deafening silence of churches, civil society and of their respective leadership to face up to

Ⓜ the issues of sexuality and the fundamental preventive aspects of HIV/AIDS

Ⓜ the alarming rise in the number of injecting drug users, with a distressing fall in the age at which people start injecting drugs in many countries

But at the same time the pandemic has also revealed that the right responses, taken by communities and applied quickly enough with courage and resolve, can and do result in lower HIV infection rates and less suffering for those affected by the virus.

The question is whether communities are equipped to respond to the crisis appropriately. Their ability to do that hinges on questions of access.

Do they have access

- Ⓜ to adequate information and education?
- Ⓜ to equity and human rights?
- Ⓜ to proven methods of prevention such as

condoms?

- Ⓜ to counselling and testing facilities?
- Ⓜ to sterile needles and to drug rehabilitation facilities?
- Ⓜ to drugs against opportunistic infections and to antiretroviral drugs?

This issue of *Contact* deals mainly with the topic of access to treatment. However, it is important to see this within the wider context of accessibility. It is vital to mobilize our communities to address these issues, to ensure we are equipped to respond to the crisis appropriately and able to act decisively without delay.

Manoj Kurian
Guest Editor

Cover
A HIV/AIDS imperiled world, held together by hope.
Credit: WCC



ACCESS TO DRUGS FOR HIV PATIENTS

Access to treatment for HIV/AIDS is without doubt essential. But the exercise is not so simple. In Africa, where the average spending on health per person is just \$10 (£7) — in some other countries it is as low as \$3 (£2.10) — even generic drugs, which will cost between \$350-\$500 (£250-£350) per person per year, will remain inaccessible. Unless sustainable solutions and health spending in these countries get priority, antiretroviral drugs will remain unaffordable, irrespective of whoever manufactures them. **Eva Ombaka** elaborates:



Eva Ombaka

Treatment options

There is yet no preventive vaccine or cure for AIDS in the sense of permanently destroying the virus. In talking about access to HIV/AIDS drugs, we are talking of options to improve quality of life. There are five categories of drugs:

- Drugs such as antibiotics to treat sexually transmitted infections (STI).

Treating STI can reduce the risk of transmission of HIV in the community.

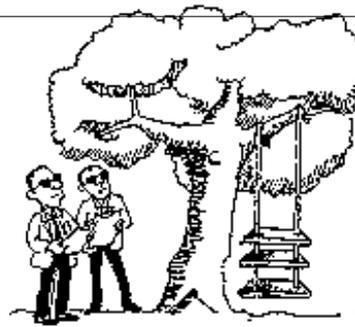
- Prophylactic (preventive) drugs for HIV positive. These include isoniazid to prevent tuberculosis and cotrimoxazole to prevent pneumonia.
- Drugs for palliative treatment, which relieve the distress. These include painkillers, anti-diarrhoea, anti-histamines or lotions to stop itching

HIV/AIDS is today, a major cause of human suffering. Vital sectors like health and education are being pushed to breaking point





What the people wanted



What the experts designed



What the people got

What is needed is political will and well-designed and adequately financed international efforts to improve the health systems.

and drugs to stop convulsions.

- Drugs to treat opportunistic infections (OI). The common OI include tuberculosis (TB), pneumonia, thrush and other fungal infections, various skin diseases and herpes.
- Antiretrovirals (ARV), which slow down (but do not eliminate) the virus, thus holding the disease at bay. These are used as a 'cocktail' regime (mixture of 2 or 3) in order to delay emergence of drug resistance.

Known as Highly Active Antiretroviral Therapies (HAART), these drugs reduce the mortality and morbidity of people with AIDS. Short courses of ARV, e.g. Nevirapine, can also prevent HIV being passed from mother to baby during birth. (See box 1)

The Bottlenecks to access

Most drugs needed for palliative care, prophylaxis or for opportunistic infections, which have been in use for decades, are on the WHO Essential Drugs List and are available at low prices. But access to them is not always assured. Weak management and inadequate financing often clamp the supply of vital antibiotics.

In the case of ARVs, however, the main bottleneck has been the very high pricing of these drugs. There has also been resistance to introduce ARV in poor settings due to difficulties in adhering to complicated treatment and monitoring regimes which, if not observed, would lead to promotion and spreading of drug resistant viruses.

There are now compelling arguments in favour of widespread use of ARV. The falling prices are removing one of the major obstacles. It is proposed that availability of ARV would in turn lead to greater participation in Voluntary Testing and Counselling and therefore positively impact on prevention programmes. Recent development of new fixed-dose combinations taken once or twice daily are making treatment regimes less complicated. What is needed is political will and well-designed and adequately financed international efforts to improve the health systems.



Peter Williams/WCC

Waiting for the healing touch.

BOX 1

The Antiretrovirals

Nucleoside analog Reverse Transcriptase Inhibitors (NRTIs)

- | | | |
|-------------------|------------------|-----------------|
| Didanosine (ddI) | Lamivudine (3TC) | Stavudine (d4T) |
| Zalcitabine (ddC) | Zidovudine (AZT) | |

Non-nucleoside analog Reverse Transcriptase Inhibitors (NNRTIs)

- | | | |
|-------------------|-----------------|------------------|
| Delavirdine (DLV) | Efavirenz (EFV) | Nevirapine (NVP) |
|-------------------|-----------------|------------------|

Protease inhibitors (PIs)

- | | | |
|-----------------|------------------|------------------|
| Indinavir (IDV) | Nelfinavir (NFV) | Saquinavir (SQV) |
| Ritonavir (RTV) | | |

Treatment regimen (HAART) involves two different types of drugs i.e. 2NRTIs + 1PI or 2NRTIs + 1NNRTI.

The patent angle

New medicines, or new processes seen as inventions, are subject to patent protection. The patent, meant as a reward to the inventor, encourages research and covers development costs. During the period of patent, the inventor has exclusive marketing rights. At the end of the patent period, other companies can also make the drug. Such drugs are known as generics. These are usually much cheaper than the branded drugs and, as more companies produce them, competition pushes the prices further down as much as ten fold or more.

Until recently, all governments were free to decide how much patent protection to give, e.g. how much time or whether to grant patent for process and not the product. However, this changed with the new rules of World Trade Organization (WTO) and the agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS). Now all members must grant patents for both process and product for a period of not less than 20 years. Production of generics during the time will therefore be illegal unless certain provisions are made in the national legislation. These provisions are recognized in the TRIPS agreement and are meant to balance the intellectual property rights with public health needs.

The main safeguards are compulsory licensing, where a country can override the patent without permission of patent holder, in order to meet public health emergencies. This is subject to various conditions. Also provided for, are parallel importing, which allow countries to "shop around" for lower-priced versions of the patented medicines and the Bolar (early working) provision, which allows preparatory work (for production of generics) to begin before the patent expires.

However, in order to be put into practice, these safeguards must be written into countries' national patent laws. Although transition periods vary between countries, all signatories of WTO are

BOX 2

Prices after 80-85% price reduction (June 2001, Kenya)

D4T + ddl	+ Nelfinavir	USD	4009	per year
AZT + 3TC	+ NVP	USD	1272	per year
D4T + ddl	+ Indinavir	USD	1008	per year
3TC + D4T	+ NVP	USD	819	per year
3TC + D4T	+ NVP (Cipla offer)	USD	350	per year

required to comply with the TRIPS agreement by 2006. Countries changing their laws must therefore consider these safeguards now.

Drug pricing

Patents tend to lead to high drug prices. This is because profits are the main motive. Prices are set according to what the market can pay, not according to production costs. Since the market of developing countries is very small the prices are set according to what USA/Europe/Japan can afford. (see box 2)

In Kenya, for example, only the wealthy few are able to access the ARVs.



CMAI

The vast majority has no option but to let nature take its course, with disastrous consequences. In these circumstances, physicians are facing a dilemma on whether or not to inform the patients about the drugs!

Other pricing factors include the pharmacy mark-up and taxes and tariffs on imports. The development and implementation of appropriate national laws and National Drug Policies (NDP) which would regulate the drug market, local production and use of drugs is therefore mandatory to address the pricing and access issues.

ARVs can hold AIDS at bay.

Prices are set according to what the market can pay, not according to production costs

TRIPS and ACCESS to MEDICINES

The recent controversy around the excessive price of patented HIV/AIDS medicines illustrated the negative impact of Trade-Related aspects of Intellectual Property Rights (TRIPS) on access to medicines. It also demonstrated the way in which powerful corporations use legal pressures to reinterpret TRIPS in their own interests.

Treatment of AIDS with a combination of drugs — called Highly Active Antiretroviral Treatment (HAART) — has decreased mortality from AIDS by 84% in developing countries. Unfortunately less than 5% of AIDS infected people across the globe have access to such treatment, because the estimated cost of this treatment is about \$12,000 per person per year.

At present rates, Zimbabwe, Uganda and Ivory Coast would require to spend 265%, 172% and 84% of their respective Gross National Products, just to buy drugs to treat all their AIDS patients! This issue has been the rallying point of a major global campaign that today is demanding a closer, critical look at the TRIPS agreement.

Thirty-nine pharmaceutical companies sued the South African government in Pretoria's High Court for allowing the country access to cheaper anti-AIDS drugs. This evoked a massive counter-response across the globe and in April 2001, the companies capitulated to mounting anger and disgust and agreed to withdraw the case unconditionally.

Brazil too moved a resolution at the UN Human Rights Commission.

They called upon all States to ensure that "the application of international agreements is supportive of public health policies which promote broad access to safe, efficient and affordable preventive, curative or palliative pharmaceuticals and medical technologies..."

The truth is, present day drug-research has little relevance to real medical needs. Medicines required to treat diseases that predominantly occur among the poor are not researched at all. Instead drugs that are being researched today, are drugs used for "lifestyle" diseases like baldness, impotence, obesity etc.



Responses to the pandemic

There has been dramatic success in the fight against HIV/AIDS in developed countries arising from availability of the various treatments and especially the ARVs. This is not so in the poorer countries where most people with HIV/AIDS live. Yet treatment is needed to treat the 36 million infected people to optimize preventive efforts, and maintain economic development.

This has meant a call for global commitment and action across the board and from all stakeholders. Where this is supported, two areas of concern have been expressed by the NGOs and civil society.

First, the initiatives taken by the pharmaceutical industry to offer discounts for ARVs. NGO's and civil society accept that these are temporary solutions. These offers are often linked to difficult conditions and are not sustainable. They argue therefore that sustainable